Interim Licensing Report

Centre name: The Whittington Hospital Fertility Unit
Centre number: 0258
Date licence issued: 01/07/2011
Licence expiry date: 30/06/2015
Additional conditions applied to this licence: None
Date of inspection: 12/02/2013
Inspectors: Sara Parlett
Date of Executive Licensing Panel: 10/05/2013

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 are recommendations for improvement in relation to two major areas of non-compliance and three 'other' areas of non-compliance.

Since the inspection, the Person Responsible (PR) has implemented the following recommendation:

'Other' areas of practice that require improvement:

- The PR should apply to vary the centre's licence to change the centre's address to accurately reflect the location of the licensed premises.

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

'Major' areas of non compliance:

- The PR should consider establishing quality indicators (QIs) for the centre's clinical pregnancy rates. These QIs should be audited regularly. The investigation into the low success rates for 2011 should be documented and submitted to the HFEA.
- The PR should ensure that QIs are established for all other licensed activities and activities carried out in the course of providing treatment services that do not require a licence.

'Other' areas of practice that require improvement:

- The PR should ensure that where sperm is procured at home the centre records this in the gamete provider's notes.
- The PR should investigate the circumstances that led to the documentation, requested by the HFEA to demonstrate the suitability of the changes to licensed premises, not being submitted. The PR is asked to provide a copy of the floor plan that defines the varied licensed premises, including the purpose of each room.

Information about the centre

The Whittington Hospital Fertility Unit is located in London and has held a licence with the HFEA since 2007. It is a satellite centre for CRM London (HFEA licensed centre 0199).

The centre provides partner intrauterine insemination treatment (IUI) only.

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 223 cycles of IUI with 14 pregnancies. This equates to a six per cent clinical pregnancy rate and is consistent with the national average, with one exception:

- In the under 35 age group for stimulated IUI cycles, the clinical pregnancy rate was below the national average at a statistically significant level.

The centre has also submitted its 2012 IUI treatment return. However, HFEA analysis of the sector's results for 2012 has not yet been performed; therefore a comparison of the centre's 2012 results against the national average cannot be made yet.

The 2011 data was discussed with the PR on inspection. The PR was aware of the low success rate and considers that this is because the treatment is offered to a wide selection of patients, who may have a low chance of success via IUI. For example, one local Primary Care Trust (PCT) currently has an 18 month waiting list for NHS funded IVF treatment. As a consequence, patients often request IUI treatment while waiting for IVF.

The centre has not established QIs for its success rates. The PR explained that he considers patient satisfaction to be a more relevant quality objective for the centre and that they have not had any complaints about the IUI service. Patients who are less likely to have a successful outcome could be refused treatment to increase success rates. However, the PR stated that he gives clear information to the patients about the chance of success, but if patients are still keen to attempt IUI and it is clinically indicated he will not refuse them.

Centre staff explained that stimulation regimes and laboratory practice, including staff competence, had been reviewed and it was concluded that no corrective action was

[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.

required following the low 2011 success rate. However, this investigation and its findings had not been documented.

See recommendation 1.

Multiple births[2]

The centre provides IUI treatment only and is not subject to HFEA regulations concerning multiple births. However, the PR explained that policies are in place to minimise the occurrence of multiple births and that patients are advised of the risks associated with multiple births. In 2012, the centre reported three multiple pregnancies out of a total of 18 pregnancies.

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 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.

Consent: Disclosure to researchers

The records of consent to disclosure to researchers, given by patients undergoing satellite IVF at this centre, are reported to the HFEA by the primary centre (centre 0199). Consent to disclosure to researchers is not required for IUI treatment. 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 but patients were attending for scan appointments. Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival and the atmosphere in the clinic appeared calm at all times.
The PR confirmed that he is currently satisfied with the staff complement. Patients interviewed on inspection commented that there were no appointment delays and 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 four patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with all four patients providing feedback to the HFEA commenting that they have compliments about the care that they received.

A copy of the centre's recent patient satisfaction survey was also reviewed on inspection and demonstrated that good feedback was received and no corrective action was necessary.

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-compliances were identified:

- The address of the licensed premises, as it appears on the front page of the centre's licence, is not the location in the hospital where licensed activities take place. Rather, it is the hospital's administrative centre (see recommendation 3).

- The form signed by the patient's partner, upon receipt of the sperm sample at the centre, includes the requirement to record where the sample has been produced. This section had not been completed in two of the ten sets of records reviewed on inspection (see recommendation 4).

- In 2011, centre staff corresponded with the HFEA regarding planned changes to the licensed premises. In September 2011 the Executive confirmed that on this occasion, a licence variation application was not required but evidence was requested to demonstrate that the changes would be fit for purpose prior to use.

  On this inspection, centre staff confirmed that the changes to the existing premises had occurred in December 2011. The andrology laboratory has been relocated to an adjacent room. The former andrology laboratory has been converted into a male production room, with a transfer hatch linking the rooms. The centre had not provided

the evidence requested (including a copy of the revised floor plan) and the HFEA had not approved the changes to existing premises before use (see recommendation 5).

Evidence reviewed on inspection demonstrated that the new andrology laboratory meets the required air quality standards and that equipment was re-validated after being relocated. The laboratory was considered secure and fit for purpose by the inspector.

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 two 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:

- The PR should establish QIs for assessing the welfare of the child, consent taking and information provision.

QIs have not been established or documented for any licensed activities, although audits are performed regularly by the centre. Guidance on establishing and documenting QIs was forwarded to centre staff after the inspection. See recommendation 2.

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 and 2012 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
1. For the year 2011, in the under 35 age group for stimulated IUI cycles, the clinical pregnancy rate was below the national average at a statistically significant level. The centre has not established QIs for its success rates. Centre staff explained that an investigation was performed following the 2011 low success rates but the investigation and findings have not been documented. SLC T35 and T36.	The PR should consider establishing QIs for the centre's clinical pregnancy rates. This will help ensure that any issues that may impact on success rates, other than the patient population being treated, are identified and investigated in a timely manner. The QIs should be audited regularly and any corrective actions identified should be documented and implemented. A copy of the documented QIs should be submitted to the centre's inspector by 12 May 2013. The investigation into the 2011 low success rates should be documented and submitted to the HFEA by 12 May 2013.	Our unit offers a service that is not solely based on pregnancy success. We view a high patient satisfaction and no complaints as a quality indicator in which we continue to score highly. IUI success rates are very dependable on which patients are put through for treatment. In evaluating our pregnancy results, we can look at our patient selection and treatment processes. This report has acknowledged that	The inspector acknowledges the PR's response. Further action is required.

	The PR should ensure that any future investigations into low success rates are documented.	our equipment is validated and processes are audited and that there are no significant discrepancies with how the treatments are carried out.	
2. As well as the QIs for success rates documented above, the centre has not established QIs for any other licensed activities and activities carried out in the course of providing treatment services that do not require a licence. SLC T35. **This was an issue at the previous inspection.**	The PR should ensure that QIs are established and documented. A copy of these QIs should be submitted to the centre's inspector by 12 May 2013.	We will supply QIs for this by the 12 May 2013. Please note that we have already implemented a QI for assessment of WOC- this is included on page 4 of our IUI consent (S-OP4) (point 3).	The inspector acknowledges the PR's response. The PR is asked to submit a copy of all QIs, including that for welfare of the child assessments, by 12 May 2013.

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
3. The address of the licensed premises, as it appears on the front page of the centre's licence, is not the location in the hospital where licensed activities take place. SLC T1.	It is recommended that the PR apply to vary the centre's licence to change the centre's address to accurately reflect the location of the licensed premises. There is not an appropriate application form by which to apply for this variation via the clinic portal. It is therefore recommended that details of the variation request are communicated via email directly to the centre's inspector by 12 May 2013.	The clinic is part of an NHS Hospital, and the Trust designate the current address for all communication. I have emailed the address of the clinic which is in a different part of the hospital.	The PR has provided the correct address for the licensed premises. A licence variation application will be considered by an Executive Licensing Panel in the near future.
4. In two of the 10 sets of notes audited on inspection, the male partner had not recorded where the sample had been produced. SLC T68.	The PR should ensure that where sperm is procured at home, the centre records this in the gamete provider's notes. Immediately 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 12 August 2013.	This information is recorded on our witnessing forms. We will audit the completion of this part of the witnessing form for 2012.	The inspector is of the opinion that as two of the 10 sets of notes audited did not include this information, corrective action is required to ensure that it is recorded in all

			cases in future. Once the corrective action is identified and implemented, it is recommended that an audit is performed within six months to ensure that the corrective action is effective. Further action is required.
5. Changes were made to licensed premises and documentation requested was not submitted to the HFEA. The HFEA must approve all changes to existing premises before use (CoP Interpretation of mandatory requirements 25A). CoP Guidance 25.4.	The PR should investigate the circumstances that led to the documentation not being submitted to the HFEA as requested. The PR should provide a summary report of this investigation, including any corrective action taken to ensure it does not occur again, to the inspector by 12 May 2013. The PR is asked to provide the HFEA with a copy of the floor plan that defines the varied licensed premises, including the purpose of each room by 12 May 2013 (CoP Guidance 25.2).	The change in our sperm preparation room where verbally discussed at our last inspection. We will forward a floor plan of the new sperm preparation room. We are not planning to move again in the forseeable future.	The inspector acknowledges the PR's response. Further action is required.

Additional information from the Person Responsible

Our quality manager has now changed to Yvonne Nicholson. Gulam Bahadur has left the unit. External validation of sperm preparation will be undertaken.

We are very aware of our drop in pregnancy rate, but we believe that this is related to our patient selection. Our ovulation induction program is very succesful and it is very straightforward for the unit to improve the IUI pregnancy rate by putting through those requiring ovulation induction through our IUI program.

HFEA Executive Licensing Panel Meeting

10 May 2013

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

Minutes – Item 3

Centre 0258 – (The Whittington Hospital Fertility Unit) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Nick Jones – Director of Compliance Ian Peacock – Analyst Programmer	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 the centre has held a licence with the HFEA since 2007.

2. The Panel noted that in 2011 the centre reported 223 cycles of IUI (intrauterine insemination) with 14 pregnancies, and that this equates to a 6% clinical pregnancy rate. Whilst the clinical pregnancy rate for patients 35 years and over is consistent with the national average, for the 35 age group having stimulated IUI, the clinical pregnancy rate was below the national average at a statistically significant level.

3. The Panel noted that the centre was inspected on 12 February 2013.

4. The Panel noted that, at the time of inspection, two major and three other areas of non-compliance were identified.

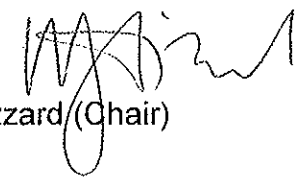
5. The Panel noted that one recommendation made during the centre's renewal inspection in 2011 has not been implemented: that the PR should establish QIs for assessing the welfare of the child, consent taking and information provision.

6. The Panel endorsed the Inspectorate's encouragement of the centre to address the recommendations in the timescales given in the report, in particular to address QIs for other licensed activities as mentioned in paragraph 6.

Decision

7. The Panel noted the pregnancy rate for stimulated IUI cycles in the under 35 age group, and urged the centre to make improvements in this area.

8. The Panel agreed to continue the centre's licence with no additional conditions.

Signed: 
Juliet Tizzard (Chair)

Date: 15/5/13