Executive Licensing Panel - minutes

Centre 0208 (CARE Tunbridge Wells)

Interim Inspection Report

Tuesday, 7 May 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Dina Halai Dan Howard	Director of Strategy and Corporate Affairs Scientific Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Jennifer Rogerson Amanda Evans	Licensing Manager Research Manager Research Manager

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:

- 9th 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 Tunbridge Wells is a private IVF clinic based in Kent and is part of the CARE Fertility group. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2004 and provides a full range of fertility services.

1.2. The panel noted that following the renewal inspection in 2017, the executive recommended the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four. The recommendation reflected concerns about the seriousness of non-compliance found on inspection. A three year licence was granted by the Executive Licensing Panel (ELP) on 6 July 2018, with a request that a targeted interim inspection be performed by 31 July 2019, to assess the implementation of the recommendations within the report, along with the effectiveness, or otherwise, resulting from the change of Person Responsible (PR).

1.3. The panel noted that, in the 12 months to 31 January 2019, the centre had provided 772 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that HFEA register data for the year ending December 2018 show the centre's success rates are in line with the national averages.

1.5. The panel noted that, in 2018, the centre reported 9 cycles of partner insemination with 2 pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.6. The panel noted that HFEA register data for the year ending December 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. 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 targeted interim inspection took place on 12 March 2019.

1.8. The panel noted that at the time of inspection there were two 'other' areas of non-compliance concerning medicines management and patient information/the centre's website. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendations made for both non-compliances identified in the report, and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.9. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

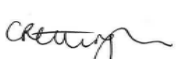
2.1. The panel particularly noted the progress made at the centre since the 2017 renewal report.

2.2. The panel was satisfied the centre was fit to have its treatment (including embryo testing) 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

14 May 2019

Interim Licensing Report

Centre name: CARE Tunbridge Wells
Centre number: 0208
Date licence issued: 1 May 2018
Licence expiry date: 30 April 2021
Additional conditions applied to this licence: None
Date of inspection: 12 March 2019
Inspectors: Lesley Brown (lead), Nicola Lawrence and Janet Kirkland (HFEA observer)
Date of Executive Licensing Panel: 7 May 2019

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 (SLCs).

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 current foci for an interim inspection are:

- **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 two 'other' areas 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 medicine management practices are compliant with regulatory requirements.
- The PR should ensure that accurate information is provided on the centre's website.

Information about the centre

CARE Tunbridge Wells is a private IVF clinic based in Kent and is part of the CARE Fertility group. The centre has held a treatment (including embryo testing) and storage licence, with the HFEA since 2004 and provides a full range of fertility services.

The centre provided 772 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2019. In relation to activity levels this is a medium sized centre.

Following the renewal inspection in 2017, the executive recommended the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four. The recommendation reflected concerns about the seriousness of non-compliance found on inspection. A three year licence was granted by ELP on 6 July 2018, with a request that a targeted interim inspection be performed by 31 July 2019, to assess the implementation of the recommendations within the report, along with the effectiveness, or otherwise, resulting from the change of Person Responsible (PR). This is the report of that targeted interim inspection.

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]

HFEA held register data for the year ending December 2018 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2018 the centre reported nine cycles of partner insemination with two clinical pregnancies. This represents a clinical pregnancy rate which is in line with 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 December 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. 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 review the centre's

[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%.

own audit of witnessing. This 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 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. The inspection team notes that there is one case in which the centre considers that samples should not remain in storage but are doing so because the patient has mounted a legal challenge to keep them. The clinic has also sought legal advice, and there is ongoing dialogue between the HFEA and the centre about the matter which will be followed up separately to this report.

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; 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: medicines management; infection control; legal parenthood; witnessing; consent to storage.

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

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:

- implications of treatment and consent
- screening

- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the use of CE marked medical devices
- HFEA Clinic Focus articles regarding: screening requirements and Zika guidance
- HFEA Alerts regarding: genetic screening services and gas cylinders

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 broadly compliant with guidance for the following reason;

- The centre keeps a stock of returned drugs to use for demonstration purposes. These were stored in an unlocked trolley within an unlocked room that could be accessed by patients. Three of these unopened drug boxes were not labelled to indicate that they were for use for demonstration purposes only. See recommendation 1.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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 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, flush solution, vitrification kits, sperm preparation kits, culture dishes, tubes and pipettes. 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. Only 17 patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. This suggests that the clinic does not direct patients to the HFEA feedback facility. This feature is

important to allow all prospective patients in the UK to compare centre ratings. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. The centre's own recent patient feedback achieves a significantly higher response rate, with an average of 61% of patients responding in a 13 month period. The results of the centre's own feedback show a high patient satisfaction rate.

No patients were available to speak to inspectors during this visit.

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 broadly compliant with HFEA requirements for the following reason:

- During a pre-inspection review of the centre's website the following sentence was noted 'Recommended as the region's top clinic for IVF patients aged under 38 by the HFEA (Human Fertilisation and Embryology Authority)'. The HFEA does not provide recommendations. See recommendation 2.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to two critical, three major and one 'other' area of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection, in November 2017, the centre has not received any performance related risk tool alerts.

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. This conclusion is based on a review of the clinic's register submissions conducted on 27 February 2019.

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.

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 sent the report of the audit to the HFEA within the required timeframe. The audit showed that 15 couples exhibited legal parenthood consent anomalies. After investigation, evidence was available for effective legal parenthood consent in eleven cases, but in four cases consent anomalies remained to be resolved. At the renewal inspection in 2017, the centre's audit from 2014 was reviewed and found to have been performed according to the method specified by the HFEA, however the centre had not taken any further action to resolve the consent anomalies in the four cases identified, and the cases had not been reported to the HFEA as incidents in line with HFEA guidance.

Since the renewal inspection, the centre has fully engaged with the HFEA and committed to address the four cases in which consent to legal parenthood is not robust. During a re-audit of records, requested by the HFEA as part of post inspection monitoring actions, one further case with an anomaly in legal parenthood consent was identified by the centre. Of the five cases identified; two couples were granted a declaration of legal parenthood through the courts and a third couple has recently indicated they may also wish to pursue a declaration of parenthood through the courts. One couple has had no further contact with the centre since December 2017. The PR is assured that this couple are well informed of the issues and are aware of how to follow up if they wish to take any action. In the fifth case, the PR has been unable to contact the affected couple, and his telephone calls, emails and recorded letters remain unanswered.

The inspection team considers that the PR has fully engaged with the HFEA and is committed to act in accordance with HFEA guidance in support of couples affected by anomalies in consent to legal parenthood. Progress with these actions will continue to be followed up by the centre's inspector.

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. Six 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		Noted.	

‘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		Noted.	

‘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. **Medicines Management** The centre keeps a stock of returned drugs to use for demonstration purposes. These were stored in an unlocked trolley within an unlocked room that could be accessed by patients. Three of these unopened drug boxes were not labelled to indicate that they were for use for demonstration purposes only. The controlled drugs (Royal Pharmaceutical Society “Professional Guidelines on the Administration of Medicines in Healthcare Settings” 2019.	The PR should ensure medicine management practices are compliant with regulatory requirements. The PR should follow best practice for medicines management both to protect patients and ensure that medicines are stored in the correct way. The PR should inform the centre’s inspector of the actions taken to address these non-compliances when responding to this report.	I have attached a copy of our Medicines Management policy as evidence that we are compliant with the relevant regulatory requirements. We have performed an RCA regarding the non-compliance, which is also attached. As a result of this a number of recommendations were made and all have been completed. A spot inspection by the PR and Nurse Manager on 10/4/19 confirmed compliance and this has been added to the regular KPI checks.	The Executive acknowledges the PR’s response and receipt of the medicines management policy and copy of the root cause analysis report. The PR should audit the effectiveness of the corrective actions, to ensure on going compliance has embedded into practice. A copy of the audit findings should be submitted to the centre’s inspector by 10 July 2019. Further action required.

2. **Patient Information/Website** During a pre-inspection review of the centre's website the following sentence was noted 'Recommended as the region's top clinic for IVF patients aged under 38 by the HFEA (Human Fertilisation and Embryology Authority)'. The HFEA does not provide recommendations. SLC T2 and CoP 4.8 (b)	The Clinic Director arranged the removal of the misleading text during the inspection visit. No further action is required.	Noted, apologies.	The Executive acknowledges the PR's response. No further action required.

Additional information from the Person Responsible