Interim Inspection Report

Date of Inspection: 7 December 2010
Length of inspection: 6 hours
Inspectors Parvez Qureshi
Wil Lenton

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 4 December 2008 and 04 March 2011

Date of Executive Licensing Panel: 04 March 2011.

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the 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	Manchester Fertility Services LTD
Centre Number	0033
Licence Number	L0033-13-D
Centre Address	Manchester Fertility Services Ltd. Bridgewater Hospital 120 Princess Road Manchester M15 5AT
Telephone Number	0161 227 0010
Person Responsible	Dr Debbie Falconer
Licence Holder	Dr Ilan Lieberman
Date Licence issued	01/05/2009
Licence expiry date	30/04/2014
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

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 area of non-compliance and two other areas of non-compliance.

Since the inspection visit on 07 December 2010 the PR has provided information that, in the view of the inspection team, provides sufficient information to conclude that the centre has implemented the following recommendations:

Major areas of non compliance:

- The PR should ensure that all critical processes are validated.

Other areas of practice that require improvement:

- The PR should keep a separate record of the name, job title and signature of all staff involved in witnessing procedures.
- The PR should amend the centre's witnessing Standard Operating Procedure (SOP) to include the need to cross reference labelling on vessels to primary documentation.
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The PR has also given a commitment to implement the following recommendations:

- The PR should ensure that all critical equipment is validated.

The inspection team considers that overall there is sufficient information on which to recommend the continuation of the centre's licence without additional conditions.

Details of Inspection findings

Brief description of the centre and its licensing history:

Manchester Fertility Services was first established in 1986 and has been licensed by the HFEA since its creation in 1990. The centre is privately owned and offers licensed treatment to both self funding and NHS funded patients.

The centre was last inspected in December 2008. The premises have not undergone any major changes since that time. Business hours are between 7.30am and 4.00pm 6 days a week.

An application to vary the centre's licence to reflect a change of Person Responsible (PR) from Professor Brian Lieberman to Dr Debbie Falconer was granted by an Executive Licensing Panel in January 2010.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 October 2009 – 30 September 2010 *
In vitro fertilisation (IVF)	286
Intracytoplasmic sperm injection (ICSI)	275
Frozen embryo transfer (FET)	293
Donor Insemination (DI)	280
Gamete intrafallopian transfer (GIFT)	0
Intra uterine insemination (IUI)	66 (Note: cycles provided in the period 1 January to 31 December 2009.

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

*These data were extracted from the HFEA register for the period 1 October 2009 – 30 September 2010. 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

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. Prior to commencement of treatment, all patients are provided with a personalised costed treatment plan. The plan provides cost details for the main elements of the proposed treatment. Patients are also informed of the cost of additional items, such as medications and for the cryo-storage of samples, which may be incurred depending on their course of treatment. Staff reported that patients are given the opportunity to discuss the costed treatment plan with the clinical staff prior to treatment. A copy of the costed treatment plan was seen to be kept in the patient's notes (Code of Practice (CoP) guidance 4.3). Patients and their partners having treatment with donor gametes or embryos who are affected by legal parenthood laws are given information regarding these both verbally and in writing. (Standard licence conditions T60 and |T61). Members of staff interviewed during the inspection demonstrated an understanding of the requirements of legal parenthood legislation. The centre has written procedures for obtaining written records of consent to parenthood. Where applicable, appropriately completed consents to parenthood were present in patient notes reviewed on inspection.
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. Six sets of patient notes audited during the inspection were found to contain appropriately completed consent forms, including those for the disclosure of information held by the HFEA to researchers and for the use and storage of gametes and embryos in the provision of treatment. (Standard licence condition T57). A sample of consents to the disclosure of personal information held on the HFEA Register was reviewed on inspection. The consents seen to be recorded in the patient notes were found to be consistent with the consents reported to the HFEA with one exception (see below). The centre has an SOP in place to ensure that all stored gametes and embryos are within their statutory and consented storage periods. The centre's procedure for withdrawing storage consent includes the provision of a 12 month 'cooling off' period in cases where one gamete provider withdraws consent to embryo storage. Staff interviewed were able to appropriately describe this process. Evidence was provided by the PR showing that the centre has established quality indicators (QIs) relevant to obtaining consent. The centre has audited their consent procedures, including consents in place for all stored samples and where required corrective actions are documented and implemented (Standard licence conditions T35

and T36).

What they could do better.
One patient's consent to disclosure of information to researchers on the HFEA CD form was different from that recorded by the centre via the electronic data interface (EDI) within the HFEA Registry. The centre staff agreed to rectify this discrepancy and include a review of the completion of this form against EDI submissions in planned future admits.

Multiple births

What the centre does well.
The PR reported an overall multiple pregnancy rate at the time of inspection of 18.0%.

The centre has a documented Multiple Births Minimisation Strategy, as required by General Direction 0003, paragraph 3(a), which includes:

- How the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection (5(a)).
- How the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (5(b)).

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for SET (3(c)). From 1 February 2010 to 31 October 2010 the centre carried out eight double embryo transfers in patients who met the criteria for SET.

Where more than one embryo has been transferred into patients who met the criteria for SET, centre staff have recorded the reason for this action and that the risks associated with multiple pregnancy have been fully discussed with the patient (7(a) (b)).

At the time of inspection, the PR reported that the centre does not provide treatment cycles in which three embryos are transferred to a patient.

The centre has carried out regular audits and evaluations of the progress and effectiveness of the Multiple Births Minimisation Strategy. Evidence of this was seen in the centres audit programme and in minutes of discussions at clinical meetings. (3(b)).

What they could do better.
Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.
The centre has a rolling programme in place for the validation of all critical equipment and processes which influence the quality and safety of gametes and embryo. The

schedule and most recent audit report to evaluate progress with the validation of equipment and processes were provided on inspection.
What they could do better. Not all critical equipment (standard licence condition T24) and processes (standard licence condition T72) have been validated.

Witnessing
What the centre does well. Review of the centre's witnessing SOP and discussions with staff demonstrated that a witnessing procedure is in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. Three sets of patient notes were audited for records of witnessing during the inspection. All seen were found to contain a record of witnessing checks (CoP 18.7). Evidence was provided by the PR showing that the centre has established QIs relevant to witnessing and these are audited against, and where required corrective actions are documented and implemented (Standard licence conditions T35 and T36).
What they could do better. A review of patient notes showed that the names, status and signatures of staff performing witnessing procedures are captured. However, the centre does not keep a separate sheet for identification of all staff involved in witnessing procedures (CoP 18.8). The centre has a witnessing SOP in place but it does not refer to the need to cross reference labelling on vessels, including witnessing of donor sperm preparation process, to primary documentation such as patient notes and laboratory sheets (CoP 18.4).

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. The centre runs a sperm donor bank and is able to supply donor sperm to other HFEA licensed centres. There is an SOP in place for the process to be followed when selecting and recruiting donors (Standard licence condition T33 (b)). A review of three patient records confirmed that donors had been selected on the basis of their age and each file included a documented health and medical history in compliance with standard licence condition T52 (a). Patient records reviewed contained screening test results indicating that donors are selected in accordance with the screening requirements of Standard licence condition T52 and relevant professional body guidelines. Evidence was seen that the laboratory tests were carried out by a laboratory accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd (Standard licence condition T53 (a). Members of staff reported that the centre can provide donors with the following information if requested: the number of persons born as a result of the donation, the sex of each of those persons and the year of birth of each of those persons in accordance with the HFE Act 1990 (as amended), Schedule 31ZD (3). Evidence was provided by the PR showing that the centre has established QIs relevant to selection and recruitment of donors which are audited against annually and where required corrective actions are documented and implemented (Standard licence conditions T35 and T36). The centre maintains a computerised log of all expenses and reimbursement for loss of earnings made to donors. A record of reimbursements made is kept in each donor's notes. Evidence of this was seen during an audit of donors' notes (General Directions 0001).
What they could do better. Nothing noted at the time of inspection.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. As the centre offers a full range of treatment services, this theme was not relevant at this inspection. However, during an audit of patients' notes the inspectorate noted they contained welfare of the child forms completed and signed by both partners.
What they could do better.

Embryo testing (if applicable)
What the centre does well. Not applicable to this centre.
What they could do better. --

2. Changes / improvements since the last inspection on 4 December 2008

Area for improvement	Action required	Action taken as evidence during this inspection
Embryo thawing SOP (OP-EM-8v1) to be amended to ensure; i. the removal of embryo straws (from their canes) to be performed over a flask of liquid nitrogen and not over the open dewar. ii. all records are contemporaneously updated. S.7.8.5(b)(c) /S.7.8.10(d) Code of Practice 7th (CoP 7th).	Amendment of SOP (OP-EM-8v1	An updated embryo thawing SOP was made available for the inspection. No further action required.
The practice of not splitting all patients' frozen embryos into two different cryo dewars to be risk assessed.	Risk assessment of current practice	Splitting of all patients' frozen embryos into two different cryo dewars is now being performed. No 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 action taken meets requirement or whether any further action is required
Has the centre established QIs for all licensed activities and other activities carried out in the course of providing treatment services that do not require a licence [Standard licence condition T35]	The PR provided an audit list showing QIs for the activities carried out by the centre.	No further action required.
Have all licensed activities or activities carried out in the course of providing treatment services that do not require a licence, been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years [Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36]	The PR provided evidence in the form of an audit list showing various activities which have been audited over the year. The PR reported this as an ongoing process.	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 or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Action required and Timescale	PR Response	Executive Review
None identified at the time of this inspection.	--	--	--

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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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	Action required and Timescale	PR Response	Executive Review
The centre has not validated all critical equipment. Standard licence condition T24.	The PR should ensure that all critical equipment is validated. An updated action plan to be submitted by the time the PR responds to this report.	Validation of critical equipment will be completed by the end of February 2011. Attached is an example of one validation process. This template has been completed for each piece of equipment. All documents will be stored on Q pulse (QMS system) along with all other information relating to the equipment i.e. service and calibration records and records of any non-conformance.	The inspectorate considers this to be an acceptable response. Progress to be monitored.
The centre has not validated all critical processes. Standard licence condition T72.	The PR should ensure that all critical processes are validated. This validation may be based on studies performed by the establishment itself, data from published studies or from well-established processing procedures, or by retrospective evaluation of the clinical and laboratory results. An updated	All critical processes have been identified and validated since completion of SAQ's. Each processes was validated by a combination of :- 1. Published studies 2. KPIs	The inspectorate considers this to be an acceptable response.

Area of practice	Action required and Timescale	PR Response	Executive Review
	action plan to be submitted by the time the PR responds to this report.	3. Process audit 4. Individual results (where applicable) The method of validation for each process is recorded at the beginning of every SOP. (see OP-EM-5 Intracytoplasmic sperm injection). All processes have undergone validation audit once in 2010 and documentary evidence of this was submitted on 21st January 2011. Kpi's and process audits are ongoing and the audit calendar for 2011 is attached. Processes are selected at random for validation depending on the workload on the day of the audit.	

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 good practice.

Area of practice	Action required and Timescale	PR Response	Executive Review
The centre does not keep a separate sheet for identification of staff involved in witnessing procedures. (CoP 18.8).	The PR should ensure a separate record of the name, job title and signature of all staff who are trained and participate in witnessing procedures is maintained. The PR should provide notice of this in her response to this report.	Completed and submitted to HFEA on 21st January 2011.	Following review of the submitted information, the inspectorate considers this to be an acceptable response.
The centre's witnessing SOP does not refer to the need to cross reference labelling on vessels, including witnessing of donor sperm preparation process, to primary documentation such as patient notes and laboratory sheets. CoP 18.4).	The PR should review the centre's witnessing SOP to ensure labels on vessels are cross referenced to their primary documentation. The PR should provide notice of this in her response to this report.	Completed and submitted to HFEA on 21st January 2011.	Following review of the submitted information, the inspectorate considers this to be an acceptable response.

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting
4 March 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0033 (Manchester Fertility Services Ltd) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Ian Peacock, Analyst Programmer	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 was first established in 1986 and has been licensed by the HFEA since its creation in 1990. The Panel noted that the centre is privately owned and offers licensed treatment to both self funding and NHS funded patients.

2. The Panel noted that the centre was last inspected in December 2008. The premises have not undergone any major changes since that time.

3. The Panel noted that they had approved a change of Person Responsible (PR) from Professor Brian Lieberman to Dr Debbie Falconer, in January 2010.

4. The Panel noted that the centre offers a full range of assisted reproduction treatments, and has carried out 1200 cycles during the period 1 October 2009 – 30 September 2010.

5. The Panel noted that at the time of the inspection there were a number of areas of practice that required improvement, including two major area of non-compliance and two other areas of non-compliance.

6. The Panel noted that since the inspection visit on 7 December 2010, the PR has provided evidence of the progress made which the Inspectorate have reviewed and conclude to be sufficient.

7. The Panel noted that the PR has given a commitment to implement the outstanding recommendations within the report, in particular the validation of critical equipment by the end of February 2011.

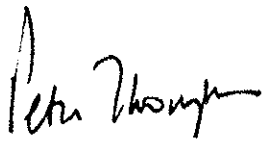
8. The Panel noted the Inspectorate's recommendation for the continuation of the centre's licence with no additional conditions.

9. The Panel noted the centres Multiple Birth rate of 18%, and praised the PR for the progress made in this area.

Decision

10. The Panel endorsed the Inspectorate's recommendation to the continuation of the centre's licence, with no additional conditions.

11. The Panel encouraged the PR to review the centres rolling programme of the validation of critical equipment and processes, and would urge the PR to ensure that the validation of critical equipment is implemented immediately.

Signed: 

Date: 22/03/2011

Peter Thompson (Chair)