Interim Licensing Report

Centre name: **Glasgow Royal Infirmary**

Centre number: **0037**

Date licence issued: **1 January 2009**

Licence expiry date: **31 December 2013**

Additional conditions of licence: **None**

Date of Inspection: **26 July 2012**

Inspectors: **Janet Kirkland, Chris O'Toole**

Date of Executive Licensing Panel: **19 October 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 centres compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

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 actions identified at the last inspection; 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 completion of all recommendations from the previous inspection.

The Executive Licensing Panel is asked to note that there is one recommendation relating to a critical area of improvement and three relating to major areas of improvement. Since the inspection visit the PR has given a commitment to fully implement all of the following recommendations made in the report.

'Critical' areas of non compliance:

- **the PR to ensure that personnel in the centre are available in sufficient numbers and are qualified and competent for the tasks they perform**

'Major' area of non compliance:

- the PR to submit a revised multiple births minimisation strategy to the executive which demonstrates how the revised strategy aims to meet the current 15% target and the timescales required
- the PR to perform a risk assessment of the state of repair of the cryostore and inform the executive of the outcome and resulting actions taken by the centre
- the PR to ensure that the outstanding registration of a number of donors is completed

Information about the centre

The Glasgow Royal Infirmary Assisted Conception Services is located in Glasgow and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services and provided 1178 cycles of treatment (excluding partner intrauterine insemination (IUI)) in the 12 months to 30 April 2012. In relation to activity levels this is a large centre.

Details of Inspection finding

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 treatments. In the calendar year 2011 the centre performed 259 cycles of IUI with 25 pregnancies this indicates a 10% success rate which is consistent with the national average.

Multiple births[2] (SLC T123)

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

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 24% 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 24%: this represents performance that is not likely to meet 15% multiple live birth rate target.
See recommendation 2.

Witnessing (SLC T71)

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: fertilisation checks; sperm preparation; preparation for embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using electronic witnessing and a manual system when required.

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[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 (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

The inspection team was able to review records that were present in the laboratory and concluded that records of both manual and electronic witnessing are maintained.

Consent : Disclosure to researchers (Direction 0007)
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 12 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.

It was however noted that the consents completed by one couple were at variance with each other. This was discussed with the PR.

Consent: To the storage of cryopreserved material (Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3, 8 (2))
A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store appear to be being stored in accordance with the consent of the gamete providers and are within the consented storage period and are being stored in accordance with statutory storage periods.

Staffing (SLC T12)
Having the right numbers of staff, competent to carry out highly technical work in 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: However, the PR informed the inspection team on arrival at the centre that there was limited activity on the day as the team had been required to reschedule seven oocyte collections until the following day due to a lack of anaesthetic cover within the hospital. This may then, in turn, have a direct impact on the patients experience the following day as the geography of the building, the pre and post operative areas, men's room and laboratory did not appear to have the capacity to cope with the increased number of cycles.

Feedback from patients about the care they received from centre staff was in general positive however several of the questionnaires returned to the HFEA referred to appointments being delayed or cancelled, long waiting times and difficulty in contacting the centre by telephone.

Discussion with the PR and other team members highlighted issues with the numbers of staff employed at the centre and the amount of time that the PR has allocated to her role.

The inspection team considered that patients were being treated with dignity and respect and receiving sufficient information but recognised that the centre appeared to be operating at capacity and that the necessity to reschedule occyte collections indicated cause for concern for quality of service and patient safety.

See recommendation 1.

Patient experience

During the inspection visit we spoke to patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 29 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive in relation to information, interactions with staff and respect to privacy and dignity with 20 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;

It was noted on inspection and from patient feedback that the centre is located over two sites which is not considered to be ideal from both a quality of service and staffing perspective. Some patients had negative comments on the general “tired” appearance of the centre.

The PR is aware of these issues and is in discussion with the Trust regarding a solution.

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:

- it was observed on inspection that the flooring on the cryostore was in a poor state of repair. See recommendation 3

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in June 2011 recommendations for improvement were made in relation to one critical area of non-compliance, five major non-compliances and seven other areas on non-compliance. The PR provided information and evidence that all of the recommendations had been fully implemented.

On-going monitoring of centre success rates

In 2012, the centre was asked to review procedures for the provision of IVF treatment for patients under 37. At that time the pregnancy rate was 22%.The PR responded to the request and during discussions at the time of the inspection, explained what the team believe to be the reason behind the reduced success rate for this group of patients and their actions to address it .At the time of the inspection the pregnancy rate for this group of patients had risen to 25%.The centre's success in improving their outcomes will continue to be monitored.

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 has a good record of current data submission and of compliance with related regulatory requirements. There are however a number of historic donors registrations outstanding. This has a potential impact on the Authority's ability to fulfil statutory obligations to donors and the donor conceived (Directions 0005). See recommendation 4.

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 non compliance 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
1. Personnel in the centre must be available in sufficient numbers and be qualified and competent for the tasks they perform(SLCT12).	The PR should assess how many cycles can be safely accommodated by the centre taking into account the staffing levels, skills mix and experience of staff, equipment and premises. A copy of this assessment should be submitted to the HFEA by 10 September 2012. The PR must ensure that the number of cycles does not exceed the number that is assessed as being safe to perform.	Medical Staffing The service has 2 whole time equivalent Consultants, 1 Associate Specialist and 1 Middle Grade Doctor. One of the Consultants and the Middle Grade Doctor have on call commitments which necessitate compensatory rest and therefore make them unavailable for the service. In addition there is an academic Consultant who contributes 2 PAs 3 weeks out of 4 to the service and a part time Consultant who is currently on sick leave. The latter is likely to	The inspector acknowledges the PR's response and assurances that the level of staffing is considered to be safe. The inspector has requested that the PR send an assessment of how may cycles can be safely accommodated by the centre: this would allow the inspector to compare the activity levels as reported to the HFEA. The activity and staffing levels will be monitored throughout the compliance cycle.

		be a recurrent feature. This level of staffing is insufficient for the size of service. I have ensured that the level of staffing for patients undergoing assisted conception treatment is safe at our current levels of activity. However in order to do this it has been necessary to reduce out patient clinic activity. One of our Consultants will cease obstetric on call in October which obviates the need for compensatory rest. In addition there have been discussions with Management regarding a locum appointment and an additional Consultant post. Embryology Staffing Levels of staffing are adequate. There is currently a vacancy for a Consultant Embryologist. This statement assumes that this post will be filled and that the three trainee posts in the laboratory are retained at the end of the training period. Currently the Consultant Embryology post is filled on a locum basis. Safety is maintained by the incumbent spending a level of time in the laboratory which exceeds that	The impact of any changes to the staffing levels and /or the number of treatment cycles performed by the centre must be assessed and necessary actions taken to maintain patient safety and satisfaction with their experience at the centre.

		normally expected in this post and is at the expense of managerial time. The laboratory would benefit from a MLA post for administrative and technical duties. Nursing Staffing This is currently adequate Administrative Staffing One additional whole time equivalent is required supported by a review of the administrative services performed some time ago.	

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
2. 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 24%: this represents performance that is not likely to meet the 15% multiple live birth rate target(SLCT123)	The PR should review the centre’s multiple births minimisation strategy in consideration of the requirement to reduce the multiple live birth rate to 10% from 1 October 2012. A copy of the revised strategy should be submitted to the HFEA by 10 September 2012	We have reviewed our multiple births minimisation strategy (revised policy attached). Our Unit rate exceeds the target figure in part due to a group of patients who for clinical reasons had all their embryos frozen. This 15.8% of those patients who we had targeted for a single embryo transfer had all embryos frozen to minimise the risk of ovarian hyperstimulation.syndrome. These patients subsequently had two frozen embryo transferred on day 2. We will initially aim to target this group of patients and aim for a single embryo transfer on their frozen cycle ideally with the use of extended embryo culture. Our projection is that this will reduce our multiple pregnancy rate to 20%. . Our failure to meet the targets to date is compounded by 13.8% of	The Inspector acknowledges the PR’s response and encourages the team in their efforts to reduce the multiple pregnancy rate. The agreed extension of the laboratory is a positive development and this, in addition to the pregnancy rates and multiple pregnany rates will be monitored throughout the compliance cycle.

		patients who meet the criteria, opting out of single embryo transfer. We propose to alter our Unit policy so that all NHS funded patients who meet the criteria, receive a single embryo transfer in their first treatment cycle. Further to discussions at the time of the inspection we are constrained in our ability to reduce this rate further at the moment due to space limitations preventing the use of extended embryo culture. To extend our single embryo transfer policy without the facility to extend embryo culture would risk a significant fall in our pregnancy rates. This was attempted in 2010 and was responsible for the marked reduction in the 2010 success rates, which were statistically below the national average for women <35 years old. We would not wish to repeat this in the interim. An extension of the laboratory premises has been agreed which will provide the infrastructure to allow extension of embryo culture and achievement of the 10% target. At present the time scale is unclear, and we would strongly welcome the support of the HFEA to achieve this.	
3. It was observed on inspection that the flooring of the cryostore was in a poor	The PR should perform a risk	This is to be addressed as part of the extension described above. A	Risk assessment received on September

state of repair (SLCT17)	assessment of the state of repair of the cryostore and inform the executive of the outcome and resulting actions taken by the centre by 10 September 2012	steel chequered plate floor has been proposed and costed.	18. The risk assessment refers to ensuring that staff have the necessary training and awareness of policies but does not provide details of how risk will be mitigated in the period prior to the extension of the laboratory. The Inspector has therefore requested that the PR arrange for an assessment of the cryostore in particular the floor and structure, to be performed by the local heath and safety inspectorate at the earliest opportunity and a report, including actions to be taken to be sent the HFEA prior to presentation to the ELP.
4. The registration of a number of donors with the authority is outstanding. (Directions 0005)	The PR to provide the inspector with a timeline for addressing the issue of unregistered donors by 10 September 2012.	This has been addressed and there are none outstanding as far as we can ascertain	On September 18 there were no recent donor registrations outstanding.

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
None noted at the time of the inspection	.		

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

19 October 2012

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

Minutes – Item 2

Centre 0037 – (Glasgow Royal Infirmary) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy & Communications (Chair) Hannah Darby – Senior Policy Manager David Moysen – Head of IT	Joanne McAlpine Neil McComb – Register Information Officer

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 centre has been licensed since 1992 and provides a full range of fertility services..

2. The Panel noted that this is a large centre, having carried out 1178 cycles of IVF and ICSI during the 12 month period to 30 April 2012.

3. The Panel noted that data held on the HFEA register for the year ending January 2012 show the centre's success rates for IVF and ICSI are in line with national averages. The Panel noted that in the calendar year 2011 the centre performed 259 cycles of IUI with 25 pregnancies resulting. This indicates a 10% success rate which is consistent with the national average.

4. The Panel noted that the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles was 24% for the time period April 2011 to March 2012 and that this is not likely to meet the 15% multiple birth rate target.

5. The Panel noted that at the time of the inspection, there were one critical and three major areas of non-compliance identified by the Inspectorate.

6. The Panel noted that, since the inspection, the Person Responsible (PR) has provided a commitment to fully address all of the non-compliances stated above.

7. The Panel noted that the Inspectorate recommends the continuation of the centre's licence with no additional conditions and noted the recommendations highlighted in report.

8. The Panel noted the PR's response to the recommendation regarding the centre's failure to meet the multiple pregnancy rate target. It also noted the centre's intention to extend the laboratory to allow space for blastocyst culture, thereby enabling them to reduce multiple pregnancy rates.

9. The Panel endorsed the Inspectorate's recommendation that the PR reviews the centre's multiple births minimisation strategy and submits it to the HFEA by 10 September 2012. It also urged the PR to address the high proportion of patients opting out of single embryo transfer, both for NHS and self-funded patients. Finally, the Panel supported the centre's efforts to obtain permission to extend its laboratory to allow for blastocyst culture and hope that this can be achieved quickly.

10. The Panel noted the PR's response to the recommendation regarding the cryostore, in particular that the safety concerns with the broken flooring. Whilst it noted the intention to address the problem as part of the planned laboratory extension, the Panel was concerned that this

might not take place soon enough. It therefore recommended that the flooring be fixed in the next three months if the laboratory extension is not due to start in that time.

Decision

11. The Panel endorsed the Inspectorate's recommendations and the timescales specified in the report. In particular, it urged the PR to address its multiple birth rate and expects to see an improvement by the time of the next inspection.

12. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed: Date: 30 October 2012
Juliet Tizzard (Chair)