Executive Licensing Panel - minutes

Centre 0199 (CARE London) Renewal Inspection Report

Friday, 2 December 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Jessica Watkin Anna Rajakumar	Director of Strategy & Corporate Affairs Policy Manager Scientific Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that CARE London is located in central London. The centre provides a full range of fertility services including embryo testing. In relation to activity levels this is a large centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 2002.

1.4. The panel noted that in the 12 months to 31 August 2016, the centre provided 1482 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period June 2015 to May 2016 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2015, the centre reported 102 cycles of partner insemination with 13 pregnancies. This represents a clinical pregnancy rate of 13 per cent.

1.7. Between June 2015 and May 2016 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target or this period.

1.8. The panel noted that at the time of the renewal inspection on 27 and 28 September 2016, one major and four other areas of non-compliance were identified.

1.9. The panel noted that the Person Responsible (PR) is encouraged to continue to use the Quality Management System to best effect to monitor and improve the success rates so as to improve the quality of the service offered to patients.

1.10. The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel noted that the centre had submitted an application form for treatment and storage. However, the PR had confirmed that he wishes the application to be considered for the renewal of the centre's treatment (including embryo testing) and storage licence. The panel was satisfied with the application form and the PR's confirmation of the required licensed activities.

2.3. The panel was satisfied that the application contained the supporting information required by General Directions 0008 and the appropriate fee had been submitted.

2.4. The panel was satisfied that the premises to be licensed are suitable for the conduct of the licensed activities.

2.5. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

16 December 2016

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 27 and 28 September 2016

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Lesley Brown, Grace Lyndon, David Gibbon.

Executive Licensing Panel: 2 December 2016

Centre name	CARE London
Centre number	0199
Licence number	L/0199/8/g
Centre address	Park Lorne, 111 Park Road, London, NW8 7JL, United Kingdom
Person Responsible	Mr Efstathios Theodorou
Licence Holder	CARE Fertility Group Ltd
Date licence issued	1 March 2013
Licence expiry date	28 February 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

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 2014 for an interim inspection.

The centre provided 1482 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2016. In relation to activity levels this is a large centre.

This current licence has been varied to reflect the following changes:
Change of centre name to CRM CARE London (28 November 2014)
Change of Person Responsible (PR) to Mrs Rebecca Ventris (27 March 2015)
Change of Licence Holder (LH) to Mr Kenneth Dowell (26 June 2015)
Change of centre name to 'CARE London' (12 February 2016)
Change of PR to Mr Efstathios Theodorou (12 February 2016)
Change of LH to CARE Fertility Group Limited (11 April 2016)

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period June 2015 - May 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported 102 cycles of partner insemination with 13 pregnancies. This represents a clinical pregnancy rate of 13 per cent.

Multiple births[2]

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

Between June 2015 – May 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[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%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major and four 'other' areas of non-compliance which have resulted in the following recommendations:

Major areas of non compliance:

- The PR should ensure all medical devices are CE marked.

'Other' areas that require improvement:

- The PR should ensure that wall mounted sinks with taps for 'hands-free' use are available in all procedural areas.
- The PR should ensure there is a suitable system for non controlled drugs management.
- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure that all licensed treatment activity is reported to the Authority accurately and within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have one major area of concern and four 'other' areas of practice that require improvement.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rate are likely to meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

The inspection team notes that the centre has used a 'Renewal of HFEA Treatment and Storage Licence' application form. The PR has confirmed that he wishes this form to be considered as an application for renewal of the centre's Treatment (including embryo testing) and Storage Licence and that the centre provides embryo testing services to patients, and wishes to do so in future.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details about their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic

siblings) from the HFEA or the clinic where they received treatment. Therefore it is important that centres use donated gametes or embryos from identifiable donors.

The centre's procedures are broadly compliant with HFEA requirements, for reasons described under '4: Information management: Obligations and reporting requirements', which ensures the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed

from them, are compliant with HFEA requirements to be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly 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.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and

conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity, with the exception of culture media with added dextran serum supplement, are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities/Infection control (Guidance note 25)
The centre has two treatment rooms used for phlebotomy. One room contained a small removable sink for hand washing purposes, the second room did not contain hand washing facilities (SLC T17). See recommendation 2.

Medicines management (Guidance Note 25)
The stock control records for non-controlled drugs could not be reconciled, i.e. the numbers in the records did not tally. In addition, discrepancies in the stock control records were not always investigated (SLC T2). See recommendation 3.

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked: Global Media with dextran serum supplement. During the inspection the centre provided assurances that

there is a commitment across the CARE Fertility Group to become fully compliant with CE marking requirements. A CE marked medium has been introduced for most patients but the non-CE marked medium is currently used for an alternative culture method applied during the treatment of a small subset of patients. An alternative CE marked medium is to be adopted for this purpose, once the necessary process validation has been completed (SLC T30). See recommendation 1.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information and every opportunity to discuss the implications of their treatment, and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further eight patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly positive, with six 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 patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better
Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and

- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
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 its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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 those findings. The centre submitted the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

At the inspection in 2014, the inspection team reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The centre responded to this communication by conducting an audit of records of donor sperm recipients from January 2014 until October 2015. The audit identified one near miss and the PR provided reassurances to the satisfaction of the Executive.

In March 2016 the CARE Clinical Governance Lead, prompted by legal parenthood consent anomalies at another centre within the Care Fertility Group, reviewed the October 2015 audit. The review of the audit and patient records identified legal parenthood consent anomalies in one case. The centre provided the couple with information about seeking a legal declaration of parentage and offered appropriate advice and support. The case has been resolved to the couple's satisfaction. The centre has since revised its procedure for obtaining legal parenthood consents. Since this incident the centre has conducted several audits which span periods between 6 April 2009 and August 2016; no additional cases with legal parenthood consenting anomalies have been identified.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed 10 sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was in place before treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases a patient's identifying information, to researchers, with their

consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research
Discrepancies were found between six of 31 completed patient/partner/donor disclosure consents on file and the related consent data submitted for inclusion on the register. All discrepancies were instances where the patient/partner/donor had consented to research but the data submitted to the HFEA indicated that they had not. Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure (CH(10)05 and General Direction 0005). See recommendation 4.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better
Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better
Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are broadly compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32)
Two per cent (3/123) of the IVF cases reviewed at inspection had not been reported to the HFEA (General Direction 0005).

A number of data quality issues were identified which have been fed back to the centre.

The centre did not submit an annual return for partner insemination treatments in 2015 within the required timeframe (General Direction 0005).

See recommendation 5.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to two areas of major non-compliance and two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

Since the interim inspection in September 2014, the centre has received five HFEA risk tool alerts relating to pregnancy rate per cycle of IVF in patients aged 38 years or over, as well as five multiple pregnancy rate related risk tool alerts. The PR responded appropriately to these risk tool alerts and has committed to continue to review the centre's multiple birth minimisation strategy.

Areas of practice requiring action

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, General Direction 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, or a significant shortcoming from the statutory requirements. 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 identified			

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
1. The following medical devices used by the centre are not CE marked: Global Media with dextran serum supplement (SLC T30).	It is recognised that the CARE Fertility Group is implementing a managed change programme to introduce an alternative media across all CARE Fertility Group centres. In consideration of this, the PR should, when responding to this report, provide the HFEA with a timetable for change, including all identified milestones with dates for achievement. The timetable should ensure full compliance is achieved by 28 December 2016.	I can confirm that the CARE Fertility Group will be discussing data to support a change to the new CE marked culture medium for use in the time-lapse imaging cases on 22nd November. It is anticipated that this review will support a move to the Vitrolife culture medium, GTL (CE marked) and away from the current culture medium, Global (non-CE marked). We will aim to start the implementation of this change by 30 November and ensure compliance is achieved by 28 December 2016.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. 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	Executive Review
2. The centre has two treatment rooms used for phlebotomy. One room contained a small, removable sink for hand washing purposes, the second did not contain hand washing facilities (SLC T17). Hand wash basins must be available in clinical areas for infection control purposes and should be 'hands-free' as well as wall mounted, sealed to a waterproof splash back and large enough to contain most splashes (Health Building Note 00-09: Infection control in the built environment document 2013).	The PR should ensure that suitable hand washing facilities are available in all procedural areas (SLC T17). Confirmation that this recommendation has been implemented should be provided to the HFEA by 28 December 2016.	During our inspection our Nurse Manager discussed those issues with one of our Inspectors (Grace Lyndon), and we have a quote and plan in place to install hands free, wall mounted hand wash basins in our recovery area. This will be installed as part of renovation works which will include a sluice area in our December shutdown. The works will be completed by 1st January 2017. In addition to the implementation of wall mounted hand wash basins in our clinical recovery area, we also have a quote and plan in place to install smaller hands free, wall mounted hand basins in each of our phlebotomy areas as part of the Christmas shutdown and renovation works. All basins	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation within a suitable timeframe. Further action required.

		are compliant with infection control requirements and will ensure that hand washing facilities are available in all procedure rooms.	
3. The stock control records for non-controlled drugs could not be reconciled. In addition, discrepancies in the stock control records were not always investigated (SLC T2 and The Code Professional standards of practice and behaviour for nurses and midwives, section 10.2 and 18.4, 2015).	The centre should review their non-controlled drugs stock systems. A copy of this review and summary of identified corrective actions should be provided to the HFEA by 28 December 2016. An audit should then be performed by 28 March 2017 to evaluate the effectiveness of corrective actions. A copy of this audit report should be submitted to the HFEA.	Following previous audits and our inspection we have performed a preliminary review of batch control and medication stock level. Our preliminary immediate actions include following on from the inspection are as follows: 1. The Drug dispensing template has been amended 2. Current stock levels of all medication stored at CARE London are being signifcantly decreased and patients will be provided prescriptions for external pharmacies or approved home care delivery suppliers. The following will also be implemented with assistance from the IT department: 1. An existing electronic Drug dispensing and Stock Control system will be implemented to ensure that all	The Executive acknowledges the PR's response and the immediate corrective actions taken. The PR has committed to provide the requested audit. Further action required.

		stock levels, dispensing and medication are accounted for. 2. All nursing staff will receive thorough training on medication stock control with the electronic system before implementation. A full medicines management audit will take place in March 2017 to ensure compliance and that all discrepancies (if any) are investigated and documented.	
4. Six discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. Thus the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure (CH(10)05 and General Direction 0005)	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time the inspection report is considered by a licensing committee and the inspector informed of the	The six discrepancies identified during the audit of patient/partner disclosure consents have been identified and corrected. It was noted that the disclosure consent on the patients file indicated Yes for research but the data submitted to the HFEA indicated No. This therefore excluded the patient/partner from non-contact and contact research. CARE London is going to implement a secondary	The Executive acknowledges the PR's response and actions taken to correct identified discrepancies. The PR has committed to provide the requested audit within six months. Further action required.

	results of the review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the HFEA.	consent check process (of the actual consent against the data that are sent to HFEA) to ensure that the consents to disclosure are accurately inputted and submitted to the HFEA by EDI. This is exepected to be implemented by 1st of December following appropriate training of the staff. CARE London will be auditing the disclosure consent information supplied to the HFEA after six months. The findings from this audit will be supplied to the HFEA.	
5. Two percent (3/123) of the IVF cases reviewed had not been reported to the HFEA. The centre have also not submitted within the required timeframe, an annual return for partner insemination treatments performed in 2015. There were also some issues with the accuracy of data submitted to the Authority which have been fed back directly to the centre.	The PR should ensure that all licensed treatment activity is accurately reported to the Authority within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting and inaccurate submission. This recommendation should be implemented by the time the inspection report is considered by a licensing committee and	A review has been conducted of the 3 IVF cases which the HFEA reported as not being submitted within the required timeframe. 2 of the cases had been reported to the HFEA at the time of audit (treatment forms T019903520901 and T019903631801). However, these were not matched by the HFEA due to date anomalies between the report provided (which used ET/Cancellation date) and the	The Executive acknowledges the PR's response and actions taken to address non-reporting and inaccurate submission of data. The PR has committed to provide the requested audit within six months. Further action required.

(General Direction 0005, SLC T41).	the inspector informed of the results of the review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the Authority.	date which the HFEA used (treatment date). Corrective Action: CARE London have checked the cycles and updated the cancellation dates. Preventative Action: CARE London will ensure there are stricter controls to date data entry for cancellations. The final case was registered on the database (I019903516201) however this cycle was in fact cancelled before treatment started. A deletion form for the ITT has been completed and sent to the HFEA. CARE London will be ensuring stricter control around the communication of data from the CARE database with the HFEA registry. The database is continually being updated to ensure data submitted is as accurate as possible. CARE London will work with the HFEA registry to audit monthly samples of data to ensure that	

		all treatments are being accurately recorded with the HFEA. The PR will ensure that EDI between CARE London and the HFEA will be audited with the help of the HFEA registry team within six months and the findings from this audit will be supplied back to the HFEA. CARE London has now submitted the annual return for partner insemination treatments performed in 2015. It was noted by the team at CARE London that there had been no correspondence from the HFEA that this data was outstanding.	

Reponses from the Person Responsible to this inspection report
Closing, I wish to thank the inspection team for their professionalism and their constructive feedback and their support to our team to continue to deliver a quality service.