Executive Licensing Panel - minutes

Centre 0199 (CARE London)

Interim Inspection Report

Thursday, 8 November 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Research Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Hannah Carpenter	Policy Officer

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that CARE London is located in central London and has held a treatment and storage licence with the HFEA since 2002, to which embryo testing was added in 2008. The centre provides a full range of fertility services.

1.2. The panel noted that the centre was acquired by the CARE Fertility Group Limited in October 2013, changing its name from CRM London to CARE London.

1.3. The panel noted that, in the 12 months to 31 July 2018, the centre provided 1,510 cycles of treatment (excluding partner intrauterine insemination). In relation to activity level this is a large sized centre.

1.4. The panel noted that in 2017 the centre reported 156 cycles of partner insemination with 11 clinical pregnancies. This represents a clinical pregnancy rate of 7%, which is comparable to the national average.

1.5. The panel noted that from 1 May 2017 to 30 April 2018 HFEA held register data showed that the centre's success rates for IVF and ICSI are in line with national averages, with the exception of clinical pregnancy rates following FET in patients aged less than 38 years, which are above average, at a statistically significant level.

1.6. The panel noted that HFEA held register data for the year ending 30 April 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.7. The panel noted that the inspection took place on 18th September 2018.

The panel noted that at the time of the inspection, two 'other' areas of non-compliance were identified concerning the centre's Quality Management System (QMS) and premises and facilities. Since the inspection visit, the PR had provided evidence that actions had been taken to implement the recommendations made in the report, and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

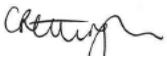
2.1. The panel noted the PR's engagement in addressing the non-compliances identified at the interim inspection and congratulated the centre on the positive patient feedback, received on the HFEA website, through the Choose a Fertility Clinic facility

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

13 November 2018

Interim Licensing Report

Centre name: **CARE London**
Centre number: **0199**
Date licence issued: **01/03/2017**
Licence expiry date: **28/02/2021**
Additional conditions applied to this licence: **None**
Date of inspection: **18/09/2018**
Inspectors: **Lesley Brown (Lead), Kathryn Mangold, Steve Pugh (Department of Health and Social Care - observer).**
Date of Executive Licensing Panel: **06/11/18**

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. The focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that this report makes recommendations for improvement in relation to no critical, no major and two 'other' area(s) of non compliance or poor practice.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

'Other' areas of practice that require improvement:

- The PR should ensure all audits are performed within documented timescales, and ensure audit reports are fully completed.
- The PR should ensure that gas cylinders are secured in accordance with compressed gas safe storage guidance, with correct emergency contact details displayed on signage.

Information about the centre

CARE London is located in central London and has held a Treatment and Storage licence with the HFEA since 2002, to which embryo testing was added in 2008.

The centre provides a full range of fertility services including embryo testing.

The centre was acquired by the CARE Fertility Group Limited in October 2013, changing its name from CRM London to CARE London.

The centre was last inspected in September 2016 for a renewal inspection.

The centre provided 1510 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2018. In relation to activity levels this is a large centre.

This current licence has been varied to reflect the following changes:
16 June 2017 - Change of PR

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are 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 2017 to 30 April 2018 show the centre's success rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following FET in patients aged less than 38 years are above average at a statistically significant level.

For the year 2017, the centre reported 156 cycles of partner insemination with 11 clinical pregnancies. This represents a clinical pregnancy rate of 7%, which is comparable to the national average

Multiple births[2]

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

HFEA held register data for the year ending 30 April 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing

[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%.

with staff and reviewed the centre's own witnessing and mismatch audit. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times and staff in the laboratory were able to carry out their activities without distraction.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing and mismatch, consent to storage and legal parenthood.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements because:

- The centre's own infection control policy requires hand hygiene audits to be completed annually. The most recent audit, available to for review, was conducted in 2016 (SLC T36).
- The centre's own legal parenthood audit, provided to the inspectors for review contained several non compliances related to the offer of counselling. The audit report did not document further investigations or corrective actions. Immediately following the inspection, the PR provided assurance that the non compliances had been raised as internal incidents, using an electronic incident management system. Each non compliance had been fully investigated, evidence of offer of counselling discovered and the incidents closed. The PR had then failed to update the audit report (SLC T36). See recommendation 1.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is

important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding EU TE coding
- awareness of recent HFEA Clinic Alerts regarding: gas cylinders, aluminium dewars and catheters.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and, with the exception of the infection control audit (discussed under QMS), found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: Media, media supplements, flush solution, vitrification kits, sperm prep kits and plasticware (culture dishes, tubes, catheters, pipettes used to handle gametes and embryos). We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 27 patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. Two patients left written comments, confirming that they had paid what they expected to.
Several patients provided individual comments to the HFEA complimenting the professional, friendly and empathetic care received at the clinic.
During the inspection the inspectors spoke to two patients who also provided positive feedback on their experiences.
On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- has staff that treats patients with empathy and understanding.

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

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements, with the exception of the safe storage of gas.

During the inspection, eight large CO_2 gas canisters were observed standing unsecured in the gas store. The emergency contact name and mobile telephone number, displayed on the outside of the gas store, belong to the previous PR (DH Health Technical Memorandum

02-01: Medical gas pipeline systems; Operational management (2006), p 55 para 8.77. SLC T17). See recommendation 2.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to no critical, no major and four 'other' area(s) of non compliance.

The previous PR subsequently provided information and evidence that some of the recommendations were fully implemented within the required timescales.

The following recommendations have now been implemented but, the previous PR sought an extension to the timescales:

- The PR should ensure that wall mounted sinks with taps for 'hands-free' use are available in all procedural areas.

On-going monitoring of centre success rates

Since the last renewal inspection in September 2016

- the centre has not received any performance related risk tool alerts.
- the centre has received two risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed

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 information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA. There are currently no significant data submission issues at this clinic apart from missing and late data. This conclusion is based on a review of the clinic's register submissions conducted on 13 September 2018.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in September 2018, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Ten sets of

records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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 made.

Critical areas 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 non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's 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 Person Responsible to carry out his/her legal duties;
- which can comprise 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. **QMS** • The centres own infection control policy directs hand hygiene audits to be completed annually. The most recent audit available for review, was conducted in 2016. • The Legal Parenthood audit report did not document further investigations or corrective actions. SLC T36	The PR should conduct a hand hygiene audit and submit the audit report to the centre's inspector for review when responding to this report. The PR should also consider if annual audits in this area are of sufficient frequency to effectively monitor infection control. The PR should review all audit reports generated in the last audit cycle, to ensure that audit reports have been fully completed to document the corrective actions taken and the date all non compliances were resolved. A copy of this review should be provided to the centres inspector by 18 December 2018.	The PR has conducted a hand hygiene audit, this was completed on 11 October 2018. The results of this audit have been shared with the centre's inspector. The CARE group will review the frequency of hand hygiene audits at the next group infection prevention and control (IPC) meeting. The CARE IPC advisor will be consulted on this point and will provide expert opinon relating to the frequency of hand hygiene audits to monitor infection control. All audit reports generated in the last audit cycle will be reviewed and a report provided to the inspector by 18	The centre’s inspector acknowledges receipt of the hand hygiene audit, and the PR’s commitment to review the frequency of audit with the CARE IPC advisor. The PR has committed to providing the requested audit review by 18 December 2018. The centre’s inspector acknowledges the LH’s commitment to share learning across the CARE group. Further action required.

	The LH should consider if learning from this recommendation is relevant to other licenced centres within the CARE group.	December 2018. The report will document the completion of audit reports and the implementation of corrective action and the date non compliances were resolved. The LH will share this area for improvement with the clinical quality & governance team who will cascade this for shared learning within the CARE group.	
2. **Premises and Facilities** • Gas canisters were standing unsecured in the gas store. • The emergency contact name and mobile telephone number, displayed on the outside of the gas store belong to the previous PR. SLC T17 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006). P 55 Para 8.77	The PR should ensure that gas cylinders are secured in accordance with compressed gas safe storage guidance. The PR should update the emergency contact details displayed on the outside of the gas store. The PR should provide confirmation of the action taken when responding to this report. The LH should consider if learning from this recommendation is relevant to	Gas cylinders are now secured in accordance with compressed gas safe storage guidance as of 04 October 2014. BOC approved cylinder wall mounts were subsequently installed to ensure secure storage. Evidence of this has been provided to the centre's inspector. Emergency contact details were updated to that of the PR on 04 October 2018. The LH will share this area for improvement with the clinical	The centre's inspector acknowledges photographic evidence provided by the PR, showing that gas cylinders are secured to wall mounts, and the PR's confirmation that emergency contact details have been updated. The centre's inspector acknowledges the LH's commitment to share learning across the CARE group. No further action required.

	other licenced centres within the CARE group.	quality & governance team who will cascade this for shared learning within the CARE group.	

Additional information from the Person Responsible