Executive Licensing Panel - minutes

Centre 0250 (Glasgow Centre for Reproductive Medicine)

Renewal Inspection Report

Friday, 20 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Erin Barton Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Policy Manager Communications Manager
Members of the Executive	Richard Chamberlain Bernice Ash	Secretary Committee Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of the 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 Glasgow Centre for Reproductive Medicine is located in the Cardonald Business Park on the outskirts of Glasgow and has held a licence with HFEA since November 2006. The centre provides a full range of fertility services for private patients. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that the centre provided 936 cycles of cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2018. In relation to activity levels this is a medium sized centre.

1.4. The panel noted that the centre had held a licence since November 2006 and its success rates were in line with the UK average and the rate for multiple births for IVF, ICSI and FET cycles was 11%, close to the target of 10%. In 2017 the centre reported seven cycles of partner insemination with no pregnancies. This is likely to be consistent with the national average. The centre did not report any data for cycles of partner insemination for the year ending 31 December 2017 until after this inspection.

1.5. The panel noted the centre previously had an embryo testing licence, which expired 31 October 2014. At that time, the PR decided not to continue to offer embryo testing and therefore applied to renew the licence for treatment and storage only. The Executive Licensing Panel minutes of 25 July 2014 approved this change, and a treatment and storage licence was issued following the renewal application. However, with further licence variations, the licence type reverted in error to one including embryo testing. This was corrected at the last variation of the panel licence application in February 2018

1.6. The panel noted that there had been three changes of PR in October 2014, April 2017, and January 2018.

1.7. An inspection was carried out at the centre on 9 and 10 May 2018

1.8. The panel noted that at the time of the inspection, there was one critical area of non-compliance regarding medicines management. There were also three major non-compliances concerning the Quality Management System (QMS), welfare of the child assessment and procedures for legal parenthood consent.

1.9. There were also five ‘other’ areas of non-compliance on documentation of witnessing checks, infection control and prevention, procedures for dealing with complaints, accuracy of information provided to the HFEA Register and obligations and reporting requirements.

1.10. The panel noted that since the inspection, the recommendations relating to the critical non-compliance on medicines management and the ‘other’ non-compliances relating to witnessing, infection control, complaints, disclosure of information held on the HFEA Register and obligations and reporting requirements, had been fully implemented. Where required, the Person Responsible (PR) will provide an update or summary of audits conducted to ensure corrective actions are effectively taken by the dates specified.

1.11. The inspection team noted that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates, meet the target. The PR is encouraged to continue to use the QMS to best effect to monitor their success rates, so as to improve the quality of the service offered.

1.12. The panel noted that the inspector will continue to monitor the centre’s performance and the implementation of this report’s recommendations within the required timescales

1.13. The panel noted the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without any additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

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

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

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

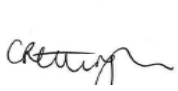
2.4. The panel noted there is now a new PR at the centre and looked forward to them working closely with the inspectorate to ensure the outstanding actions are completed to the required timescales and good practice is continued.

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 the report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

30 July 2018

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 Licence Committee (LC/ 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: 9 and 10 May 2018

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: Polly Todd; Vicki Lamb; Janet Anderson-Pearce; Susan Jolliffe (observer)

Date of Executive Licensing Panel: 20 July 2018

Centre name	Glasgow Centre for Reproductive Medicine
Centre number	0250
Licence number	L/0250/5/d
Centre address	21, Fifty Pitches Way, Cardonald Business Park, Glasgow, G51 4FD, United Kingdom
Person Responsible	Ms Clare Noble
Licence Holder	Dr Mark Gaudoin
Date licence issued	1 November 2014
Licence expiry date	31 October 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Glasgow Centre for Reproductive Medicine is located in Cardonald Business Park on the outskirts of Glasgow and has held a licence with the HFEA since November 2006.

The centre provides a full range of fertility services for private patients. Other licensed activities at the centre include the storage of gametes and embryos.

The centre provided 936 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2018. In relation to activity levels this is a medium centre.

The centre previously had an embryo testing licence, which expired 31 October 2014. At this time, the PR decided not to continue to offer embryo testing and therefore applied to renew the licence for treatment and storage only. The Executive Licensing Panel minutes of 25 July 2014 approved this change, and a treatment and storage licence was issued following the renewal application. However, with further licence variations, the licence type reverted in error to one including embryo testing. This was corrected at the last variation of licence application in February 2018.

This current licence has been varied to reflect the following changes:

- 17 January 2018 – Change of Person Responsible (PR)
- 21 April 2017 – Change of PR
- 31 October 2014 – Change of PR

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period December 2016 to November 2017 show the centre's success rates are in line with national averages.

For 2017 the centre reported seven cycles of partner insemination with no pregnancies. This is likely to be consistent with the national average.

The centre did not report any data for cycles of partner insemination for the year ending 31 December 2017 until after this inspection.

General Direction 0005. (See recommendation 9).

Multiple births[2]

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

Between December 2016 and November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. 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 – of draft by PR

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 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 her 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 the centre's 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 one critical, three major and five 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that the corrective actions taken are effective.

Critical areas of non-compliance:

- **The PR should ensure that medicines management practices are compliant with regulatory, and professional body guidance.**

'Other' areas that requires improvement:

- The PR should ensure that documentation of witnessing checks is completed at the time the procedure takes place.
- The PR should ensure there is a designated, suitably trained, person to lead infection prevention and control practice and procedure within the centre.
- The PR should ensure that all complaints are investigated and any corrective actions, implemented.
- The PR should ensure that information provided to the Authority, which the Authority is required to hold on its Register of Information is accurate.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

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

Major areas of non-compliance:

- The PR should perform a comprehensive review of the centre's QMS to ensure its effectiveness, and address the issues identified in this report.
- The PR should ensure that welfare of the child assessment is compliant with statutory and regulatory requirements.
- The PR should ensure that procedures for legal parenthood consents are robust and compliant with statutory and regulatory guidance.

Recommendation to the Executive Licensing Panel – post-review by PR

The centre has one critical area of concern.

The inspection team notes the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates, meet the target. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor their success rates, so as to improve the quality of the service offered.

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

The inspection team recommends the renewal of the centre's Treatment 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 broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
In one of five records audited the witnessing signature was missing for the disposal of the gametes.

SLC T71. (See recommendation 5).

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)

It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/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 broadly 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 not compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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

Multiple births (Guidance note 7; General Direction 0003)

The centre's procedures are compliant with HFEA 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 partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better
Infection control (Guidance Note 25)
The centre does not have a designated person to undertake the lead for infection prevention and control.

SLC T2. (See recommendation 6).

Medicines management (Guidance Note 25)
The following issues were noted:

- in all five records reviewed, the time of administration of a controlled drug was not recorded in the patient's records;
- the centre's nominated controlled drugs accountable officer was unaware of her role.

SLC T2; 'Controlled Drugs in Perioperative Care' 2006; NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'; DH: Controlled Drugs (Supervision of management and use) Regulation 2013. (See recommendation 1).

Quality management system (QMS) (Guidance note 23)
The following issues were noted:

- the audit of storage consents did not check against the consent in the patient records;
- some audits did not have any corrective actions recorded when non-compliances had been found (welfare of the child, submission of data to the HFEA, provision of information);
- the centre has no current process for reviewing the robustness of audits as part of the quality management system;
- the counselling audit lacked robustness in that it did not audit the quality of service provision, only the number of patients having counselling. In addition, there were no quality indicators for the audit of counselling;
- the centre does not conduct an audit of the patient records, they audit certain elements of the records, but do not audit in line with SLC requirements;
- there is no SOP for record keeping standards;
- the timeframe for the completion of corrective actions is not recorded.

SLC T33b; T35; T36. (See recommendation 2).

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 biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

What the centre could do better
Welfare of the child (Guidance note 8)
the following issues were noted:

- the centre does not have an SOP for 'welfare of the child' assessments;
- the centre uses their own version of a welfare of the child patient history form but the form does not provide for recording if any further information is sought, the source of that information and actions taken in the event of a concern.

SLC T2; T33b; T56; HF&E Act 1990 (as amended) section 13 (5). (See recommendation 3).

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 preimplantation genetic screening or embryo testing and sex selection, 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 three patients who provided feedback on their experiences. A further 30 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 17 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) 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, with the exception noted in the QMS section of this report. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)

The centre'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, and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are broadly 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
Complaints (Guidance note 28)
the following issues were noted:

- the centre did not respond to a patient's complaint by implementing appropriate corrective actions which resulted in the same issue occurring again when the patient came for further treatment;

CoP 28.2. (See recommendation 7).

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 the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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 in post at the time, responded to this communication and provided the required reassurances to the satisfaction of the Executive. At the inspection in May 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Seven sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially 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
Legal Parenthood
The following issues were noted:

- in one record, section one of the WP (your consent to your partner being the legal parent) form had been correctly completed by the patient having treatment, but section one of the PP (your consent to being legal parent) form, also, incorrectly, contained the details of the patient having treatment instead of those of her partner. The patient had received treatment using donated sperm, but no pregnancy resulted from this treatment. The centre had not identified this anomaly at the time of treatment or through legal parenthood audits.

- in four of the seven records reviewed the marital status of the couple could not be determined;
- in one record, the offer of counselling had not been recorded;

SLC T2; T57; T60; T61. (See recommendation 4).

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Five discrepancies were found between ten completed patient/partner/donor disclosure consents on patient files and the corresponding data submitted for inclusion in the register. Whilst this failing would not lead to the risk that the HFEA may release patient identifying information to researchers without consent, it does mean that the patient's wishes were not followed.

SLC T9(e); CH(10)05; General Direction 0005. (See recommendation 8).

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 and 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

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 and 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
2% of the donor insemination (DI) treatments and 4% of the IVF treatments reviewed had not been reported to the HFEA as required by General Direction 0005.

Of the treatments that had been reported to the HFEA, 40% of the DI and 22% of the IVF treatments had been reported to the HFEA outside the period required by General Direction 0005.

Additionally, the record of licenced activity provided for review was incomplete (i.e. in that it did not contain some treatments recorded on the HFEA register).

The centre did not submit data for partner insemination cycles until after the inspection. This information should have been submitted on or before 28 February 2018.

General Direction 0005; SLC T9 (e); T41(See recommendation 9).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to one area of critical non-compliance, three areas of major non-compliance and two 'other' areas of practice that required improvement.

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

On-going monitoring of centre success rates

The centre has not received any risk tool alerts relating to success rates.

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 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.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Medicines management On inspection the following issues were noted: ○ in all five records reviewed, the time of administration of a controlled drug was not recorded in the patient's records; ○ the centre's nominated controlled drugs accountable officer was unaware of her role.	The PR should ensure that medicines management practices are compliant with regulatory, and professional body guidance. The PR should review practices and procedures relating to medicines management, including, but not exclusively, the issues identified in this report. A summary report of this review, including any	The document for recording case by case controlled drug administration (FRM-Clin027) has been updated to incorporate the time of administration, to ensure this information is captured. The audit of Controlled Drugs (FRM-QMS102) has been updated to include a review of the time of administration recorded on FRM-Clin027.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of an audit of medicines management practices due by 9 November 2018.

Medicines management was a critical non-compliance at the last inspection in 2016. SLC T2; 'Controlled Drugs in Perioperative Care' 2006; NICE Guideline [NG46] April 2016; 'Controlled drugs: safe use and management'; DH: Controlled Drugs (Supervision of management and use) Regulation 2013.	corrective actions, staff training, with timescales, should be provided to the centre's inspector when responding to this report. Three months after the implementation of corrective actions the PR should audit medicines management practice and procedure to ensure that corrective actions implemented, have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 9 November 2018. The PR should ensure that the designated CDAO is aware of their role and responsibilities, and is suitable to undertake the role. The PR should inform the centre's inspector of the actions taken to ensure compliance with this element of the recommendation when responding to this report.	A summary report of audits related to Medicines Management processes shall be provided in due course. Noted The designated CDAO for GCRM Ltd is the centres Clinical Care Manager (CCM). The job role requirements (JOB-HR008) of the CCM have been updated. The Controlled Drugs Governance Primary Care (Provider) Self-Assessment Tool supplied by the Care Quality Commission has been completed	

		to ensure compliance with the governance of controlled drugs	

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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. The Quality Management System (QMS). On inspection the following issues were noted: ○ the audit of storage consents did not check against the consent in the patient records; ○ some audits did not have any corrective actions recorded when non-compliances had been found (welfare of the child, submission of data to the HFEA, provision of information); ○ the centre has no current process for reviewing the	The PR should perform a comprehensive review of the centre's QMS to ensure its effectiveness, and address the issues identified in this report. The PR should provide a summary report of this review, and an action plan with timescales for implementation, to the centre's inspector by 5 August 2018. The PR should ensure the development of documented SOPs to ensure compliance with this recommendation.	Noted	The Executive acknowledges the PR's response and awaits the summary report of the review of the QMS due by 5 August 2018. Further action required.

robustness of audits as part of the quality management system; ○ the counselling audit lacked robustness in that it did not audit the quality of service provision, only the number of patients having counselling. In addition, there were no quality indicators for the audit of counselling; ○ the centre does not conduct an audit of the patient records, they audit certain elements of the records, but do not audit in line with SLC requirements; ○ there is no SOP for record keeping standards; ○ the timeframe for the completion of corrective actions is not recorded. SLC T33(b); T35; T36.	The PR should provide the centre's inspector with copies of the developed SOPs by 5 November 2018.		
3. Welfare of the child On inspection the following issues were noted: ○ the centre does not have an SOP for	The PR should ensure that welfare of the child assessment is compliant with statutory and regulatory requirements.	The internal Welfare of the Child form (FRM-Clin001) has been updated to include the recording of further information sought and the source of that information, with further actions required in	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

‘welfare of the child’ assessments; o the centre uses their own version of a welfare of the child patient history form but the form does not provide for recording any further information sought, the source of that information and actions taken in the event of a concern. SLC T2; T33(b); T56. HF&E Act 1990 (as amended) section 13 (5).	The PR should review procedures for undertaking welfare of the child assessment. A summary report of this review, including any corrective actions and timescales for implementation, should be provided to the centre’s inspector by 5 August 2018. Three months after the review, the PR should audit welfare of the child assessment procedures to ensure that corrective actions implemented, have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre’s inspector by 5 November 2018. The PR should ensure there are standard operating procedures in place for welfare of the child assessments. A copy of the procedure should be provided	the event of concern now also documented. A new SOP (SOP-Clin180 HFEA Consent Forms and Process) has been developed to instruct the process of completing a 'welfare of the child' assessment and the necessary steps to take in the event of concern. The audit of Welfare of the Child assessments shall be performed in conjunction with the changes detailed above, to ensure compliance. Noted	

	to the centre's inspector by 5 November 2018.		
4. Legal Parenthood. The following issues were noted on inspection: ○ in one record, section one of the WP (your consent to your partner being the legal parent) form had been correctly completed by the patient having treatment, but section one of the PP (your consent to being legal parent) form, also, incorrectly, contained the details of the patient having treatment instead of those of her partner. The patient had received treatment using donated sperm, but no pregnancy resulted from this treatment. The centre had not identified this anomaly at the time of treatment or through legal parenthood audits. ○ in four of the seven records reviewed the marital status of the	The PR should ensure that procedures for legal parenthood consents are robust and compliant with statutory and regulatory guidance. The PR should undertake a full review of legal parenthood consenting processes, including staff training requirements, actions taken and timeframes for implementation of corrective actions. A summary report of this review should be provided to the centre's inspector when responding to this report. To provide assurance of the validity of all consents in place, the PR should conduct a full audit of all consents given in circumstances where donated gametes or embryos were/are planned to be used in treatment.	A full audit of consents performed in circumstances where donated gametes or embryos were/are planned to be used in treatment is underway. A new SOP (SOP-Clin180 HFEA Consent Forms and Process) has been developed to provide guidance in relation to the forms required as part of the legal parenthood consenting process. The internal Welfare of the Child form (FRM-Clin001) has been updated to ensure far more robust processes for capturing marital status.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

couple could not be determined; ○ in one record, the offer of counselling had not been recorded; ○ in four of the records audited, the offer of counselling was made on the same day as the patient signed their consent forms. The inspection team are concerned that patients may not have been given enough time to consider the offer before signing their consent forms. SLC T2; T57; T60; T61.	The Executive acknowledges that a robust audit of all relevant consents will take a period of time. In that consideration, the PR should provide a report of the audit to the centre's inspector by 5 November 2018. If any anomalies with legal parenthood consents are found, the PR should inform the HFEA immediately.	The results of the full audit and summary of the review of practices related to legal parenthood consenting and additional training requirements, where necessary, shall be provided in due course.	

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.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
5. Witnessing. In one of five records audited, the witnessing signature was missing for the disposal of gametes. SLC T71.	The PR should ensure that documentation of witnessing checks is completed at the time the procedure takes place. The PR should take immediate action to ensure that witnessing is recorded at all critical points of the clinical and laboratory process. The inspector should be advised of the measures taken to ensure that this happens by 5 August 2018. Three months after the implementation of any changes to the witnessing procedures, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be	Noted	The Executive acknowledges the PR's response. No further action beyond submission of a witnessing auditing report due by 5 November 2018.

	provided to the centre's inspector by 5 November 2018.		
6. Infection control. The centre does not have a designated infection prevention and control lead. SLC T2.	The PR should ensure there is a designated, suitably trained, person to lead infection prevention and control practice and procedure within the centre. The PR should inform the centre's inspector when a suitably experienced member of staff has been identified to undertake this role. It is expected that the centre will have a designated infection prevention and control lead by 5 August 2018.	I can confirm that there has been a designated, suitably trained person to lead infection for The Fertility Partnership. GCRM will provide training to an appointed member of staff to lead infection control within the unit.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required.
7. Complaints On inspection the following issues were noted; o the centre did not respond to a patient's complaint by implementing appropriate corrective actions which resulted in the same issue occurring again when the patient came for further treatment;	The PR should ensure that all complaints are investigated and any corrective actions, implemented. Three months after the implementation of any corrective actions, the PR should audit the management of complaints to see that actions implemented have been effective in achieving and maintaining compliance.	Noted	The Executive acknowledges the PR's response. No further action beyond submission of an audit summary due by 5 November 2018.

CoP 28.2.	A summary report of this audit should be provided to the centre's inspector by 5 November 2018.		
8. Disclosure of information, held on the HFEA Register. Five discrepancies were found between ten completed patient/partner/donor disclosure consents on patient files and the corresponding data submitted for inclusion in the register. Whilst this failing would not lead to the risk that the HFEA may release patient identifying information to researchers it does mean that the consent wishes of the patient may not be followed. SLC T9(e); CH(10)05. General Direction 0005.	The PR should ensure that information provided to the Authority, which the Authority is required to hold on its Register of Information is accurate. The PR should review procedures for data submission in relation to consent to disclosure of information and provide a summary report of this review, including any corrective actions implemented, to the centre's inspector by 5 August 2018. Six months after the review, the PR should audit data submission practice and procedure to ensure that any corrective actions implemented have been effective in ensuring compliance.	The discrepansies noted within the inspection report have been relayed to the approporiate senior clinical staff. I can confirm these have been amended and submitted. In response to the discrepancies noted, requirements to update the related training logbooks has been implemented, and these shall be completed in due course where applicable. An audit of patient registration shall be performed in response to the discrepancies noted.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of an audit summary due by 5 November 2018.

	A summary report of this audit should be provided to the centre's inspector by 5 November 2018. The PR should correct the consent to disclosure discrepancies identified at this inspection and provide confirmation of this to the centre's inspector when responding to this report.		
9. Obligations and reporting requirements. 2% of the donor insemination (DI) treatments and 4% of the IVF treatments reviewed had not been reported to the HFEA as required by General Direction 0005. Of the above treatments that have been reported to the HFEA, 40% of the DI and 22% of the IVF treatments had been reported to the HFEA outside the period required by General Direction 0005. Additionally, the record of licenced activity provided for review was incomplete (i.e. in that it did not contain some	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 review data submission procedures and investigate why data submission has not been compliant with the requirements of General Direction 0005. A summary report of this review, including corrective actions taken, should be provided to the centre's inspector when responding to this report. Six months after the review, the PR should conduct an	The transition from patient management systems (Acubase to IDEAS) in 2017 has had an impact upon timeous submission of licensed activity to the HFEA register. The multidisciplinary team were aware of this issue. The required training and necessary SOP's were implemented upon making this transition. Communications with the software developers to correct the issues related to submission of data through IDEAS are ongoing. Noted	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of audit summary due by 5 November 2018.

treatments recorded on the HFEA register). The centre did not submit data for partner insemination cycles until after the inspection. This information should have been submitted on or before 28 February 2018. General Direction 0005 SLC T9 (e); T41.	audit of data submission practice and procedure to ensure that any corrective actions implemented, have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 5 November 2018. The PR should correct all the data discrepancies and ensure all treatments are reported to the HFEA, that have been identified at this inspection. The PR should confirm to the centre's inspector when this has been completed. It is expected that this will be completed by 5 August 2018.	Noted Complete	

Reponses from the Person Responsible to this inspection report