# Interim Licensing Report

**Centre name:** **Glasgow Centre for Reproductive Medicine**

**Centre number:** **0250**

**Date licence issued:** **01/11/2010**

**Licence expiry date:** **31/10/2014**

**Additional conditions of licence:** **None**

**Date of Inspection:** **3 May 2012**

**Inspectors:** **Debra Bloor (lead), Paul Knaggs, Rebekah Dundas (observer)**

**Date of Executive Licensing Panel:** **25 July 2012**

## Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the recommendations made in the last inspection report; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

## Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note: the progress made by the centre in meeting the HFEA multiple birth rate targets and; the positive comments made by patients in relation to their experiences.

At the time of the inspection, the team made recommendations for improvement in relation to three **major** areas of non-compliance and five '**other'** areas of non-compliance. The Person Responsible (PR) has provided evidence that the following recommendations have been implemented and/or acted upon:

**'Major' areas of non-compliance**

- When treatment is provided where the child is not to be raised by the carrying mother (ie, in a surrogacy arrangement), the centre should assess both those commissioning the surrogacy arrangement and the surrogate and the surrogate's partner, if she has one.
- The centre should continue to investigate and report all breaches of confidentiality so that continued efforts can be made to identify and implement corrective actions.

**'Other' areas of practice that require improvement**

- The PR should review procedures for submission of HFEA register information to ensure on-going compliance with Directions 0005.
- The PR should take reasonable steps to satisfy himself that the requirements of Directions 0001 v3 are met and must keep a record of the steps taken for this purpose when a third party introduces a gamete donor.

In his response to the report the PR gave a full commitment to the implementation of the following recommendations:

**'Major' areas of non-compliance**

- Confirmation that a planned audit of procedures for selecting and recruiting donors has been completed should be provided to the HFEA.

**'Other' areas of practice that require improvement**

- The PR should ensure that it is possible to link the electronic and manual witnessing checks to a patient treatment to ensure compliance with Standard Licence Condition (SLC) T102.
- The PR should ensure that the patient history is sufficient to identify where additional screening may be indicated and that staff are trained to carry out this screening (SLC T50).
- Where treatment services are provided using donated gametes the PR should ensure that information about the importance of informing any resulting child at an early age that they were born as a result of such treatment and suitable methods of informing such a child of that fact are provided (SLC T63).

The implementation of these recommendations within the prescribed timescales will be subject to on-going monitoring.

## Information about the centre

The Glasgow Centre for Reproductive Medicine is located in a business park on the outskirts of Glasgow and has held a licence since 1 November 2006.

The centre provides a full range of fertility services and, at the time of the inspection, was in the process of applying to have their licence varied to allow treatment involving embryo testing to be provided.

The centre provided 1124 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to March 2012. In relation to activity levels this is a large centre.

## Details of Inspection findings

## Quality of Service

Each interim inspection focuses on the following themes:  they are very important indicators of centres' ability to provide high quality patient care and to meet the requirements of the law.

### Outcomes[1]

HFEA held register data for the year ending January 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages for all age bands and all treatment types.

### Multiple births[2]

The single biggest risk of fertility treatment is multiple pregnancy. In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 29%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this also represents performance that is not likely to be statistically different from the 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. The inspection team congratulates the centre on this achievement.

### Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur.  The following laboratory activities were observed in the course of the inspection: egg collection; fertilisation checks; thawing of

[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.

[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate target to a multiple pregnancy rate target. The derived multiple pregnancy rate targets for the specified multiple birth rate targets are as follows; 01/04/2010 – 31/03/2011,  25%; 01/04/2011 – 30/09/2012, 19%

gametes; sperm preparation; preparation for embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system.

The scientific inspector was able to review records that were present in the laboratory and concluded that records of both manual and electronic witnessing are maintained. The centre does not maintain a copy of the witnessing records in patient records (either electronic or hard copy) however, and witnessing records were not readily accessible for inspection for patients not actively in treatment. This could impact on the ability of the centre to facilitate the traceability of information relating to the safety of gametes and embryos (SLC T102 – see recommendation 4)

### Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 10 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all of the records reviewed. In the records of patients having DI treatment, two patients had not completed the consents and three patients had completed the consents: one patient involved in a surrogacy treatment had also not completed the consent. This does indicate inconsistency in the completion of these consents but it is acknowledged that the HFEA requirements in relation to advice on the completion of consent by patients undergoing treatment with donated gametes is in the process of changing and that there is currently no negative impact associated with this inconsistency.

### Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

### Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

## Patient experience

During the inspection visit the inspection team spoke to six patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 21 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 16 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 prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

## Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

## Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self-assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- Treatment involving surrogacy has been provided without the surrogate's partner having been subject to a welfare of the child assessment. This is non-compliant with the requirements of SLC T56 and guidance at 8.4 of the CoP (see recommendation 1)
- Procedures for selecting and recruiting donors have not been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years (SLC T36 – see recommendation 4).
- The centre does not, in appropriate circumstances carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi) (SLC T50(g) – see recommendation 7).
- Where a third party or a patient has been involved in introducing a donor, the centre does provide patients with information about what reimbursements are permitted but does not have specific procedures for obtaining reassurance that the donor has not received more than the prescribed amount of compensation (Directions 0001 version 2 – see recommendation 8).
- It is the responsibility of the centre's counsellor to provide information to parents about how to tell a child that he or she results from the gametes of a person who is not their parent. Where the recipients of donor gametes choose not to see a counsellor this information is not made available (SLC T63 – see recommendation 9).

## Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2010 recommendations for improvement were made in relation to seven major non-compliances and two 'other' areas of non-compliance. The PR provided information and evidence that all of the recommendations had been fully implemented before the report was considered by a licensing committee.

The renewal report included the following recommendations:

- The PR should review incidents related to patient confidentiality breaches including analysis and remedial actions in order to devise a plan to minimise the risk of recurrence and protect the confidentiality of all patients and donors at the centre as required by S33 of the HFE Act 1990 (as amended).
- The PR should consider a review of the centre's incident reporting standard operating procedure to include notification to the HFEA of less serious incidents and near misses as recommended by G27.5.

In responding to the report immediately after the inspection, the report of a full audit of the relevant incidents and information about corrective actions intended to minimise the risk of recurrence of breach of confidentiality incidents were submitted to the HFEA.

Since the last inspection the centre has reported incidents, including a number related to breaches of confidentiality, in accordance with HFEA requirements: this is considered indicative of a proactive and compliant approach to incident reporting reflective of compliance with the latter recommendation.

It is noted however, that two near misses and nine incidents related to breaches of confidentiality have been reported to the HFEA since the last inspection and this was discussed at the interim inspection. The PR and quality manager confirmed that the centre has been monitoring these occurrences very closely and has made considerable efforts to ensure that staff are suitably trained and aware of the implications of such incidents. The PR did estimate that more than 10,000 pieces of correspondence are sent out by the centre in a year and that this reflects an error rate in the region of 0.1%. While the centre's efforts are acknowledged, breaches of confidentiality constitute a breach of S.33A of the 1990 Human Fertilisation and Embryology Act (as amended) and are considered very serious and it is concluded that on-going action is required by the centre in relation to incidents of breach of confidentiality (see recommendation 3).

## On-going monitoring of centre success rates

In March 2012, the centre was asked to review procedures for the provision of donor insemination treatment on the basis of on-going monitoring of success rates. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep success rates in this group of patients under review.

## Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre is responsive and generally acts promptly when alerted to data validation and verification issues. Although most other data submissions are timely, there are a small

number of submissions that relate to 2011 that remain outstanding and some late submission of intention to treat and treatment form data. This is non-compliant with Directions 0005 version 2 (see recommendation 5).

**Annex 1**

# Areas of practice that require the attention of the Person Responsible

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 noncompliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. 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 | Inspection team's response to the PRs statement |
|---|---|---|---|
| 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 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 | Inspection team's response to the PRs statement |
|---|---|---|---|
| 1. Treatment involving surrogacy has been provided without a surrogate's partner having been subject to a welfare of the child assessment. This is non-compliant with the requirements of SLC T56 and guidance at 8.4 of the CoP. | When treatment is provided where the child is not to be raised by the carrying mother (ie, in a surrogacy arrangement), the centre should assess both those commissioning the surrogacy arrangement and the surrogate and the surrogate's partner, if she has one.<br><br>The centre's standard operating procedures/processes and staff training needs for conducting a welfare of the child assessment should be reviewed and a summary of any actions taken should be provided to the HFEA by 3 August 2012. | In line with my previous advice, we have undertaken a full review of all our surrogacy policies and paperwork.<br>We have updated our surrogacy paperwork to ensure that the Welfare of the Child form is now completed by a surrogate's partner to ensure that all aspects of WoC are covered. | The PR has provided a checklist document that clearly indicates that a welfare of the child assessment is required for a surrogate's partner before treatment involving surrogacy is provided.<br><br>**No further action required.**<br><br>The centre's adherence to the revised policy should be audited at the time of the next inspection. |

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| 2. Two near misses and nine incidents related to breaches of confidentiality have been reported to the HFEA since the last inspection.<br><br>This was identified as an area for improvement at the time of the last inspection. | Breaches of confidentiality constitute a breach of S.33A of the 1990 Human Fertilisation and Embryology Act (as amended) and are considered very serious.<br><br>It is acknowledged that the centre has acted to minimise the risk of such breaches occurring and it is recommended that the centre continues to investigate and report all such incidents so that efforts continue to be made to identify and implement effective corrective actions. | As we discussed at our inspection, we take these breaches seriously. Further retraining has been completed by all administrative staff, who continue to be diligent in this area.<br>GCRM would like to point out that as we send out in excess of 12,000 letters in a year, this it is a non-compliance rate of 0.075%<br>We feel this is realistically a 'reasonable' non-compliance rate for any manual input system.<br><br>Whilst I understand that any breach is a serious matter dealing with it under the 'Major area of non-compliance' perhaps explains why centres such as ours that report such incidents feel some level of unjust consideration by the HFEA.<br>I acknowledge that addressing these issues is an important part of the regulators role but feel it may be better dealt with under a different section. | **No immediate further action required.**<br><br>The centre's progress in relation to this recommendation will be subject to on-going monitoring by the HFEA's clinical governance team. |

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| 3. Procedures for selecting and recruiting donors have not been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years (SLC T36). | Following the inspection the centre's quality manager has confirmed that the audit will be completed in the next six months. Confirmation that the audit has been completed should be provided to the HFEA by 3 November 2012. | We have adjusted a current audit to ensure this is checked every 6 months in our current audit system. | **Further action as documented required.**<br><br>To be subject to on-going monitoring. |

## 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 | Inspection team's response to the PRs statement |
|---|---|---|---|
| 4. The centre does not maintain a copy of the witnessing records in patient records (either electronic or hard copy) and in the course of the inspection it was not possible to access the witnessing records.<br><br>It is acknowledged that guidance at 18.7 of the CoP simply requires that records are retained but SLC T102 requires the centre to record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. | The PR should ensure that it is possible to link the electronic and manual witnessing checks to a patient treatment to ensure compliance with SLC T102.<br><br>The HFEA should be advised of the measures taken to ensure that it is possible to link these documents by 3 August 2012. | The laboratory notes and the clinical notes are all stored in our electronic patient records database (ACUBase).<br><br>The lab notes detail who has witnessed each step in the procedure and these notes are clearly identifiable in the 'attachments' section of the database.<br><br>At the time of inspection there were 4 'boxes' of laboratory case notes that had not been scanned into the database due to staff sicknesses. We are in the process of correcting this and hope to have completed the scanning in of all these documents by the end of August. | **Further action as documented required: to be subject to on-going monitoring.** |
| 5. There are a small number of register submissions that relate to 2011 that remain outstanding and some late submission of intention to treat | The PR should review procedures for submission of HFEA register information to ensure on-going compliance with Directions 0005. | I believe these have all been corrected now, if this is not the case please can you notify me what areas require attention? | **No further action required.**<br><br>The centre's progress in relation to this |

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| and treatment form data. This is non-compliant with Directions 0005 version 2 | | | recommendation will be subject to on-going monitoring by the HFEA's business intelligence team who will also provide feedback to the PR. |
| 6. Where a third party or a patient has been involved in introducing a donor, the centre does provide patients with information about what reimbursements are permitted but do not have specific procedures for obtaining reassurance that the donor has not received more than the prescribed amount of compensation (Directions 0001 version 3). | The PR should take reasonable steps to satisfy himself that the requirements of Directions 0001 v3 are met and must keep a record of the steps taken for this purpose.<br><br>The HFEA should be advised of the measures the centre intends to take to provide reassurance that donors sourced by a third party are only reimbursed in line with the requirements of Directions. The centre should provide this information by 3 August 2012.<br><br>Steps taken to obtain this reassurance should be documented with immediate effect when suitable procedures have been devised. | The consent forms have been updated to ensure that all parties sign to say they are aware of their requirement to comply with the allowable compensation limits. | **No further action required.**<br><br>Documentation of the steps taken will be monitored at the time of the next inspection. |
| 7. The centre reported in their SAQ that they do not, in appropriate circumstances carry out additional testing depending on the patient's | While it is acknowledged that the centre has not had cause to carry out additional screening of patients, the PR should ensure that the patient history is | As part of the response to this issue we aim to address a more comprehensive document and subsequent training to ensure this is | **Further action as documented required: to be subject to on-going monitoring.** |

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| travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi) ? [T50(g)] | sufficient to identify where such screening may be indicated and that staff are trained to carry out this screening when it is indicated.<br><br>The HFEA should be advised of the measures the centre intends to take to in relation to this recommendation by 3 August 2012. | addressed.<br><br>We aim to complete this by 3rd August as requested. | |
| 8. Where the recipients of donor gametes choose not to see a counsellor, information about how to tell a child that he or she results from the gametes of a person who is not their parent is not made available (SLC T63). | Where treatment services are provided using donated gametes the PR should ensure that the person receiving treatment and any intended second parent, is provided with information about the importance of informing any resulting child at an early age that they were born as a result of such treatment, and suitable methods of informing such a child of that fact.<br><br>The HFEA should be advised of the measures the centre intends to take in relation to this recommendation by 3 August 2012. | We strongly believe that the best person to present this information is the counsellor and all patients are strongly encouraged to attend this. We shall update our paperwork that is provided to donors and recipients at their consent appointment to cover this issue. | **Further action as documented required: to be subject to on-going monitoring.** |

| Additional information from the Person Responsible |
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# HFEA Executive Licensing Panel Meeting

**25 July 2012**

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

## Minutes – Item 2

**Centre 0250 – (Glasgow Centre for Reproductive Medicine) – Interim Inspection Report**

| Members of the Panel: | Committee Secretary: |
|---|---|
| Juliet Tizzard, Head of Policy & Communications (Chair)<br>Charlotte Augst, Head of Business Intelligence Paula Robinson, Head of Business Planning | Joanne McAlpine |

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

**The Panel also 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 noted that this is a large centre which has been licensed since 1 November 2006 and provides a full range of fertility services. The centre reported 1124 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to March 2012 and its success rates are in line with national averages for all age bands and all treatment types.

2. The Panel noted that at the time of the inspection, the centre was in the process of submitting an application to have its licence varied to allow treatment involving embryo testing to be provided.

3. The Panel noted the good progress that the centre has made in relation to multiple births and encouraged the Person Responsible (PR) to continue this progress.

4. The Panel noted that, at the time of the inspection, the Inspectorate identified three major areas of non-compliance and five other areas of poor practice which required improvement.

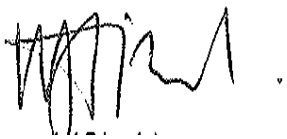
5. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that two of the major areas of non-compliance and two of the other areas of poor practice have been addressed, and noted that the PR had given a commitment to fully address the other outstanding areas of non-compliance identified, within the prescribed timescales.

6. The Panel noted that two near misses and nine incidents relating to breaches of patient confidentiality had been reported to the HFEA since the last inspection and that this had been discussed on inspection. Whilst the Panel recognised that this represents a low ratio of incidents in comparison to the volume of patients treated at the centre, it agreed with the Inspectorate that such a non-compliance should be regarded as ‘major’. The Panel noted the PR’s comment that the centre takes such incidents seriously.

7. The Panel noted the Inspectorate’s recommendation for the continuation of the centre’s licence with no additional conditions.

## Decision

8. The Panel endorsed the Inspectorate’s recommendations in the report. The Panel agreed to the continuation of the centre’s licence with no additional conditions.

Signed:  Date: 03/08/2012

Juliet Tizzard (Chair)