

Inspection Report

Date of Inspection: 29 March 2012
Purpose of inspection: Interim inspection of treatment licence
Length of inspection: 6 hours
Inspectors: Gill Walsh and David Gibbon

Inspection details:

The report covers the pre-inspection analysis, the visit and information received from the centre between 17 February 2010 and 15 June 2012

Date of Executive Licensing Panel: 27 June 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	Fertility Unit, Barking, Havering and Redbridge Hospitals Trust
Centre Number	0291
Licence Number	L/0291/3/c
Centre Address	Queen's Hospital, Rom Valley Way, Romford, Essex, RM7 0AG
Person Responsible	Mr Satha Sathanandan
Licence Holder	Mr Stephen Burgess
Date Licence issued	1 August 2010
Licence expiry date	31 July 2014
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:

This is a small NHS centre which has been licensed by the HFEA to provide partner intra uterine insemination (IUI) since 2007. The centre was last inspected for renewal of their treatment licence in February 2010. A four year licence was subsequently granted.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 January 2011 to 31 December 2011*
Partner insemination	113
Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	N/A
Storage of embryos	N/A
Research	N/A

Outcomes*

For the year 2011 the centre reported 113 cycles of partner insemination with 11 pregnancies. This equates to a 10% pregnancy rate which is consistent with the national average.

*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 Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major areas of non-compliance and three other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- Witnessing protocols should be followed when any of the following clinical or laboratory procedures take place: 18:4
 - (c Preparing sperm - cross-check information on tubes against the documents and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column).
 - (e) Transferring gametes between tubes or dishes cross-check information marked on dishes and tubes against the patient's records, and the information marked on the dishes and tubes that the gametes are being transferred from. However, as part of their risk assessment for sperm preparation, centres may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage in it. (Guidance 18:30)
- The PR must ensure that there are sufficient numbers of staff who are trained and assessed as being competent to conduct witnessing procedures when required. The continuing competence of staff to conduct witnessing should be assessed periodically, especially where a person conducts witnessing procedures infrequently.

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

Other areas of practice that require improvement:

- The centre should provide for the privacy, dignity and respect of all prospective and current patients and their partners. The centre should take steps to minimise the opportunity for patients to overhear foetal monitoring machines and ante natal discussions by working with midwifery service colleagues to minimise noise in the waiting area, ensuring adjoining doors are kept closed and foetal monitoring equipment volume is not excessive;
- The PR should ensure that staff are supported in their on-going clinical professional development to maintain registration with their respective professional bodies and demonstrate adequate knowledge and understanding of the relevant clinical / scientific processes to perform their designated tasks;
- The PR should ensure that the information giving process to patients and their partners is audited against the approved protocols, regulatory requirements and the centre's own quality indicators.

Recommendation to the Executive Licensing Panel

The inspection team recommend the continuation of the centre's licence without additional conditions subject to compliance with the remaining recommendations made in this report being implemented within the prescribed timescales.

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.

The centre offers partner intra uterine insemination (IUI) treatment to NHS commissioned patients only, therefore the provision of costed treatment plans or the provision of information regarding legal parenthood does not apply.

Five sets of patient records were audited on inspection, all of which contained documented effective consent by the male partner for the use of his gametes in the treatment of his partner.

What they could do better.

Nothing noted.

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well.

No treatment information relating to IUI patients is held by the HFEA therefore consent to disclosure to researchers does not apply.

The centre provides partner IUI treatment only, consent to storage does not apply.

What they could do better.

Nothing noted.

Validation of critical equipment and processes

What the centre does well.

Documentation available on inspection as part of the quality manual demonstrated that both the clinical and laboratory processes for the IUI procedure have been validated. (SLC T72).

Service records and other documentation seen on inspection demonstrated that all critical equipment is regularly maintained (SLC T28) and has been validated. (SLC T24) Evidence of recalibration and revalidation following repair of one piece of equipment was also seen. (SLC T25)

What they could do better.
Nothing noted.

Witnessing

What the centre does well.

It was not possible to observe witnessing in practice on the day of inspection. Assessment was made by discussing the process with staff, a review of documentation and an audit of patient records. The inspectors concluded that the centre double checks the identification of samples and the patients to whom they relate at all critical points in the clinical and laboratory process with one exception noted during a witnessing record audit conducted on inspection.

Witnessing checks are completed and recorded at the time the relevant clinical or laboratory procedure takes place and a record of the witnessing checks made is kept in each patient's medical record. (SLC T71) There is a standard operating procedure (SOP) in place to direct witnessing procedures and quality indicators have been established. (SLC T35)

Evidence of training and the assessment of competence and a 'master' list of who is authorised to witness was available to see on inspection. (SLC 15(a))

What they could do better.

An audit of 10 patient witnessing records demonstrated non compliance with the centre's witnessing procedures in three instances. During the sperm preparation process, the cross checking of information on tubes to documentation and information on the sperm receptacle when sperm is transferred to a new tube and each subsequent tube and during transfer was not documented as having been witnessed on two occasions. Verification of the sperm provider's identifying information against the sperm container (preparation tube) was not documented on one occasion. When the audit findings were discussed it was explained that the omission was made at a time of staff shortage and that the operator was a locum employee. A record of witnessing training and competence assessment for the locum employee was seen on inspection.

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.

Prior to any woman being provided with treatment account is taken for the welfare of any child who may be born as a result of the treatment or any existing child who may be affected by that birth. Five sets of patient records were audited

The centre has an SOP in place for the process to be followed when carrying out a welfare of the child (WoC) assessment (SLC T33(b)). Evidence of this was seen from an audit of five sets

of patients' notes which confirmed that both patient and partner had completed WoC forms which had been reviewed by the clinical staff prior to treatment (SLC T56).

The Clinical Nurse Specialist was able to provide documented evidence of the assessment of her competence to conduct WoC assessments (SLC T15(a)).

The centre has established quality indicators (QIs) relevant to assessment of WoC (SLC T35). Audit reports for the period January to December 2010 and January to December 2011 were seen to include welfare of the child procedures and documentation. No non conformities were reported. (SLC T36)

What they could do better.

Nothing noted.

Patient selection criteria and laboratory tests

What the centre does well.

Patient and partner records seen on inspection confirmed that patient partners providing fresh semen samples for use in partner treatment are screened for HIV1 and HIV2, hepatitis B and hepatitis C, which is consistent with the European Union Tissue Directive (EUTD) 2006/17/EC Annex III 2.2. Partners are also tested for Treponema pallidum. There are also mechanisms in place to identify when screening or further testing may be required (standard licence conditions T50(d)).

Diagnostic semen analysis is conducted at the centre to a standard considered equivalent to Clinical Pathology Accreditation (CPA) (UK) Ltd. (SLC T21) for andrology in that the centre;

- operates a quality management system which is acceptable to the HFEA;
- uses validated procedures for semen analysis;
- the laboratory manager is appropriately qualified to perform and interpret semen assessment (as demonstrated by completion of the Association of Clinical Embryologists (ACE) certificate and Health Professionals Council (HPC) registration;
- participates in National External Quality Assessment Service (NEQAS) for andrology

In addition, the centre is working towards ISO 15189:2007 accreditation for medical testing laboratories.

What they could do better.

Nothing noted.

2. Changes / improvements since the previous inspection on 17 February 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
<p>Validation of critical processing procedures and equipment had not been performed.</p> <p>SLC T72 and T24</p>	<p>Critical processing procedures must be validated and must not render the gametes clinically ineffective or harmful to the recipient. Validation may be based on studies performed by the establishment itself or data from published studies or from well-established processing procedures or retrospective evaluation of clinical results.</p>	<p>Evidence was provided to the Executive that this had been implemented prior to 1 July 2010 and was confirmed in documentation see on the day of inspection.</p> <p>No further action is required.</p>
<p>Procedures for the operation of each piece of critical equipment and the actions to take in the event of malfunction or failure had not been established.</p> <p>SLC T27</p>	<p>A documented procedure for the operation of each piece of critical equipment and the actions to be taken in the event of malfunction or failure determined.</p>	<p>Evidence was provided to the Executive by the PR that this had been implemented in his response to the renewal report. This was confirmed in documentation seen on the day of inspection.</p> <p>No further action is required.</p>
<p>The was no SOP in place to direct the process for assessing welfare of the child.</p> <p>SLC T33</p>	<p>A documented procedure to direct this process should be established.</p>	<p>A copy of the SOP was provided by the PR at the time of the last report.</p> <p>No further action is required.</p>
<p>Quality indicators for a number for the centre's key activities had not been established or audited for compliance with the quality indicators, approved protocols and regulatory requirements within two</p>	<p>The outstanding quality indicators should be established and audits conducted to evaluate compliance against these, approved protocols and regulatory requirements.</p>	<p>The PR submitted evidence of the required quality indicators at the time of response to the renewal report and committed that the outstanding audits would be completed.</p>

Area for improvement	Action required	Action taken as evidenced during this inspection
<p>years. SLC T35 and T36</p>		<p>The audit of witnessing procedures has now moved to a 'rolling' monthly audit. Evidence of this and other audits conducted has been provided.</p> <p>No further action required.</p>
<p>Third party agreements had not been reviewed or evaluated in accordance with SLC T112 and T114</p>	<p>The agreements in place should be reviewed within the time specified and evaluated the ability of the third parties to meet the requirements of SLC T114 and Code of Practice guidance.</p>	<p>The PR committed to a review and evaluation of all third party agreements in response to the last report.</p> <p>An audit of four third party agreements (total number held) was conducted on this inspection. All agreements were seen to have been reviewed and no non-conformities were noted.</p> <p>No further action is required.</p>
<p>Confidentiality and privacy There was no documented procedure in place to ensure all information is kept confidential. SLC T33(b) and T43</p> <p>Access to patient areas is shared with other services. There is the potential that patient confidentiality and privacy may be compromised.</p> <p>Guidance 25.7</p>	<p>Access to patient areas should be reviewed to reduce the risk of the centre's patient confidentiality and privacy being compromised.</p>	<p>In response to the last report the PR confirmed that a SOP was in place.</p> <p>A tour of the centre premises on the day of inspection demonstrated that the confidentiality and privacy of the patients and their partners attending the centre is considered by centre staff where possible. However, it was observed that the close proximity of the centre facilities to the ante natal and early foetal monitoring unit means that patients attending the fertility clinic</p>

Area for improvement	Action required	Action taken as evidenced during this inspection
		<p>are commonly in an environment where ante natal consultations and the sound of foetal monitoring can be clearly heard whilst in the waiting areas. As such the privacy, dignity and respect for sub-fertile patients attending the centre may be compromised.</p> <p>Further action is required.</p>

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 reviewed 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
Does the centre have a documented induction training procedure? (SLC T15)SAQ = 2	The recently recruited senior nurse was able to demonstrate and describe that she had participated in the Trust with induction programme and had received local induction to the centre from the laboratory manager, PR and former senior nurse in post.	No further action required.
Do all staff participate in CPD?(SLC T15) SAQ = 3	The PR and staff described that currently no funding from the Trust for fertility centre staff to attend professional development opportunities that require any funding. Staff wishing to participate in professional development or training to maintain their respective professional registration do so at their own expense.	Further action required.
Can all staff provide documented evidence of their competence in the performance of their designated task?	Staff from all disciplines, clinical, laboratory and clerical, were able to demonstrate documented competence	No further action required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
(SLC T12 and T15(a)) SAQ = 2	assessments for a wide variety of allocated activities and tasks.	
Has your centre audited how far your procedures for the provision of information comply with approved protocols, regulatory requirements and quality indicators in the last two years? (SLC T36) SAQ = No	The centre has not audited their procedures for the provision of information within the last two years.	Further action required.
Has your centre audited how far procedures for taking consent comply with approved protocols, regulatory requirements and quality indicators in the last two years? (SLC T36) SAQ = No	The audit reports of consent procedures conducted in 2010 and 2011 were available to see on inspection.	No further action required.

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
None			

▶ Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties

- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
<p>Witnessing of all stages of the semen preparation process in accordance with the centre’s own SOP and SLC 71 CoP Guidance 18:4</p>	<p>Witnessing protocols should be followed when any of the following clinical or laboratory procedures take place: 18:4 (c Preparing sperm - Cross-check information on tubes against the documents and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column).</p> <p>(e) Transferring gametes between tubes or dishes - Cross-check information marked on dishes and tubes against the patient’s records, and the information marked on the dishes and tubes that the gametes are being transferred from. However, as part of their risk assessment for sperm preparation, centres may consider witnessing the cross-</p>	<p>This has been done.</p>	<p>Immediately post inspection the laboratory manager stated that the witnessing processes has been risk assessed and the person providing holiday cover has been given refresher training and his competence to perform and supervise witnessing procedures has been reassessed.</p> <p>No further action required.</p>

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	<p>checking of information on tubes only at the start and end of the procedure, not at every stage in it. (Guidance 18:30)</p> <p>With immediate effect.</p>		
<p>Availability of sufficient numbers of staff who are trained and available to conduct witnessing procedures. SLC T12</p>	<p>The PR must ensure that there are sufficient numbers of staff who are trained and assessed as being competent to conduct witnessing procedures when required. The continuing competence of staff to conduct witnessing should be assessed periodically, especially if the person conducts witnessing procedures infrequently.</p>	<p>This has been done.</p>	<p>Since the day of inspection the Quality Manager has conducted a further audit of witnessing procedures and documentation where a non-compliance was identified. Details of corrective action and retraining where required have been provided (as above). Witnessing training is also to be provided to additional centre staff to increase the number of people who may be called upon to witness sperm preparation procedures.</p> <p>No further action required.</p>

▶ **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
Audit of information giving processes. SLC T36	<p>The PR should ensure that the information giving process to patients and their partners is audited against the approved protocols, regulatory requirements and the centre's own quality indicators.</p> <p>To be completed by 30 September 2012</p>	<p>As explained at the time of inspection, due to lack of staff it has not been possible for us to carry out all the necessary audits within the required time frame. I am happy to inform that the sub-fertility unit now has it's full compliment of staff and a Clinical Research fellow is a new addition to the team. I have asked this fellow to be in charge of all the audits and to ensure that specified areas mentioned here are audited. The audit forms once created and when each audit is completed with the necessary outcomes and actions taken will be forwarded to you.</p>	<p>The centre's inspector notes the PR's commitment to the implementation of this recommendation. Progress will be monitored.</p>

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Staff participation in clinical professional development. SLC T15	<p>The PR should ensure that staff are supported in their on-going clinical professional development to maintain registration with their respective professional bodies and demonstrate adequate knowledge and understanding of the relevant clinical / scientific processes and principles and competence to perform their designated tasks.</p> <p>30 September 2012 (to be monitored)</p>	<p>Our lead nurse will organise a structured Fertility CPD for all the nurses in the department. The CPD programme will be monitored and where necessary appropriate action will be taken to enhance the knowledge of the fertility nurses.</p> <p>Our laboratory manager will contact the trust Education Department to explore what CPD opportunities are available for him.</p>	The centre's inspector notes the PR's commitment to pursue this on behalf of the centre team. Progress in achieving suitable CPD opportunities will be monitored.
Privacy and dignity of patient and their partners. Guidance 25:7	<p>The centre should provide for the privacy, dignity and respect of all prospective and current patients and their partners.</p> <p>The centre should take steps to minimise the opportunity for patients to overhear foetal monitoring machines and ante natal discussions by working with the midwifery service</p>	After our meeting with the Associate Director, Women, Children and Support Services I was informed that as the hospital is a PFI Building, It is very difficult to carry out building alteration and thereby limiting any major structural changes. However, we are beginning to explore if the sub-fertility unit can be relocated	No further action required at this time.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	<p>colleagues to minimise noise in the waiting area, ensuring adjoining doors are kept closed and foetal monitoring equipment volume is not excessive.</p> <p>30 June 2012</p>	<p>into the community. Currently no suitable building has been identified. However, trust may find such a move financially challenging. Trust is also in discussion with the various commissioners to find a possible solution. In the mean time, as a temporary measure, the antenatal unit has been asked to turn down the volume on the foetal monitoring units. This will be monitored on an on-going basis.</p>	

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

27 June 2012

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

Minutes – Item 2

Centre 0291 – (Fertility Unit, Barking, Havering and Redbridge Hospitals Trust) – Interim Inspection Report

Members of the Panel: Mark Bennett, Director of Finance & Facilities (Chair) Rachel Fowler, Policy & Information Manager Dave Moysen, Head of Information	Committee Secretary: Joanne McAlpine
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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

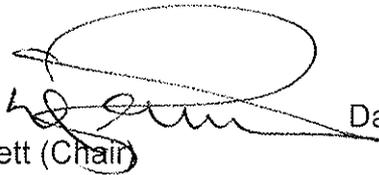
1. The Panel noted that this centre is a small NHS centre which has been licensed by the HFEA to provide partner intra uterine insemination (IUI) since 2007.
2. The Panel noted that the centre was last inspected for renewal of its licence in February 2010 and a four year licence was subsequently granted.
3. The Panel noted the centre reported 113 cycles of partner insemination with 11 pregnancies for 2011. This equates to a 10% pregnancy rate which is consistent with the national average.
4. The Panel noted that, at the time of the inspection, there were two major areas of non-compliance and three other areas of non-compliance or areas of poor practice.
5. The Panel noted that, since the inspection, the Person Responsible (PR) has confirmed and provided evidence that the two major areas of non-compliance have been remedied and has given a commitment to implement the three other areas reported within the prescribed timescales.
6. The Panel noted that the Inspectorate recommended that the centre's licence continue without additional conditions.

Decision

7. The Panel noted that the centre had implemented all recommendations made from the previous inspection.
8. The Panel agreed with the Inspectorate's recommendations made in the report. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed:

Mark Bennett (Chair)



Date:

17 July 2012