Interim Licensing Report

Centre name: **Manchester Fertility Services Ltd**

Centre number: **0033**

Date licence issued: **01/10/2011**

Licence expiry date: **30/04/2014**

Additional conditions of licence: **None**

Date of Inspection: **19 July 2012**

Inspectors: **Wil Lenton (HFEA, Lead) & Debra Bloor (HFEA).**

Date of Executive Licensing Panel: **19 October 2012**

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 centres 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 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 (ELP) 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 inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences at the centre.

The ELP is asked to note that at the time of the inspection there were two areas of practice that required improvement, including one major area of non-compliance and one other area of non-compliance or area of poor practice.

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented

Major area of non compliance:

- Licenced treatment data that the HFEA is required to hold on its register is submitted within the times stipulated in General Direction 0005.

'Other' area of non compliance:

- Laboratory witnessing documentation, contained within patient records, reflects the witnessing activities undertaken.

Information about the centre

Manchester Fertility Services Ltd is located in the Bridgewater Hospital, Princess Road, Manchester and has held a licence with the HFEA since 1990.

The centre provides a full range of fertility services.

The centre provided over 1000 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2012. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

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

Outcomes[1]

HFEA held register data for the year ending 30 June 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages, with the following exception:

- clinical pregnancy rates following FET (IVF/ICSI own eggs) in patients aged 16-39 are lower than the national average

This has been the subject of on-going monitoring and following a review of their freeze/thaw processes, the laboratory introduced changes to their practice, which have resulted in recent improvements to clinical outcomes. Centre staff gave a commitment to keep success rates in this group of patients under review.

Multiple births[2] (SLC T123)

The single biggest risk of fertility treatment is a multiple pregnancy.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 24%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 24%: this also represents performance that is not likely to be statistically different from 15% live birth rate target.

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[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.

The inspection team acknowledge the centre's continued monitoring of their on-going clinical multiple pregnancy rates from 2010/11 to 2011/12 and their efforts in adapting their strategy to meet the HFEA's multiple birth rate target. It is noted however that the centre's strategy may need further revision in consideration of the 10% live birth rate target that comes into force in October 2012.

Witnessing (SLC T71)
Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. On the day of inspection there were no laboratory procedures being undertaken for the inspection team to observe.

The inspection team was able to review witnessing documentation in the records of five patients that were made available on the day of inspection and concluded that effective manual witnessing documentation is maintained. However during the above review of witnessing documentation it was observed that the records do not reflect the witnessing activities undertaken **(see recommendation 2)**. The senior embryologist reported that these activities could be identified by cross reference to the witnessing standard operating procedure (SOP).

Consent : Disclosure to researchers (General Direction 0007)
A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 12 patients were reviewed in the course of the inspection. The consents were completed appropriately and reported to the HFEA accurately in all of the records reviewed.

Consent: To the storage of cryopreserved material (Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3, 8 (2))
A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

During the review of the electronic cryostorage database, a typographical error was found which was readily resolved by staff. It is noted that the centre's bring forward system is reliant on the accurate recording of consent expiry and the inspection team suggests that the accuracy of these electronic records is sampled during the routine audit of cryopreserved material.

Staffing (SLC T12)
Having the right numbers of staff, competent to carry out highly technical work in non-pressured environment is important in infertility services.

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; the atmosphere in the clinic appeared calm at all times.

Patient experience

During the inspection visit we spoke to patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 12 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very 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 prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

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 inspection team identified no non-compliances with standard licence conditions.

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2010 recommendations for improvement were made in relation to two major non-compliances and two other areas of non-compliance. Centre staff provided information and evidence that all of the recommendations had been fully implemented within the time frames given in the report.

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.

This centre has a good record of current data submission and compliance with regulatory requirements. There are, however, a number of historic treatments in which donor gametes were used where the donors have still to be registered. The HFEA is keen to ensure that historic donor issues are resolved as soon as possible as this is something that impacts upon the Authority's ability to fulfil statutory obligations to donors and the donor-conceived.

The centre has been in communication with the Register team concerning this matter and is currently working with the Authority in order to resolve any outstanding issues (General Direction 0005) **(See recommendation 1)**.

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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PRs statement
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 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 PR 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 PRs statement
1. Some licenced treatment data that the HFEA is required to hold on its register has not been provided by the centre at the time of inspection. General Direction 0005 and SLCs T9(e) & T41.	The PR must ensure that data which the Authority is required to hold on its Register is provided by the dates specified in General Direction 0005 or in writing. The PR should continue to liaise with the HFEA Register team in order to successfully resolve outstanding issues. The process for submitting licensed treatment data to the authority should be reviewed and enhanced to ensure compliance with submission times detailed in General Direction 0005 is achieved. The PR should forward an action plan and timeline for the resolution of this issue, together with a report detailing progress made to date, to the inspector by 19 October 2012.	We were under the impression that the supply of outstanding historic data to the HFEA was complete and the two outstanding pieces of information were sent to the HFEA by recorded delivery at the beginning of August.	Following post-inspection discussions between the Executive, PR and the Register team it was established that this issue has been successfully resolved. No further action required.

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 PRs statement
2. The witnessing documentation observed within patients' records does not reflect the witnessing activities undertaken. (SLC T71).	The PR should review the laboratory witnessing documentation to ensure that it reflects the witnessing activities undertaken. Details of the review and any amended documentation should be forwarded to the HFEA by 19 October 2012.	The apparent non-compliance related to the lack of instruction on the witnessing form on how to verify the patients name and date of birth at the time of egg collection. I have reviewed the witnessing documentation and precise details of each witnessing step are documented in the witnessing SOP. This SOP is used to train new staff need and only staff that are deemed to be competent are allowed to take part in witnessing procedures. The observation by the Inspector on the day of the inspection was discussed with the Senior Embryologist and it was established that the SOP cannot be replicated on the form. To comply with your recommendation all witnessing forms will be amended to have a cross reference to the SOP at the top of the forms immediately.	Issue resolved. No further action required.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

19 October 2012

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

Minutes – Item 4

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

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair)	Joanne McAlpine
Hannah Darby, Senior Policy Manager	Observing:
David Moysen, Head of IT	Neil McComb, Register Information Officer

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1990 and is currently operating on a five-year licence.

2. The Panel noted that this is a large centre which carried out over 1000 cycles of treatment in the 12 months to 30 June 2012.

3. The Panel noted that the centre had a 24% multiple clinical pregnancy rate for all IVF, ICSI and FET cycles carried out between April 2011 and March 2012. This represented performance which is not likely to be statistically different from the 15% multiple birth rate target.

4. The Panel noted that at the time of the inspection one major area of non-compliance and one other area of non-compliance were identified by the Inspectorate.

5. The Panel noted that, since the inspection, the PR has provided evidence to the Inspectorate that both areas of non-compliance have been addressed.

6. The Panel noted the positive feedback obtained from patients at the centre.

7. The Panel noted that the Inspectorate recommended that the centre's licence continue without additional conditions.

Decision

8. The Panel endorsed the Inspectorate's recommendation and agreed to the continuation of the centre's licence with no additional conditions.

Signed:  Date: 30/10/12

Juliet Tizzard (Chair)