HFEA Executive Licensing Panel Meeting

28 November 2014

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

Minutes – Item 1

Centre 0199 – CRM London – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard (Chair) Director of Strategy & Corporate Affairs Ian Peacock – Analyst Programmer Joanne Anton – Policy Manager	Dee Knoyle

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

The Panel 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

1. The Panel noted that CRM London has held an HFEA licence since 2002. The centre provides a full range of fertility services and is located in central London

2. The Panel noted that the centre's licence is due to expire on 28 February 2017.

3. The Panel noted that the inspection took place on 9 September 2014.

4. The Panel noted that in the 12 months to 31 July 2014, the centre provided 1429 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that in 2013, the centre reported 63 cycles of partner insemination with three pregnancies. This equates to a 5% clinical pregnancy rate which was consistent with the national average.

6. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 May 2013 to 30 April 2014 showed the centre's success rates were in line with national averages with the following exception:

    - success rates following ICSI treatment in women under 38 years old were higher than average at a statistically significant level

7. Between 1 October 2012 and 30 September 2013, HFEA-held register data indicated that the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 12%. This was not significantly different from the 10% maximum multiple live birth rate target for this period.

8. Between 1 May 2013 and 30 April 2014, HFEA-held register data indicated that the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%. This represented performance that was greater than the 10% maximum multiple live birth rate target for this period.

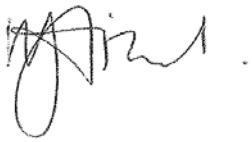
9. The Panel noted that at the time of the interim inspection on 9 September 2014, two major and one other area of non-compliance were identified. The Panel noted, in particular, the non-compliances relating to high multiple pregnancy rates and data submissions to the HFEA and urged the Person Responsible to fully implement the recommendations within the prescribed timescales.

10. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

11. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

Decision

12. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.



Signed: Date: 3 December 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: CRM London
Centre number: 0199
Date licence issued: 01/03/2013
Licence expiry date: 28/02/2017
Additional conditions applied to this licence: None
Date of inspection: 09/09/2014
Inspectors: Andrew Leonard (Lead); Susan Jolliffe
Date of Executive Licensing Panel: 28 November 2014

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 unannounced 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 (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 robust systems used to ensure cryopreserved samples are stored with the consent of the gamete providers

The ELP is asked to note that recommendations for improvement are made in relation to two major and two 'other' areas of non-compliance. The PR has responded with appropriate corrective action plans which he has committed to implement, regarding the following recommendations:

Major areas of non compliance:

- The report of the multiple births minimisation strategy audit, planned for December 2014, should be provided to the inspector by 31 January 2015 and should include appropriate corrective actions to address any poor performance identified.

- The Person Responsible (PR) should ensure all treatment information, including that related to treatment using donated gametes, is accurately reported to the HFEA register within the timeframes specified in General Direction 0005.

'Other' areas of practice that require improvement:

- The PR should ensure that access to the patient records store and other areas in the centre where confidential identifying information can be seen, is restricted to authorised persons.

The PR has also provided information and evidence such that after further review the inspection team consider no further action is required to implement the following recommendation:

'Other' areas of practice that require improvement:

- The PR should consider the need for signs on consultation room doors to indicate that they are occupied or should ensure that practices at the centre will prevent patient privacy being compromised while they are within the consultation rooms.

Information about the centre

CRM London is located in central London and has held a licence with the HFEA since 28 February 2002.

The centre provides a full range of fertility services.

The centre provided 1429 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2014. In relation to activity levels this is a large centre.

CRM London was acquired by the CARE Fertility Group Limited in October 2013 and has been renamed CRM CARE London. The PR has applied to the HFEA to change the name of the centre and this application will be considered by the ELP at the same time as this inspection report.

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.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 May 2013 – 30 April 2014 show the centre's success rates are in line with national averages with the following exception:

- success rates following ICSI treatment in women under 38 years old are higher than average at a statistically significant level

In 2013, the centre reported 63 cycles of partner insemination with three pregnancies. This equates to a 5% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

For treatments between 1 October 2012 – 30 September 2013, HFEA held register data indicate the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 12%: This was not significantly different from the 10% multiple live birth rate target for this period.

For treatments between 1 May 2013 – 30 April 2014, HFEA held register data indicate the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: this represents performance that is likely to be greater than the 10% multiple live birth rate target for this period (see recommendation 1).

[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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

On inspection, the PR provided reports of detailed audits of the effectiveness of the multiple births minimisation strategy (performed in September 2013 and June 2014). These reports indicated that effective monitoring of the centre's performance in this area is established and on-going. The reports identified problems with the multiple pregnancy rates associated with patients treated by clinicians from some of the centre's satellite clinics. Discussions between the PR and the inspection team indicate that the PR understands his responsibilities in relation to practices at the centre and the audit reports record that the satellite clinicians were informed about the centre's multiple births minimisation strategy and that they are contracted to abide by it. Another audit of the strategy is planned in December 2014 to assess the effectiveness of these corrective actions.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; thawing of embryos; sperm procurement and preparation. All of the activities were witnessed in accordance with HFEA requirements using a manual system.

The inspection team also audited the documentation in the records of seven patients of witnessed checks of identifiers during gamete and embryo processing. This allowed the inspection team to conclude that records of manual witnessing are effectively maintained.

Consent: Disclosure to researchers

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; 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 ten 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

A review of the centre's database indicated that gametes and embryos currently in store are being stored within their consented storage period. The storage periods for three sets of embryos as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the three sets of records checked, the embryos were being stored in accordance with the consenting decisions.

Staffing

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 was 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 we spoke to four patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further seven patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive. Four of the seven individuals providing written feedback to the HFEA commented that they have compliments about the care that they received.

A report of the centre's own patient satisfaction survey was also reviewed. In the 18 months up to June 2014, 1210 patients responded to this survey, comprising 699 patients treated at the centre after attending satellite clinics and 511 patients treated only at the centre. The inspection team considered the report good evidence that the centre values patient feedback, collects it in a very effective manner and responds positively to patient suggestions to improve the service.

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 personal dignity and confidentiality of patients in the clinic;
- has facilities appropriate to the needs of the patients
- has a committed and capable staff group who are appreciated by the 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, the inspection team identified the following non-compliances:

- There is a door at the rear of the centre's patient records store which is not locked even though it opens to an area accessible to unaccompanied patients. Access to confidential patient identifying information is therefore not completely restricted to people authorised by the Person Responsible (see recommendation 3). It is noted however that no breach of confidentiality has been identified.
- The inspection team had a minor concern regarding the centre's premises in relation to patient privacy: Specifically there are no signs on consultation room doors to indicate when the rooms are occupied to alert staff and avoid them disturbing patient consultations (see recommendation 4).

The PR advised the HFEA in June 2013 about a redesign and renovation project at the centre, scheduled for October 2013. The locations within the centre where licensed activities occur were not to be significantly changed, therefore no variation of licence was considered necessary. On this inspection a new administration area on the first floor and

redesigned laboratory and post-procedure recovery area on the ground floor were seen. The inspection team confirmed that the changes made were not significant enough to necessitate a licence variation. The inspection team discussed the project with centre staff and reviewed evidence of cleaning and re-validation. The team concluded that the premises remain suitable.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in September 2012, recommendations for improvement were made in relation to two major and two 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within reasonable timescales

One of the recommendations made at the last inspection concerned the timeliness and accuracy of the reporting of treatment data to the HFEA register. Actions were taken to improve the centre's performance in this area and these were effective. Concerns have however recently arisen about some aspects of the centre's treatment data reporting; these are discussed below in 'Provision of information to the HFEA' (see recommendation 2)

On-going monitoring of centre success rates

The centre has received no risk tool alerts regarding its success rates in the last two years. An alert message has however been sent about the multiple pregnancy rate within the last year and evidence seen on inspection indicated that the PR responded to it appropriately. The PR is however reminded to update the centre's inspector, within 10 working days of the receipt of the alert message, regarding any investigation and corrective action taken, as is required within the alert message text.

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 received five risk tool emails in the last year about the use of unregistered donors and three about the non-reporting of the outcomes of treatments in which donated gametes have been used. On 13 August 2014, HFEA register staff reported that donors were not specified for 18 treatments with donated gametes reported by the centre and donor registration forms had also not been submitted to the register for 11 donors used in treatment. Discussions with centre staff suggest that data submission problems have arisen because of the transfer of treatment information to the electronic system used by centres within the CARE Fertility Group. The PR provided evidence of collaboration with CARE Fertility Group to facilitate the correction of these data submission issues (see recommendation 2).

The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to them. On this inspection we reviewed the centre's audit and found that it had been

performed according to the method specified by the HFEA and that appropriate actions had been taken in response to the audits findings.

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 at 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, 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. The centre is unlikely to meet the current multiple birth rate target (SLC T2). An audit of the multiple births minimisation strategy will be repeated in December 2014 to assess the strategy’s effectiveness.	The report of the multiple births minimisation strategy audit planned for December 2014 should be provided to the inspector by 31 January 2015. The report should include appropriate corrective action to address any poor performance identified. The inspector should be informed regarding the implementation of these corrective actions.	This will be provided to inspector by 31st Jan 2015 as requested	14 October 2014: The inspector is reassured that the centre are addressing this issue and will continue to do so. This issue will be monitored by the inspector going forward to ensure completion of the planned audit, the implementation of any corrective actions and the control of the multiple pregnancy and birth rates at the centre. The PR has committed to complete further actions to address this issue.
2. The centre has received five risk tool emails in the last year about the use of unregistered	The PR should ensure all treatment information is accurately reported to the HFEA	For action plan please in section below "Additional information from the Person	16 September 2014: The PR has initiated actions to address the problem with the

donors and three about non-reporting of the outcomes of treatment with donated gametes. On 13 August 2014, HFEA register staff reported that donors were not specified for 18 treatments with donated gametes reported by the centre and donor registration forms had also not been submitted to the register for 11 donors used in treatment (General Direction 0005)	register within the timeframes specified in General Direction 0005. An action plan to achieve this should be reported to the HFEA by the time the PR responds to this report. The actions required should be implemented by the 9 December 2014 and should be reported to the HFEA when completed. Within 6 months, the centre should audit the submission of treatments involving donor gametes to ensure that corrective actions have been effective. A summary report of the audit should be provided to the HFEA.	Responsible". We will endeavor to achieve this by 9th Dec but can not guarantee this date because (as can be seen from the enclosed plan) some of the issues may involve HFEA IT systems and these interactions will be between IT professionals of CARE and HFEA over which I, as the PR of a clinic, have no control. This will however be given the highest priority	patient information management system. These actions need to be progressed. 14 October 2014: The inspector considers that the PR has provided an appropriate action plan, which needs to be implemented to address this non-compliance. The PR has committed to implement the plan. The PR should advise the inspector by 9 December 2014 of the completion of these actions. The success of these actions should be assessed by audit and a summary report provided to the inspector within 6 months thereafter. Completion of these actions will be reviewed by the Compliance team through the on-going monitoring system.

‘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. There is a door to the rear of the centre's patient records store which is not locked even though it opens to an area accessible to unaccompanied patients. The inspection team therefore considered that access to confidential identifying information is not restricted to people authorised by the Person Responsible (HF&E Act 1990 (as amended), Section 33(1)). It is noted however that no breach of confidentiality has been identified.	The PR should ensure that access to the records store and other areas in the centre where confidential identifying information can be seen is restricted to authorised persons. This recommendation should be implemented by the time the PR responds to this report and the PR should advise the HFEA of the actions taken.	A digital locking mechanism has been ordered for this door and will be fitted as soon as available	14 October 2014: The inspector considers that appropriate actions are being taken to improve the security of the records store. The PR should advise the HFEA when these actions have been completed.
4. There are no signs on consultation room doors to indicate when the rooms are occupied (SLC T17).	The PR should consider the need for signs on consultation room doors or should ensure that practices at the centre prevent patient privacy being compromised during consultations. The PR should advise the HFEA	As discussed during inspection consultations take place in all 3 consulting rooms continously from 9am to 5.30pm Monday to Friday. The default situation is therefore that the consulting rooms are occupied and any sign affixed to the outside will	14 October 2014: This issue was discussed with the PR at the centre on 16 September 2014. The PR described and provided evidence of appropriate working practices and administrative arrangements which prevent staff entering rooms in which

	of the actions taken by 9 December 2014.	be permanently showing occupied. No staff member will enter a consulting room without knocking (or telephoning) first. We agree that patient privacy is the first priority but do not agree that the suggested solution will in any way enhance that. However we do think that it would be an improvement to patient privacy if the glass panel in the consulting room door is covered with a frosted screen and we will organise this (hopefully by 9th Dec but screen will have to be sourced to match existing décor)	patient consultations are occurring. The inspector considered these measures will be effective in preventing the disturbance of consultations. The PR cannot remember any of his consultations being disturbed nor has the centre had any complaints from patients on this matter. The PR has agreed to monitor for such complaints and will take corrective actions if necessary. Given these facts, the inspector considers that no further action need be taken on this matter.

Additional information from the Person Responsible*
Action plan to resolve EDI reporting issues. Please see below details from email from Head of Care IT to address identified problems “To resolve all of the above we need a small team to work through the various issues and provide training where required. The plan as I see it is a first step for XXXXX and myself to go through every error (there are 268 errors relating to around 100 forms) and split them between errors which are for IT, the clinic or the HFEA to resolve. I can then spend time with XXXXX and very likely XXXXX to go through this process whilst XXXXX deals with the IT related ones to show them how to identify the problem and who should resolve it. The process is actually fairly straightforward. Are the forms correct? If yes, then contact the HFEA to ensure a) they have received them b) that they do not need to “reprocess them” (a common problem they have when one form arrives before the patient/donor registration form) If no, then is the data correct on CIS? If no, correct the data on CIS and create a correction (this may be automatic depending on the location of the data being corrected). If the correction does not make the form look correct, or the data on CIS is already correct then contact IT to advise/resolve. As an action plan I propose the following : 1. IT put aside a day in the next week to assess each and every error and decide the appropriate action for it 2. Errors which can be resolved by the clinic will be sent to you with the issue which needs resolving (data entry, form submission etc) for you to decide the appropriate resource to resolve. 3. I will make a trip to London to spend time with XXXXX and whoever else requires the training to ensure they are fully averse with the mechanisms in CIS to correction, delete and check form submissions with the list in 1 as examples. 4. IT will work on the errors which are system related, and send the list to the HFEA of the ones they need to resolve. 5. I will assess each error to ensure any code changes or controls which need to be added to stop re-occurrence are applied or scheduled for completion. 6. Additional information and training will be completed along with guidance notes on surrogacy cycles and how to enter them. Given the number of errors, the time to train staff and make operational and code changes I think we need to set ourselves a sensible timeframe for this. This will depend on both IT time and clinic time (for training as well as correcting and checking), but it needs to be one we stick to and achieve.

If you want to talk to the team and consider what's required with their workloads and let me know a) if you are happy with the planned method and b) what sort of time frame you were thinking about, and I'll see what resource we can provide to make it happen.
Thanks
XXXXX"

*This response has been redacted by the lead inspector to remove identifying information.