Interim Licensing Report

Centre name: Reproductive Medicine Clinic, Bristol
Centre number: 0276
Date licence issued: 01/07/2011
Licence expiry date: 30/06/2015
Additional conditions applied to this licence: None
Date of inspection: 10/01/2013
Inspectors: Mrs Sara Parlett
Date of Executive Licensing Panel: 15/03/2013

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) 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 inspector to form a conclusion on the continuation of the centre's licence.

The inspector recommends the continuation of the centre's licence. In particular, she notes the positive comments made by patients in relation to their experiences.

The inspector has made recommendations for improvement and these should be implemented within the time specified.

The Executive Licensing Panel is asked to note that there were recommendations for improvement in relation to four 'other' areas of non-compliance as follows:

'Critical' areas of non compliance:

None

'Major' areas of non compliance:

None

'Other' areas of practice that require improvement:

- The Person Responsible (PR) should ensure that all witnessing checks are completed and recorded at the time the relevant procedure takes place.
- The PR should ensure that where sperm is produced at home, the centre records this in the gamete provider's records.
- The PR should ensure that future traceability audits include the traceability of any relevant products/materials that come into contact with gametes.
- The PR should ensure that corrective actions identified and implemented following an audit are documented.

Since the inspection, the PR has provided evidence which demonstrates that all four recommendations have been implemented.

Information about the centre

The Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol, NHS Foundation Trust and has held a licence with the HFEA since 2007.

The centre provides partner intrauterine insemination treatment (IUI) only. The centre does not have facilities for the analysis or preparation of semen for use in treatment on site. This service is provided by the nearby Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295). The male partner attends centre 0295 for sample production. Following preparation for insemination, the sample is transported by the male partner to the centre.

Details of Inspection findings

Quality of Service

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

Outcomes[1]

For the year 2011, the centre reported 81 cycles of IUI with 17 pregnancies. This equates to a 21% clinical pregnancy rate and is consistent with the national average.

Multiple births[2]

The centre provides IUI treatment only and is not subject to HFEA regulations concerning multiple births. However, the PR advised the inspector that a key objective of the centre is to minimise the occurrence of multiple births. No multiple births were reported in 2011.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. No procedures were taking place on the day of inspection and therefore witnessing in practice could not be observed. However, staff described the centre's witnessing procedure in detail and it was considered to be in accordance with HFEA requirements using a manual system.

The inspector was able to review ten sets of patient notes and concluded that records of witnessing are accurately maintained, with two exceptions:

[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.

- In one of the ten sets of notes audited the active identification of the female, prior to insemination, was not recorded.
- In one of the ten sets of notes audited the cross-checking of identifying information on the sperm receptacle by a member of staff at centre 0295 was not recorded.

See recommendation 1.

Consent: Disclosure to researchers

No treatments requiring consent to disclosure to researchers are undertaken at this centre, which provides IUI treatment only, therefore this theme was not relevant at this inspection.

Consent: To the storage of cryopreserved material

No gamete or embryo storage occurs at this centre, therefore this theme was not relevant at this inspection.

Staffing

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

No procedures were carried out on the day of inspection and therefore the inspector cannot comment on staffing levels observed on the day. However, the PR confirmed that he is currently satisfied with the staff complement and an external review of the centre's staffing levels has also recently been carried out. Patients interviewed on inspection were satisfied that staff were always available when needed to provide support and advice.

Patient experience

During the inspection visit the inspector spoke to two patients who provided feedback on their experiences. A further 25 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with ten 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.

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 following non-compliance was identified:

- The laboratory form signed by the patient's partner and member of staff, upon receipt of the sperm sample at centre 0295, includes the requirement to record where the sample has been produced. This section had not been completed in the ten sets of records reviewed on inspection (see recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2011, recommendations for improvement were made in relation to three major areas of non-compliance and four 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented, with one exception.

The following recommendation has not been implemented to the satisfaction of the inspector:

- Audits against compliance with approved protocols, regulatory requirements and quality indicators have not been performed in the last two years for consent procedures or traceability.

The PR provided confirmation that these audits had been completed following the renewal inspection and these audit reports were reviewed in the course of this inspection. It was noted that the traceability audit scope included the traceability of gametes from procurement to patient treatment or disposal, but not of any relevant products/materials that come into contact with the gametes. In response to this observation, an audit of traceability of products/materials coming into contact with gametes was performed on the day of inspection and the audit report, documenting full compliance, was provided to the inspector (see recommendation 3).

The centre's most recent consent and provision of patient information audit was also reviewed. The results of the provision of patient information section of the audit demonstrated that the centre's quality indicator thresholds had not been met. The quality manager described the corrective action that had been taken, but the identification and implementation of this corrective action had not been documented (see recommendation 4).

On-going monitoring of centre success rates

The HFEA risk tool is used to monitor the success rates of centres providing IVF and ICSI treatments. This IUI centre is not subject to on-going monitoring through the HFEA risk tool and has not therefore been issued with any performance alerts.

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 provided its annual IUI treatment return for 2011 within the required timescale.

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 PR's statement
None 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 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 PR’s statement
None noted			

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 PR's statement
1. Two witnessing steps were not recorded in the patient notes audited on inspection. SLC T71, CoP Guidance 18.4(b) and (g).	The PR should ensure that all witnessing checks are completed and recorded at the time the relevant procedure takes place. It is recommended that the PR identify the corrective action required to ensure that this occurs. This may include a review of the centre's standard operating procedure and worksheets for witnessing and/or providing further staff training. The corrective action identified and implemented should be reported to the inspector by 10 April 2013.	This relates to two areas of practice: active identification of the female at insemination was not recorded and cross checking of identifying information on the sperm pot by staff at centre 0295 was not recorded. We have removed the potential for the first matter by alteration of the form 1.24 Intrauterine Insemination (IUI) Treatment Hand-held record. BCRM have revised their witnessing form and this is attached. This should simplify the process and mean that these errors don't recur. The complexity of the previous form was leading to errors whereby signing off of samples was not being correctly completed.	The inspector is satisfied with the PR's response. It is expected that the effectiveness of this corrective action will be monitored via the centre's audit programme. No further action is required.
2. The laboratory form signed by the patient's partner and member of	The PR should ensure that where sperm is procured at home, the centre records this in the gamete	The form produced by BCRM to record receipt of the sample now assumes that the sample is	The inspector notes the PR's response and awaits the audit report

staff, upon receipt of the sperm sample at centre 0295, includes the requirement to record where the sample has been produced. This section had not been completed in the records reviewed on inspection. SLC T68.	provider's records. CoP Guidance 15.7 gives further guidance on the information that should be recorded. It is recommended that the PR identify the corrective action required to ensure that this occurs. This may include a review of the centre's relevant standard operating procedure and/or providing further staff training. The corrective action identified and implemented should be reported to the inspector by 10 April 2013. The PR should perform an audit within six months to ensure that the appropriate records are kept. A copy of this audit report should be submitted to the inspector by 10 July 2013.	produced at BCRM which is the situation in 99.9% of the time. If there is any deviation from this, this will be recorded in BCRM's records on the patients. I have confirmed this with the Laboratory Manager in centre 0295. I note the requirement for that to be reviewed by audit and reported by July 2013.	due to be submitted by 10 July 2013.
3. The centre's traceability audit scope did not include the traceability of any relevant products/materials that come into contact with	The PR should ensure that future traceability audits include the traceability of any relevant products/materials that come into contact with the gametes.	This was a helpful clarification and we will now include this as part of those audits Please see the audit plan which we have drawn up to ensure that none	The submitted audit schedule documents the requirement for traceability audits to include details of any relevant

the gametes. This audit was performed on the day of inspection. SLC T36.	Confirmation of this should be provided by the time the PR responds to this report.	of these aspects gets omitted by accident.	products/materials that come into contact with the gametes. No further action is required.
4. The corrective action identified and implemented following a provision of patient information audit was not documented. SLC T36.	The PR should ensure that corrective actions identified and implemented following an audit are documented. Confirmation of this should be provided by the time the PR responds to this report.	While staff have been alerted to this, we will formalise this in our monthly meeting in February 2013 (now that we have the report, it has been included in the agenda) and will ensure that all staff providing such information are aware of the need to document its provision, and review its implementation in audit in June-July 2013. While this specific audit lacked the appropriate corrective actions, we fully support the expectation that any such corrective actions should be reviewed at our monthly meeting, and action plans should be formulated and included within the minutes of the meeting, and in our non-conformity log.	The inspector is satisfied with the PR's response. No further action is required.

Additional information from the Person Responsible

. Please see attached forms to support this response:

IUI SEMEN PREPARATION WORKSHEET (Centre 0295 form)

Audit log plan RMC for HFEA compliance

1.24 Hand held record.doc 2013

HFEA Executive Licensing Panel Meeting

15 March 2013

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

Minutes – Item 1

Centre 0276 – (Reproductive Medicine Clinic, Bristol) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Ian Peacock – Analyst Programmer Matthew Watts – Regulatory Policy Manager	Rebecca Loveys

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 small centre providing partner intrauterine insemination (IUI) only, and has been licensed since 2007.

2. The Panel noted that the centre's current licence is due to expire on 30 June 2015.

3. The Panel noted that for the year 2011 the centre reported 81 cycles of IUI with 17 pregnancies, which equates to a 21% clinical pregnancy rate and is in line with the national average.

4. The Panel noted that, during the inspection, the Inspectorate identified no critical, no major and four other areas of non-compliance.

5. The Panel commended the centre's clinical pregnancy success rate, whilst recognising it was in line with national averages.

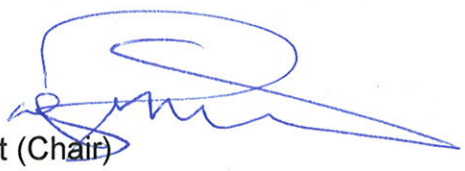
6. The Panel noted that there were no multiple births reported in 2011.

7. The Panel noted the positive comments made by patients regarding their experiences at the clinic.

8. The Panel noted the completion of recommendations made at the previous inspection with one exception. The exception, relating to performing and documenting audits against compliance, had been completed apart from documenting the corrective action taken.

Decision

9. The Panel agreed to the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

Signed: 
Mark Bennett (Chair)

Date: 26 March 2013