Interim Licensing Report

Centre name: **CARE Manchester**

Centre number: **0185**

Date licence issued: **1 October 2010**

Licence expiry date: **30 September 2014**

Additional conditions of licence: **None**

Date of Inspection: **18 April 2012**

Inspectors: **Bhavna Mehta (lead), Vicki Lamb, Susan Jolliffe (observer)**

Date of Executive Licensing Panel: **27 June 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).

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 to make a decision about the continuation of the licence and which will consider the recommendations made along with any further information provided by the licensed centre.

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 progress made by the centre in meeting the HFEA multiple birth rate targets and the positive comments made by patients in relation to their experiences.

In making this recommendation it is noted that no areas for improvement were identified at this inspection.

Information about the centre

The centre CARE Manchester is located in the Victoria Park area of Manchester and has held a licence with the HFEA since 1999.

The centre provides a full range of fertility services including treatment involving embryo testing. Additionally, the centre recruits sperm donors, egg donors and egg sharers.

The centre provided 2106 cycles of treatment (excluding partner intrauterine insemination cycles) in the 12 months to 31 March 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 January 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

Multiple births[2] (SLC T123)

The single biggest risk of fertility treatment is multiple pregnancy. For the time period April 2010 to March 2011 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 19%: this also represents performance that is not likely to be statistically different from 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. The inspection team congratulate the centre on this achievement.

Witnessing (SLC T71)

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification error do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; sperm preparation; preparation for

[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.

embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system.

The inspectors were able to review patients' records and concluded that records of both manual and electronic witnessing are maintained. The centre maintains a copy of the witnessing records in patient records (either electronic or hard copy).

Consent: Disclosure of identifying information to researchers (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 10 patients were reviewed in the course of the inspection. The consents were completed 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, 2 (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.

Staffing (SLC T12)
Having the right numbers of staff, competent to carry out highly technical work in a 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; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit a number of patients provided feedback on their experiences and interactions between centre staff and patients were observed. A further five patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with four 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;
- 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, no non-compliances were identified.

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2011 recommendations for improvement were made in relation to four major non-compliances and one other area of non-compliance.

The PR has supplied within the required timescales, enough information and evidence to allow the inspector to assess that the centre is now compliant with those regulatory requirements and no further action is required.

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.

In recent months the centre has made efforts to reduce a historic backlog of register errors and omissions. This effort has succeeded in significantly reducing the backlog, but it needs to be sustained to deal with the remainder.

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 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
None			

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	Executive Review
None			

Additional information from the Person Responsible
I have read the above report. It has highlighted no areas of non-compliance or areas which require improvement and therefore does not require a response except to say i feel it accurately reflects the situation at CARE Manchester. The inspection, although not unannounced, was carried out in the same style as such an inspection would be. The inspection caused minimum disruption to the clinic.

HFEA Executive Licence Panel Meeting

27 June 2012

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

Minutes – Item 3

Centre 0185 – (CARE Manchester) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Rachel Fowler, Policy & Information Manager Dave Moysen, Head of Information	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 has held a licence with the HFEA since 1999 and provides a full range of fertility services, including treatment involving embryo testing and the recruitment of sperm donors, egg donors and egg sharers.

2. The Panel noted that the centre provided 2106 cycles of treatment (excluding partner intrauterine insemination cycles) in the 12 months to 31 March 2012 and is a large centre.

3. The Panel noted that, for April 2011 to March 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19% and this represented performance that was not likely to be statistically different from the 15% live birth rate target.

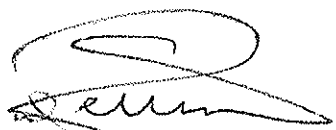
4. The Panel noted that the centre has provided evidence that all areas from the previous inspection have been addressed. The Panel also commended recent efforts made to reduce a historic backlog of register errors and omissions and that it needed to be sustained to deal with the remainder.

5. The Panel noted that the Inspectorate identified no areas of practice for improvement during this inspection. The Panel commented that this is a positive reflection on the attitude and behaviour of the Person Responsible and clinic staff.

6. The Panel noted that the Inspectorate recommends that the centre's licence continue without additional conditions.

Decision

7. As there are no non-compliances reported, the Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed:  Date: 17 July 2012

Mark Bennett (Chair)