HFEA Executive Licensing Panel Meeting

25 July 2014

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

Minutes – Item 1

Centre 0250 – (Glasgow Centre for Reproductive Medicine) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Paula Robinson (Chair) – Head of Business Planning Nick Jones – Director of Compliance & Information Ian Peacock – Analyst Programmer	Dee Knoyle

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:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment (including embryo testing) and storage centre which provides a full range of licensed treatments including embryo testing for a small number of patients. The Panel noted that in relation to activity levels this is a large centre.

3. The Panel noted that the centre has been licensed by the HFEA since November 2006 and is on a four-year licence due to expire on 31 October 2014.

4. The Panel noted that on 18 May 2012 the Executive Licensing Panel agreed to add 'embryo testing' to the centre's licence as the Person Responsible (PR) wished to offer pre-implantation genetic screening. This treatment was provided to a small number of patients, but the PR has decided not to continue to offer this service and does not wish 'embryo testing' to remain on the licence. Therefore, the PR has applied to renew the licence for treatment and storage.

5. The Panel noted that in the 12 months to 31 March 2014 the centre provided 1081 cycles of treatment (excluding partner intrauterine insemination).

6. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 January 2013 to 31 December 2013 show that the centre's success rates are in line with national averages.

7. The Panel noted that in 2013, the centre reported seven cycles of partner insemination with no pregnancies. This is consistent with the national average.

8. Between 1 January 2013 and 31 December 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

9. The Panel noted that at the time of the inspection on 7 and 8 May 2014, the Inspectorate identified nine major and nine other areas of non-compliance. The Panel noted that since the inspection, the Person Responsible (PR) has addressed some of the non-compliances. The Panel noted that the PR was committed to fully implementing the outstanding recommendations.

10. The Panel noted that the Inspectorate recognised that a significant number of non-compliances were identified during this inspection. However, the Inspectorate did not consider these to be an immediate risk to patients, gametes and embryos and therefore recommended 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 the inspection report being implemented within the prescribed timescales.

Decision

11. 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.

12. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

13. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

14. The Panel reviewed each non-compliance and echoed the Inspectorate's observation that significant improvement is required in order for the centre to reflect suitable practices. The Panel noted that the centre has a quality management system (QMS) in place. The PR is encouraged to continue to use the QMS to best effect, so as to monitor and improve the service provided.

15. The Panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance and emphasised that failure to implement the recommendations relating to the various areas of non-compliance within the prescribed timescales may result in the submission of a further report to a licensing committee, with the recommendation that appropriate regulatory action should be taken in accordance with the Authority's Compliance and Enforcement Policy.

16. The Panel endorsed the Inspectorate's recommendation to renew the centre's treatment and storage licence (without embryo testing) for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

Signed: Date: 31 July 2014

Paula Robinson (Chair)

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: 7 and 8 May 2014

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

The centre wishes to remove the following activity from their existing licence:
Embryo testing

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

Inspectors: Vicki Lamb, Sara Parlett, Lisa Beaumont, Cathy Hodgson, Barbara Lewis, Karen Conyers (HFEA observer)

Date of Executive Licensing Panel: 25 July 2014

Centre name	Glasgow Centre for Reproductive Medicine
Centre number	0250
Licence number	L/0250/4/c
Centre address	21, Fifty Pitches Way, Cardonald Business Park, Glasgow, G51 4FD, UK
Person Responsible	Professor Richard Fleming
Licence Holder	Dr Mark Gaudoin
Date licence issued	01/11/2010
Licence expiry date	31/10/2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Glasgow Centre for Reproductive Medicine has held a treatment and storage licence with the HFEA since November 2006 and provides a full range of fertility services.

On 18 May 2012 an ELP agreed to add 'embryo testing' to the centre's licence as the Person Responsible (PR) wished to offer preimplantation genetic screening. This treatment was provided to a small number of patients, but the PR has decided not to continue to offer this service and does not wish 'embryo testing' to remain on the licence. He has, therefore, only applied to renew the licence for 'treatment and storage'.

The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 1081 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/03/2014. In relation to activity levels this is a large centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 January 2013 to 31 December 2013 show that the centre's success rates are in line with national averages.

In 2013, the centre reported seven 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 1 January 2013 and 31 December 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable, except as detailed below;
- the centre's practices are suitable, except as detailed below;
- the application contains the supporting information required by General Directions 0008, in application for renewal of the 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 nine major and nine 'other' areas of non-compliance.

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

Major areas of non compliance:

- The PR should ensure corrective actions are documented and implemented.
- 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.

'Other' areas of non-compliance:

- The current practice for thawing embryos should be reviewed.
- The PR should consider the risks of not labelling the tubes used during egg collection.
- The PR should ensure a suitable third party agreement is established with the blood testing laboratory.

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

Major areas of non compliance:

- The PR should ensure that controlled drugs are stored appropriately.
- The PR should take immediate action to ensure that all relevant data about anything coming into contact with gametes or embryos is traceable.
- The PR should ensure the establishment of quality indicators (QIs) for all activities.
- The PR should ensure that wherever possible CE marked equipment is used.
- The PR should ensure all critical equipment is validated.
- The PR should ensure all procurement and processing procedures are validated.
- The PR should ensure register submissions are accurate.

'Other' areas of non-compliance:

- The PR should ensure the development of documented standard operating procedures (SOPs) for recall, withdrawal of consent, use of embryos in training and screening donors where additional testing may be required.
- The PR should inform the Lead Inspector when the final inspection for accreditation of the blood testing laboratory takes place, and inform the Lead Inspector when validation of diagnostic semen analysis procedures has been completed.
- The PR should ensure that appropriate taps, soap dispensers and bins are available in all clinical areas
- The PR should ensure that drugs wastage is documented in the controlled drugs log.
- The PR should ensure that relevant staff receive training in safeguarding.
- The PR should ensure that patient / partner consents to disclosure of identifying information to researchers are reported accurately to the HFEA.

Recommendation to the Executive Licensing Panel

The centre has more than 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 rates indicate that the multiple birth rates are likely to meet the target.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) in place. The PR is encouraged to continue to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and is pleased to see that some of the recommendations have already been implemented. Failure to implement the recommendations relating to the areas of non-compliance within the prescribed timescales may result in the submission of a further report to the ELP with the recommendation that appropriate regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recognises that a significant number of non-compliances were identified during this inspection. However, the inspection team does not consider these to be an immediate risk to patients, gametes and embryos and is satisfied that it can recommend the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are broadly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; Directions 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

SOPs for screening of donors do not include that in certain circumstances additional testing may be required depending on the donor's history and the characteristics of the gametes donated (standard licence condition (SLC) T33 and T52h). See recommendation 10.

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

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

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

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are 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; Directions 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements, keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are broadly 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; Directions 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 broadly compliant with HFEA requirements.

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

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

The centre is partially compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)

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

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

What the centre could do better

Safety and suitability of premises and facilities
Some embryology staff re-use dishes during embryo thawing, utilising the previously unused wells and removing the previous patient's dish label. Although this does not present a direct infection risk to patients, the inspection team were concerned that this practice could lead to mis-matches if the previous patient's dish label was not removed completely (SLC T2). See recommendation 11.

Laboratory accreditation
The centre's laboratories which undertake diagnostic semen analysis and blood testing are not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. Once validation of equipment for diagnostic semen analysis procedures has been undertaken the centre will meet the criteria for accreditation equivalent to CPA (UK) Ltd for diagnostic semen analysis. Centre staff informed the inspection team that they have applied for accreditation for the blood testing laboratory and are awaiting a final inspection (SLC T21). See recommendation 12.

Infection control
The centre does not have hands-free operation taps, hands-free operation soap dispensers and pedal bins in all clinical areas (SLC T17). See recommendation 13.

Medicines management
The controlled drugs cabinet is not fixed to a solid wall and has no red light on top to indicate when it is unlocked. The drugs fridge in theatre has no lock and is not subject to independent temperature monitoring (SLC T17). See recommendation 1.

Drugs wastage is not documented in the controlled drugs log (SLC T2). See recommendation 14.

Transport and distribution of gametes and embryos
There is no recall procedure that defines the responsibilities and actions required when a distribution is recalled (SLC T33b). See recommendation 10.

Traceability
On inspection, the batch numbers of four consumables were checked to ensure the batch numbers recorded in the patient records were the same as the batch numbers actually used. In one instance this was not the case (SLC T99). See recommendation 2.

At egg collection not all containers used during the procurement of eggs are labelled with

the patient's/donor's full name and a further identifier (SLC T101). See recommendation 15.

Quality management system (QMS)
The centre has not established QIs for all activities (SLC T35). See 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). See recommendation 4.

Third party agreements
The third party agreement with the company that conducts blood testing does not include a description of how any test results are relayed to the centre (SLC T114f). See recommendation 16.

Equipment and materials
Some consumables, such as pipettes and egg collection tubes, currently in use are not CE marked. Centre staff are aware of this and gave assurances that they are actively seeking suitable CE marked equivalents (SLC T30). See recommendation 5.

Staff at the centre gave verbal confirmation that critical equipment had been validated, but no documentation was available (except for the facilities monitoring system and a Class II hood) so the inspection team could not confirm that the validation had been performed (SLC T24). See recommendation 6.

Process validation
Staff at the centre gave verbal confirmation that critical processes had been validated, but no documentation was available (except for semen analysis) so the inspection team could not confirm that the validation had been performed (SLC T72). See recommendation 7.

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 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 (T/1106/7).

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 for taking into account the welfare of the child are compliant with HFEA requirements. This is important 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.

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

What the centre could do better

Staff have not received training in safeguarding (SLC T15). See recommendation 17.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

The centre no longer provides embryo testing and the PR wishes this activity to be removed from the centre's licence.

What the centre could do better

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further 31 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 22 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. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Directions 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA

requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipients.

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

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

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and 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 broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents

before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (Directions 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 assisted reproductive technology (ART) and those born following ART treatment.

What the centre could do better

Consent (Guidance note 5; 6)
There is no SOP for withdrawal of consent by a patient (SLC T33b). See recommendation 10.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
An audit of patient consent to disclosure decisions recorded in 17 patient notes and that submitted for inclusion on the HFEA register showed that in two instances discrepancies were found between patient disclosure consent decisions recorded in patient files and the related consent data submitted for inclusion on the register. See recommendation 18.

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 The centre's procedures for using embryos for training staff are partially 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 There is no SOP for using embryos in training, including procedures in place to avoid any perceived conflict of interest. See recommendation 10. Information provided to patients when considering whether to consent to the use of their embryos in training does not include all the HFEA requirements. See recommendation 8.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; Directions 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.

What the centre could do better

The HFEA register audit team found some evidence of problems with the accuracy of the centre's submission of data to the Register. These included a number of data quality issues which would impact on the HFEA's ability to supply accurate information to a donor-conceived person and their parents (Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007). See recommendation 9.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, recommendations for improvement were made in relation to three areas of major non-compliance and five 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

The centre has not received any HFEA Risk Based Assessment Tool (RBAT) alerts relating to their 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, 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. The controlled drugs cabinet is not fixed to a solid wall and has no red light on top to indicate when it is unlocked. The drugs fridge in theatre has no lock and is not subject to independent temperature monitoring. SLC T17	The PR should ensure that controlled drugs are stored as per the specifications set out in the Misuse of Drugs (Safe Custody) Regulations 1973, specifically ensuring that the controlled drugs cabinet is fixed to an appropriate wall. The PR should inform the Lead Inspector what action has been taken to address this issue. The PR should ensure that drugs are stored in a fridge with a lock and appropriate temperature monitoring. The PR should inform the Lead Inspector what action has been taken to address this issue. By 8 November 2014.	As discussed at the inspection we were aware that a new controlled drugs cabinet was required. The new controlled drugs cabinet is now attached to a brick wall and has a light & alarm when opened. This cabinet meets the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973 and testing to BS2281 standards. The drugs fridge in theatre contains emergency procedure drug. It does not lock, in accordance with our risk assessment. NB it is in a restricted access area. The theatre fridge referred to	The Lead Inspector is satisfied that the controlled drugs cabinet is now appropriately fixed and alarmed, and the theatre fridge will be appropriately monitored. The Lead Inspector will liaise with the PR to obtain further information on the drugs contained in the fridge and the security measures that are appropriate in those circumstances. Further action required.

		has not been subject to data monitoring due to an oversight. It has been added to the schedule, and is currently being validated.	
2. The batch numbers of four consumables were checked to ensure the batch numbers recorded in the patient records were the same as the batch number actually used. In one instance this was not the case. SLC T99	The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable. The Lead Inspector should be advised of the measures taken to ensure that this happens by 8 August 2014. Within six months of the implementation of procedures, the centre should conduct an audit to evaluate whether this information is accurately documented and a summary report of the findings of the audit should be provided to the Lead Inspector.	Current audit did not catch this issue. A new weekly check has been implemented to compare 'live' goods against computer records to ensure compliance for traceability of embryology laboratory media and relevant consumables. We are also creating an additional monthly audit to ensure that the weekly check is serving its purpose (adaptation of audit 8.2). This will revert to a 6 monthly audit when we are satisfied that the new system is robust. Audit findings will be submitted to Lead Inspector following the audit of the July weekly checks.	The Lead Inspector is satisfied that appropriate measures have been taken to address this issue, and looks forward to receipt of the audit of the July weekly checks. Further action required.
3. The centre has not established QIs for all	The PR should ensure the establishment of QIs for all	INF-QMS004 denotes our QIs, which we believe now	The version of document INF-QMS004 provided to the Lead

activities SLC T35	activities. Documentation demonstrating the establishment of the QIs should be provided to the Lead Inspector by 8 August 2014.	addresses the few gaps identified in the inspection. As you are aware the focus of our QI system was on the scientific side of our practice, we have now extended that to cover all QM sections.	Inspector did not include all the expected QIs for the centre. The Lead Inspector will liaise with the PR to resolve this issue. Further action required.
4. 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 PR should review the findings of the audits for which there was no documentation of corrective actions. The Lead Inspector should be provided with a summary report documenting any required corrective actions and the timescale for their implementation by 8 August 2014. Where it is not possible to establish the corrective actions identified as required by audits then consideration should be given to repeating these audits. The HFEA should be advised of the anticipated timescale for repeat of any audits where the corrective actions cannot be established by 8 August 2014. The PR should ensure that corrective actions are	The audits are presented at the weekly QM meetings and reviewed at the quarterly management review (QMR) meetings. The findings at the QMR are minuted. We have created a log (FRM-QMS073 attached) of these minutes. In future this log will be presented at each QMR for documentation of actions, implementation and timescale.	Document FRM-QMS073 was provided to the Lead Inspector. This document details the corrective actions required following audits and the completion of these corrective actions. All corrective actions required had been completed. No further action required.

	documented in future. The PR should provide monthly updates to the HFEA on progress in completing any audits identified as required and/or in implementing corrective actions.		
5. Some consumables currently in use are not CE marked. SLC T30	The PR should ensure that wherever possible CE marked equipment is used. 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, the PR should provide the Lead Inspector with a list of all medical devices currently in use that are not CE marked. The list should include either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance within the next year. The list should be submitted to the Lead Inspector by 8 August 2014.	As explained during the inspection we have undertaken to use CE marked products where it is appropriate. List of non-CE marked products used at GCRM Limited is attached for Lead Inspector to review. Please note that we have an audit to compare our consumable goods against CE marking and we continually monitor this issue. All non- CE marked goods are risk assessed and we give our undertaking to make a change if/when appropriate.	A list of all medical devices currently in use at the centre that are not CE marked was provided, along with a timescale for actions. The Lead Inspector will follow up the actions proposed at the appropriate times. Further action required.

6. Staff at the centre gave verbal confirmation that critical equipment had been validated, but no documentation was available (except for the facilities monitoring system and a Class II hood) so the inspection team could not confirm that the validation had been performed. SLC T24	The PR should provide a list of all critical equipment including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the Lead Inspector by 8 August 2014. The PR should provide monthly updates to the Lead Inspector on progress in completing validation. It is expected that validation will be prioritised on the basis of risk and that validation will be complete by 8 November 2014. On completion of the validation programme the Lead Inspector will ask for a sample of validation documents to be submitted for review.	We have completed a full review of all equipment in the laboratory and a validation/calibration programme will be set by 8 August. Monthly updates will be provided in accordance with Lead Inspectors request.	The Lead Inspector awaits submission of the list by 8 August 2014. Further action required.
7. Staff at the centre gave verbal confirmation that critical processes had been validated, but no documentation was available (except for semen analysis) so the inspection team could not confirm that	The PR should provide a list of all procurement and processing procedures that are considered critical including the date of validation or the planned date by which validation is expected to be complete. The list should be	INF-QMS004 denotes our QIs, KPIs and validation method. We believe this fully addresses this requirement.	The version of document INF-QMS004 provided to the Lead Inspector did not include all the expected information. The Lead Inspector will liaise with the PR to resolve this issue. Further action required.

the validation had been performed. SLC T72	provided to the Lead Inspector by 8 August 2014. The PR should provide monthly updates to the Lead Inspector on progress in completing validation. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that validation will be complete by 8 November 2014. On completion of the validation programme the Lead Inspector will ask for a sample of validation documents to be submitted for review.		
8. Information provided to patients when considering whether to consent to the use of their embryos in training does not include all the requirements of SLC T97.	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 Lead Inspector by 8 August 2014.	CON-GCRM046 has been updated and is attached for review by the Lead Inspector.	The Lead Inspector is satisfied that information provided to patients when considering whether to consent to the use of their embryos in training now includes all the requirements of SLC T97. No further action required.
9. The HFEA register audit team found some evidence of problems with the	The PR should: • correct the submissions that have been	We were advised on the day of our inspection that the data integrity was 100% compliant.	Centre staff have made good progress in resolving this issue.

accuracy of the centre's submission of data to the Register. SLC T9e	identified as being incorrect by 8 August 2014 • review systems and processes used for licensed treatment data submission to enable the reasons for poor quality submissions to be identified and addressed and inform the Lead Inspector of the findings and corrective actions by 8 August 2014 • 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 Lead Inspector by 8 March 2015.	The inspection team revealed a report from the HFEA that listed a number of 'errors' - this after the register co-ordinator had advised us that we had no outstanding issues. We have addressed the issues presented in the report and we now have a weekly audit of this report. There are a couple of on-going issues that Roup (@HFEA) is looking into. SOP-Admin151 attached documents how this is being handled at GCRM Ltd. A number of these issues that were listed were not errors. The data submitted to the EDI computer algorithm does not accept our report that a pregnancy scan had two sacs and 1 fetal heart. This means that the data we have to submit to avoid this error is biologically inaccurate.	The Lead Inspector will liaise with the PR to ensure this continues, and awaits submission of the audit. Further action 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
10. There is no SOP to direct the following procedures SLC T33(b): • Recall of a distribution • Withdrawal of consent • Use of embryos in training including procedures in place to avoid any perceived conflict of interest • Screening of donors where additional testing may be required depending on the donor's history and the characteristics of the gametes donated SLC T52h.	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the Lead Inspector by 8 November 2014.	SOP-Lab045 covered recall of a tank prior to delivery at another centre but we are modifying it to cover recall process after a delivery has been made. Withdrawal of consent SOP is being updated. SOP-Lab099 (attached) covers the SOP requirements for use of embryos in training procedures. Screening of donors SOPs (SOP-Clin027, SOP-Clin028 & SOP-Clin048 attached) have all been checked and are consistent with the INF documents to detail when additional testing is required.	The PR provided SOPs for the following procedures: • Use of embryos in training including procedures in place to avoid any perceived conflict of interest • Screening of donors where additional testing may be required depending on the donor's history and the characteristics of the gametes donated SLC T52h. The Lead Inspector awaits SOPs for the following procedures: • Recall of a distribution • Withdrawal of consent Further action required.
11. Some embryology staff re-use dishes during thawing,	The current practice should be reviewed and a summary	This practice was discontinued with immediate effect.	The Lead Inspector is satisfied with the response.

utilising the previously unused wells and removing the previous patient's dish label. SLC T2	report of the review including any changes of practice submitted to the Lead Inspector by the time this report goes to ELP.	Laboratory SOPs for vitrification & thawing have been updated accordingly.	No further action required.
12. The centre's laboratories which undertake diagnostic semen analysis and blood testing are not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. Centre staff informed the inspection team that they have applied for accreditation for the blood testing laboratory and are awaiting a final inspection. SLC T21	The PR is asked to inform the Lead Inspector when the final inspection for accreditation of the blood testing laboratory takes place. The PR is reminded that once validation of equipment for diagnostic semen analysis procedures has been undertaken the centre will meet the criteria for accreditation equivalent to CPA (UK) Ltd for diagnostic semen analysis. The PR should inform the Lead Inspector when validation has been completed. By 8 November 2014.	CPA (UK) Ltd is no longer available. We do not perform external diagnostic semen analysis. Regarding the blood service, in January 2012 HFEA Scientific Inspector Dr Andrew Leonard documented in an e-mail to us that "As you are aware, it is acceptable that HFEA regulated units use your services if you are working towards ISO 17025 accreditation. I do not think any more detailed information is necessary" Since then we have upgraded our accreditation towards ISO 15189. We understand that we are further through the ISO 15189 process than any other lab in the UK. ISO 15189 has proven to be exceptionally difficult for most	The Lead Inspector will continue to follow up with the PR on progress with accreditation. Further action required.

		diagnostic laboratories that have attempted it. So far feedback in the industry is that most labs have given up with trying to obtain it. We anticipate closure of our ISO 15189 application in 3 months.	
13. The centre does not have hands-free operation taps, hands-free operation soap dispensers and pedal bins in all clinical areas. SLC T17	The PR should ensure that appropriate taps, soap dispensers and bins are available in all clinical areas. The PR should inform the Lead Inspector of the action taken to address this issue. By 8 November 2014.	We are aware of this. The status quo was modelled on the taps, sinks and soap supply in the scanning unit at the local private hospital, which we believe is governed by the Scottish equivalent of the CQC. Hands-free operation taps are available in theatre. In other areas the risk assessment has documented that the procedures undertaken in these areas are 'clean' procedures (not sterile) and therefore there is not an absolute requirement for hands free taps. Risk Assessment FRM-H&S004Z6 attached. Similarly, we deemed there to	The Lead Inspector will liaise further with the PR to confirm that the centre's policies for hand washing are in line with relevant requirements and provide adequate protection for patients and staff. Further action required.

		be no need for hands free soap dispensers as you always wash your hands after dispensing soap. Lids have been removed from bins.	
14. Controlled drugs wastage is not documented in the controlled drugs log. SLC T2	The PR should review the procedure for documenting drugs wastage, and provide evidence to the Lead Inspector that action has been taken to ensure controlled drugs wastage is documented. . By 8 August 2014.	SOP-Clin119 Ordering and Maintaining Controlled Drugs has been updated and is awaiting approval.	The Lead Inspector will request submission of the SOP once it has been approved. Further action required.
15. At egg collection not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier. SLC T101	While it is acknowledged that only one egg collection takes place at a time, the PR should consider the risks of not labelling the tubes used during egg collection. The Lead Inspector should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by 8 August 2014.	The practice of labelling the egg collection tubes being passed from theatre into the laboratory has been risk assessed (FRM-H&S004Z5) and determined that labelling these tubes would be a risk-prone practice. Alternative practice has been to ensure hot blocks were clear prior to starting the next procedure with documentation on the theatre 'whiteboard'.	The Lead Inspector is satisfied with this response. No further action required.

		Following inspection we have moved the documentation of the hot block checks onto the paper records. Six laboratory forms have been updated to require a signature to confirm that the laboratory hot block is clear prior to starting an OPU and the patients theatre paperwork has also been updated to request a signature to confirm the block is clear in theatre after the OPU.	
16. The third party agreement with the company that conducts blood testing does not include a description of how any test results are relayed to the centre. SLC T114f	The PR should ensure a suitable third party agreement is established with the blood testing laboratory and a copy of this is forwarded to the Lead Inspector by 8 August 2014.	Third Party agreement attached. Point 3.4 documents that the results will be faxed to the centre.	The Lead Inspector was provided with the revised third party agreement which now incudes a description of how any test results are relayed to the centre. No further action required.
17. Staff have not received training in safeguarding. SLC T15	The PR should ensure that relevant staff receive appropriate training in safeguarding. The PR should inform the Lead Inspector when training has been completed.	The Centre Manager and the Medical Director have completed Safeguarding Training to Level 3. The Quality Manager has also completed safeguarding training.	The Lead Inspector is satisfied with this response and will follow up with the PR to confirm that training has been undertaken as planned. Further action required.

	By 8 November 2014.	All clinical employees will complete Safeguarding training to level 1 within 1 month and the remaining employees will undertake in-house training also within 1 month.	
18. An audit of patient consent to disclosure decisions recorded in 17 patient notes against those submitted for inclusion on the HFEA register showed that in two instances discrepancies were found between patient disclosure consent decisions recorded in patient files and the related consent data submitted for inclusion on the register. Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007	The PR should correct the submissions that have been identified as being incorrect and review 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 by 8 August 2014. Six months after implementing any changes to this process the PR should audit the submission of consent to disclosure data to confirm that any changes made to systems and processes are having the desired effect. A summary of this audit should be provided to the Lead Inspector by 8 March 2015.	An audit is being devised to check the paper copies of the HFEA CD form against the information supplied through the EDI system. This audit will be completed every 6 months through our standard QI document (INF-QMS004). The identified issues will be corrected by 8 August 2014.	The Lead Inspector is satisfied with this response and will follow up with the PR to ensure the corrections have been made and an audit is performed at the appropriate time. Further action required.

	(NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).		

Reponses from the Person Responsible to this inspection report
It is clear from the inspection and the report that the inspection was focussed upon interpretation of the BFS quality manual. We have recently been upgrading our ISO 9001 certified QM System (Document control for the whole centre) to incorporate major components of ISO 15189 for the clinic/laboratory services. This is reflected in our KPI structure and approach. However, the inspection identified areas where our progress in the areas of administration and information are deficient. We believe that we can put all improvement in place by the indicated timescales. There are 13 documents submitted at this stage.