Interim Inspection Report

Date of Inspection: 20 October 2011
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 9 hours
Inspectors: Wil Lenton (HFEA Executive, Lead)
Helen Kendrew (External inspector)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 24 September 2009 and 13 Jan 2012.

Date of Executive Licensing Panel: 27 January 2012

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Regional Fertility Centre, Belfast
Centre Number	0077
Licence Number	L0077/17/C
Centre Address	Royal Maternity Hospital Grosvenor Road Belfast Northern Ireland United Kingdom BT12 6BB
Person Responsible	Dr Peter McFaul
Licence Holder	Mr Brian Barry
Date Licence issued	01/10/2011
Licence expiry date	28/02/2013
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The centre has been licensed since 1992 and offers treatment to NHS and privately funded patients, including IVF, ICSI, egg sharing, and egg donation.

The centre is a self-contained unit situated within the Royal Hospital (Belfast) with the patient waiting room situated just outside the entrance. Access to the centre is through doors with controlled access.

The centre is generally open six days a week, Monday to Saturday, but staff will be available on Sundays as and when required. The centre attempts to meet patient's requests for treatment throughout the week if possible, following consultation.

The Person Responsible (PR), Dr Peter McFaul, has been in post since February 2005, is registered with the General Medical Council (GMC), is on the specialist register for Obstetrics and Gynaecology and has successfully completed the HFEA Person Responsible Entry Programme (PREP# T/1045/7).
The centre was last inspected by the HFEA on 24 September 2009 for licence renewal The Executive Licensing Panel (ELP) considered the renewal application on 3 December 2009, and issued the current licence which expires on 28 February 2013. More recently, an application to vary the centre's licence to reflect a change of Licence Holder was agreed by ELP on 22 July 2011.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 October 2010 to 30 September 2011
In Vitro Fertilisation (IVF)	557
Intra Cytoplasmic Sperm Injection (ICSI)	573
Frozen Embryo Transfer (FET)	265
Donor Insemination (DI)	0
Intra Uterine Insemination (IUI)	50*
Egg donation (non egg share)	18

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	X

*IUI data is unverified for the period 1 January to 31 December 2010 and represents stimulated cycles using partner sperm.

Outcomes**

For IVF/ICSI, HFEA held register data for the period March 2010 - February 2011 show the centre's success rates are in line with national averages.

For the year 2010 the centre reported 50 cycles of partner IUI with 3 clinical pregnancies. This equates to a clinical pregnancy rate of 6%.

**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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

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 three major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented;

Major areas of concern

- The donor payments protocol has been amended to ensure that the centre retains receipts and invoices relating to compensation paid to sperm donors
- The process for the selection and recruitment of sperm donors has been audited and quality indicators (QI) developed.

Other areas of concern

- A standard operating procedure (SOP) for the audit of its witnessing practice has been formalised
- Witnessing QI are being formally record
- The centre has amended its witnessing laboratory sheet to ensure that fertilisation checks and the disposal of sperm samples are individually witnessed
- The centre has amended its practice to ensure that the reasons for any three embryo transfer are recorded in each patients records

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

Major areas of concern

- The diagnostic semen analysis laboratory should be clinical pathology accredited (CPA)

The inspection team recommends the continuation of the centre's licence without additional conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales. It is acknowledged that although the centre has made progress in achieving CPA accreditation within the diagnostic semen analysis laboratory, there is still further work to be undertaken. The Executive will closely monitor this situation and require regular updates from the centre concerning the full implementation of this recommendation. In the event of there being are any further substantive delays the issue will be referred back to the ELP for re-consideration.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed Treatment Plans:** Staff explained that patients are provided with information about the cost of treatment from various sources. On initial enquiry prospective patients are given both verbal information concerning the cost of the treatment services and if required sent an information pack which includes a comprehensive price list. At an initial consultation the patients are again given verbal information about treatment costs, together with any more specific details associated with their treatment and are able to discuss these costs with staff. During the review of five sets of patient records, invoices giving details of individual treatment costs were seen (Code of Practice (CoP) Guidance G4.3). Staff were able to demonstrate that the process for the provision of patient information had been audited in August 2011 and that quality indicators (QI) were in place (standard licence condition (SLC) T 36; T35). Documented evidence of the assessment of staff competence when providing information to patients was reviewed. Medical staff are assessed by the PR and other staff by their line-manager (SLC T15a). **Legal Parenthood:** Staff explained that there is a SOP to follow when taking patient consent (SLC T33b), and that patients and partners are informed about parenthood laws by the counsellor, prior to any consent to treatment being taken (SLC T63). Staff explained the process of informing the patient about the requirements for any second parent, when applicable, including which consent forms would need to be signed and also the process to be followed should a patient or patient partner wish to withdraw or vary their consent (SLC T64).
What they could do better. Nothing noted.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to disclosure of identifying information to researchers** The centre seeks patient consent to identifying information from the HFEA Register being disclosed to researchers. The HFEA Register information demonstrates that 20% of all patients and partners, who have been registered at the centre since October 2009, have consented to disclosure if requested A sample of consents to the disclosure of personal information held on the HFEA Register was reviewed on inspection. The consents, recorded in all six sets of patient records reviewed, were found to be consistent with the consenting decisions reported to the HFEA. **Consent to storage** The centre has a documented SOP in place for the storage of patient gametes and embryos (SLC T33b). The PR stated that presently only medical staff seek patient consent, including that for the storage of gametes and embryos. The laboratory manager stated that consents to storage are checked prior to freezing of any licensed material and that the centre has a 'bring forward' system in place in order to continually monitor patient storage consent expiry dates. (G17.17). The PR demonstrated an awareness of the statutory cooling off period to be initiated in the event that there is a dispute between gamete providers regarding the continued storage of their embryos and stated that the centre presently has no embryos in storage under these terms. Evidence that the procedures for the taking of patient consent had been audited during the last two years and that QI were in place was seen (SLC T36; T35). Documented evidence of the assessment of staff competence whilst taking patient consent was provided (SLC T15a).
What they could do better. Nothing noted.

Multiple births
For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to meet the target at a statistically significant level, which is unlikely to be due to random variation.
What the centre does well. On-going monitoring of the centres multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123) The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that: • staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates; • staff at the centre have audited their strategy and protocols as part of the quality management audit programme; • staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer; • staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.
What they could do better. In one set of patient records reviewed, there was no explanation as to why three embryos were transferred (General Direction 0003; 1a).

Validation of critical equipment and processes
What the centre does well. Documentation is in place concerning the validation of all critical processes and equipment presently in use (SLC T24; T72). The centre has recently purchased new electronic witnessing equipment which is still in the process of being validated. The laboratory manager explained that manual witnessing procedures would remain in place until the new electronic equipment had been fully evaluated against the manual process and had been fully validated. Critical procurement and processing procedures are documented in SOPs as part of the centre's Quality Management System (QMS) (SLC T33b). A review of equipment logs demonstrated that critical equipment has been serviced and maintained at regular intervals. Critical parameters such as, individual incubator temperatures and carbon dioxide levels, cryo-vessel temperatures and liquid nitrogen levels are monitored and logged at regular intervals (SLC T23; T24). Laboratory key performance indicators (KPIs) are recorded and evaluated periodically by laboratory staff (SLC T72; T24).
What they could do better. Nothing noted.

Witnessing
What the centre does well. To ensure that patients receive treatment using the correct gametes or embryos, the centre double checks the identification of gametes and embryos against the patient or donor to whom they relate, at all critical points of the clinical and laboratory process. The centre has a SOP in place for the witnessing process, which was last reviewed in January 2011 (SLC T33b). During the review of five sets of patient notes the witnessing process was seen to be generally compliant with SLC T71, except for the issue noted below. The centre is intending to install an electronic witnessing system in the near future, once full validation has been completed. The centre undertakes an audit of witnessing practice at regular intervals Ten sets of patient records are reviewed as part of each audit. The last audit took place 17-18 October 2011. Any corrective actions are implemented and the outcomes of the audit and action points are discussed at the next staff meeting (SLC T36). Assessment and recording of staff competence when performing witnessing procedures is undertaken periodically (SLC T15a).
What they could do better. Currently there are no formal QI in place for witnessing (SLC T35). Although witnessing of fertilisation checks and the disposal of sperm samples was occurring, the format of the laboratory witnessing sheet did not provide the opportunity for these actions to be individually witnessed. Although a regular audit of witnessing practice is occurring, there is no formalised SOP in place describing the process (SLC T33b).

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. The centre have SOP's in place for the selection and recruitment of both egg and sperm donors (SLC T33b). The laboratory manager stated that only two sperm donors had been recruited since the last inspection in 2009. Both egg and sperm donors are selected on the basis of their age and via the completion of a socio-medical questionnaire undertaken by a clinician. During the review of four sets of egg/sperm donor records, it was established that all required, applicable screening tests are currently being undertaken by the centre in accordance with professional guidelines. These are recorded on a donor recruitment checklist, which gives details of all screening tests completed (SLC T52). There is also a dedicated egg donor coordinator in post. Audits of egg donation practice were reviewed electronically and centre practice found to be compliant with current regulations (SLC T36). QI have been established for the egg donation process (SLC T35). All donor screening tests are undertaken in a NHS Trust CPA-accredited pathology laboratory (SLC T53a). The centre maintains a log of all births resulting from donated gametes in order that information concerning the number, gender and birth year of offspring born can be provided to gamete donors upon request (HF&E Act 31ZD).
What they could do better. The centre presently compensates sperm donors at the end of each cycle of donation, up to a maximum of £250 for loss of earnings, plus travel expenses. Donors are asked to keep all travel invoices and receipts until the end of the donation cycle. Presently the centre has no record of individual donor travel expenses or loss of earnings. (General Direction D0001; paragraph 5). The procedure for selecting and recruiting sperm donors has not been audited against compliance with the approved protocols and regulatory requirements in the last two years (SLC T36). Quality indicators have not been developed for the process of selecting and recruiting sperm donors (SLC T35).

2. Changes / improvements since the previous inspection on 24 September 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Accreditation of diagnostic semen testing services Diagnostic semen analysis for patients at the centre is performed by a laboratory service on the floor above the centre. This service is not accredited by Clinical Pathology Accreditation (CPA) or equivalent. This was not compliant with the requirements of SLC T21	The PR should review the requirement for accreditation of the semen analysis laboratory to ensure compliance with Licence Condition T21 of the 8th HFEA COP. It is recommended that the centre draw up a plan for ensuring compliance with CPA accreditation requirements or another body accrediting to an equivalent standard. Progress with implementation of the plan to be included in a quarterly update to be submitted to the HFEA until validation is complete. Updates received January, April and September 2010. The latter report indicates that an application for CPA accreditation of the lab has still not been submitted. Updated information sent 07/12/2010. Mock CPA inspection due February 2011.	A full discussion of the present situation concerning the attainment of CPA accreditation for the diagnostic semen analysis laboratory was undertaken with the PR and senior management team during the inspection. A mock CPA inspection was undertaken in April 2011. An action plan is in place to address the required improvements. This has now been affected by the need for remedial building works in some clinic areas, under health and safety guidelines. The inspection team were given a firm assurance by the PR and senior management team that the required improvements to both premises and practice will be implemented during early 2012. The PR should forward an action plan and time-line for the attainment of CPA accreditation of the diagnostic semen analysis laboratory. The PR is required to forward quarterly updates to the Executive until CPA accreditation is achieved. **Further action required.**

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Nothing noted.		

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor, embryo or to a 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	Executive Review
Nothing noted			

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
Diagnostic testing of semen samples is currently being performed in a non-CPA accredited laboratory. (SLC T21)	The laboratory performing diagnostic semen analysis should be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. The PR should forward an updated action-plan and time-line for the attainment of CPA accreditation for the diagnostic semen analysis laboratory to the inspector by 20 December 2011. PR to forward quarterly updates to Executive until accreditation achieved.	An updated plan of actions taken towards CPA accreditation is attached. Capital has been released by the Trust for the upgrade to the laboratory to create a small reception area and to improve the facilities. The refurbishment will be completed by 31 March 2012. The CPA application will be submitted one month later on 30 April 2012.	The PR should contact the inspector by the end of April 2012 to provide an update on the action plan for CPA accreditation. Monitoring to continue until accreditation is in place. **Further action required.**
The centre has no record of individual donor travel expenses or loss of earnings. (General Direction D0001)	The PR should ensure that receipts and invoices concerning payments to sperm donors are documented and retained. Evidence that the centre's procedure has been amended should be forwarded to the inspector by 20 December 2011.	Our SOPs and protocols have been amended to correct this. Updated SOP number 757 forwarded to Executive..	No further action required

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre has not audited its procedure for the selection and recruitment of sperm donors within the last two years and QIs have not been developed. (SLC T36; T35)	The process for the selection and recruitment of sperm donors should be audited and quality indicators (QI) developed. Evidence that the process has been audited and QIs developed should be forwarded to the inspector by 20 December 2011.	Audits of practice have been forwarded and QI developed. Evidence forwarded to Executive.	No further action required

Other areas of practice that require improvement

Other areas of practice that require 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
The laboratory witnessing sheet requires amendment to provide the opportunity for fertilisation checks and the disposal of sperm samples to be individually witnessed. (SLC T71)	The PR should ensure that the laboratory witnessing sheet is reviewed and amended to provide the opportunity for fertilisation checks and the disposal of sperm samples to be individually witnessed. Evidence that the laboratory witnessing sheet has been amended should be forwarded to the inspector by 20 December 2011.	Review has taken place and the amended witnessing form number 299 forwarded to the Executive.	No further action required
No formal quality indicators have been developed for witnessing (SLC T35)	The PR should ensure that QI are developed for witnessing. Evidence to be forwarded to the inspector by 20 December 2011.	Formal QI have been added to the end of the witnessing SOP number 298 and forwarded to the Executive.	No further action required
No formal SOP has been developed for the auditing of witnessing practice. (SLC T33b)	The PR should ensure that a formal SOP is developed for the audit of witnessing practice. To be forwarded to the inspector by 20 December 2011.	The completed SOP, RFC document 809 forwarded to the Executive.	No further action required

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
There was no explanation in one set of patient records reviewed as to why a woman was given a three-embryo transfer. (D0003; Para 1(a))	The PR should ensure that an explanation as to why a woman is having a three-embryo transfer is recorded in patient notes. A retrospective audit of all three-embryo transfer cases undertaken since the last inspection should be undertaken to ensure that such information has been appropriately recorded. The results of the audit to be forwarded to the inspector by 20 December 2011.	Audit report number 84 undertaken on 14 December 2011and forwarded to the Executive. Non-compliance note issued by PR reminding all staff of the requirement to record the reasons for a three embryo transfer in each patients medical record.	No further action required

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting
27 January 2012

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

Minutes – Item 2

Centre 0077 – (Regional Fertility Centre, Belfast) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Danielle Hamm, Senior Policy Manager	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 centre has been licensed since 1992 and offers treatment to NHS and privately funded patients, including in vitro fertilisation (IVF), intra cytoplasmic sperm injection (ICSI), egg sharing, and egg donation.

2. The Panel noted that the centre was last inspected by the HFEA on 24 September 2009 for licence renewal. The Executive Licensing Panel (ELP) considered the renewal application on 3 December 2009 and issued the current licence which expires on 28 February 2013.

3. The Panel noted that it had considered an application to vary the centre's Licence Holder and approved this change at its meeting on 22 July 2011.

4. The Panel noted that the data held on the HFEA register for the period March 2010-February 2011show that the centre's success rates for IVF/ICSI are in line with the national average.

5. The Panel noted that for the year 2010 the centre also reported 50 cycles of partner IUI with 3 clinical pregnancies, and this equates to a clinical pregnancy rate of 6%.

6. The Panel noted that at the time of the inspection there were a number of areas of practice that required improvement: three major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

7. The Panel noted that since the inspection visit the Person Responsible (PR) has provided evidence that two of the major areas and the four other areas of non-compliance/areas of poor practice have been fully implemented.

8. The Panel noted the one outstanding area of non-compliance: the failure to arrange for Clinical Pathology Accreditation (CPA) of the diagnostic seaman analysis laboratory. The Panel also noted this issue was identified at the previous inspection in 2009. The PR had given a commitment to fully implement this recommendation and explained that the delay was due to building work. The Panel accepted the PR's explanation.

9. The Panel noted that the centre was due to submit an audit report to the Inspectorate on 14 December 2011, and asked the Inspectorate to review this report and if it raises any concerns to bring this to the Panel's attention.

10. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions, subject to compliance with the recommendations made in the report being implemented within the prescribed timescales.

11. The Panel noted the progress that has been made at the centre since the last inspection, and encouraged the PR to continue to work with the Inspectorate to resolve the outstanding non -compliance as soon as possible.

Decision

12. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

Signed: Peter Thompson Date: 7/2/12
Peter Thompson (Chair)