Executive Licensing Panel - minutes

Centre 0208 (CARE Tunbridge Wells) Interim Inspection Report

Friday, 29 January 2016

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

Panel members	Juliet Tizzard (Chair) Joanne Anton Anjeli Kara	Director of Strategy & Corporate Affairs Policy Manager Regulatory 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 noted that CARE Tunbridge Wells, centre 0208, has held a licence with the HFEA since 2004. The centre provides a full range of fertility services

1.2. The panel noted that the centre's licence is due to expire on 30 April 2018.

1.3. The panel noted that the inspection took place on 3 November 2015.

1.4. The panel noted that in the 12 months to 31 August 2015 the centre provided 604 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending 31 May 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014, the centre reported 25 cycles of partner insemination with four pregnancies. This was consistent with the national average.

1.7. Between 1 June 2014 and 31 May 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 25%. This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% maximum multiple live birth rate target. This was discussed during the inspection and the Person Responsible (PR) provided good evidence of appropriate review of the clinic's multiple births minimisation strategy, corrective actions in response to that review and monthly monitoring of the multiple pregnancy rate to assess the effectiveness of those actions and the strategy in general.

1.8. The panel noted that at the time of the interim inspection on 3 November 2015, two major and five other areas of non-compliance were identified. The panel noted that since the inspection the PR has implemented some of the recommendations and has committed to implementing the outstanding recommendations.

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

2. Decision

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

2.2. The panel urged the PR to continue to address the centre's multiple pregnancy rate. The panel expects to see significant progress by the time the centre's licence is due for renewal.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

9 February 2016

Interim Licensing Report

Centre name: CARE Tunbridge Wells
Centre number: 0208
Date licence issued: 01/05/2014
Licence expiry date: 30/04/2018
Additional conditions applied to this licence: None
Date of inspection: 03/11/2015
Inspectors: Grace Lyndon (Lead), Andy Leonard
Date of Executive Licensing Panel: 29 January 2016

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 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

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

The ELP is asked to note that at the time of the inspection, recommendations for improvement are made in relation to two major and five 'other' areas of non compliance or poor practice.

Since the inspection, the PR has implemented the following recommendations:

'Other' areas of practice that require improvement:

- The PR should review the centre's website content and take actions to ensure that it is compliant with HFEA requirements.
- The PR should ensure that medicines are managed in a manner compliant with current medicines management regulations and best practice guidance.
- The PR should ensure the centre continues to strive to reduce the multiple pregnancy rate but the inspection team notes the actions already taken by the centre before the inspection and makes no specific recommendations.

The PR has committed to implement the following recommendations within the required timescales:

Major areas of non compliance:

- The PR should ensure the quality management system (QMS) is effective, such that learning from guidance issued by the HFEA and other sources is embedded in the centre's practices.
- The PR should ensure that only CE marked medical devices are used.

'Other' areas of practice that require improvement:

- The PR should review post procedure care to ensure the patients are recovered safely.
- The PR should conduct a review of infection control practice to ensure that the clinical environment meets infection prevention and control requirements.

Information about the centre

CARE Tunbridge Wells has held a HFEA treatment and storage licence since 2004.

The centre provides a full range of fertility services. The centre provided 604 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2015. In relation to activity levels this is a medium-sized centre.

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 year ending 31 May 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 25 cycles of partner insemination with four pregnancies; this success rate is consistent with the national average.

Multiple births[2]

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

Between 1 June 2014 and 31 May 2015, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%. This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% multiple live birth rate target. This was discussed on inspection and the PR provided good evidence of appropriate review of the multiple births minimisation strategy, of taking corrective actions in response to that review, and of monthly monitoring of the multiple pregnancy rate to assess the effectiveness of those actions and the strategy in general (see recommendation 3).

Witnessing

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

[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%.

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; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

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 follow prescribed 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 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, consent to storage, infection control and the management of controlled drugs. The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements: the centre's own audits of infection control and medicines management practices failed to identify non compliance with regulatory requirements (see recommendation 1).

The inspection team 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;
- knowledge of a recently issued field safety notice concerning a PVP preparation used in sperm processing for ICSI, sent by the HFEA to all PRs;
- 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;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- patient and donor screening tests.

The centre's QMS is partially effective in implementing learning from guidance provided by the HFEA (see recommendation 1) however:

- the centre is using a non-CE marked medical device (a culture media supplement) (see recommendation 2). The laboratory manager acknowledged the non compliance which has been observed on HFEA inspections of other clinics in the CARE group. She advised that the CARE group of clinics were together implementing corrective actions to address this matter, at timescales already agreed with the HFEA Executive;
- the centre's website content is not compliant with Chair's Letter (11)02, the success rate data on the website being over three years old (see recommendation 6).

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. Two boxes of drugs stored in the controlled drugs cabinet had passed their expiry dates; nursing staff were not aware of this. Amendments within the controlled drugs book were not made in a manner compliant with requirements (see recommendation 7).

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 broadly compliant with guidance. A review of records of procedure room cleaning indicated that although daily cleaning is generally performed, the room had not been cleaned after use on the day before inspection. The floor in the first floor scanning room meets directly with the skirting board creating sharp angles which are difficult to clean (see recommendation 5). It is acknowledged that the centre has reported no incidence of infection.

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 and vitrification solutions. The centre is partially compliant with HFEA requirements to use CE marked medical devices wherever possible. The following medical devices are not CE marked: the supplement added to embryo culture media (see recommendation 2).

Pre-operative assessment and the surgical pathway

The centre has policies and procedures in place that are broadly 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 procedure. Patients recover post procedure in the procedure room until they are considered safe to be transferred to the recovery area, where they finish recovering in single rooms with windowless doors. It was not clear that these doors remain open at all times during recovery and the patients are not monitored. The inspection team was concerned because if patients develop a medical problem and are in distress, the nursing staff may not be able to observe this if the door has been closed. This could delay assistance being provided (see recommendation 4).

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. 41patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was mainly positive giving compliments about the care 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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

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 fully compliant with HFEA requirements except where noted elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, recommendations for improvement were made in relation to seven 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations have been fully implemented.

On-going monitoring of centre success rates

In the last year the centre has received one risk tool alert related to multiple pregnancy rates. The PR responded to this alert in an appropriate manner and during discussions on inspection, provided a commitment to continue monitoring the concerns raised and to take further corrective actions if necessary.

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, although the Register team is working with the centre to address some issues related to the use of unregistered donors, which do not require escalation into a non-compliance at this stage.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order 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.

On inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that appropriate actions had been taken in response to the audit findings.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

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

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

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. The centre's QMS does not ensure that learning from guidance issued by the HFEA is consistently embedded in the centre's practices. In addition, the centre’s audits of compliance with infection control and medicines management requirements, did not detect the non compliances in these areas of practice (SLC T32).	The PR should ensure the QMS is effective, such that audits are robust and learning from guidance is embedded in the centre’s practices. The PR should take immediate action to investigate the failings within the QMS identified in this report. This should include a review of potential barriers to the implementation of learning and to effective audit. A report of the investigation and proposed corrective actions, with timescales for implementation, should be	All audit non-conformances and observations are raised through the Q-Pulse QMS to the PR, Quality Lead, monthly senior management meeting and quarterly Quality and Governance meetings. This process has been ratified and approved by the ISO 9001-2008 inspection process. Learning and actions from HFEA Clinic Focus are cascaded through the centre by the PR and discussed where appropriate at the time of publication. Further actions include having Focus review as an agenda item at all centre meetings of senior management and clinical staff. The PR will maintain responsibility for agreeing and monitoring actions plans arising from Clinic Focus. The centre’s audit of controlled drugs	The inspection team acknowledge the PR’s response but note that the QMS, irrespective of its ISO9001-2008 certification and the features identified by the PR, failed to detect the non compliances identified. A report of the investigation of any failings in the QMS which caused this, including the proposed corrective actions, was not submitted with the report to the HFEA. The PR should complete and document this investigation and submit it to the HFEA by 3 February 2016.

	submitted to the HFEA by the time the PR responds to this report. Actions should be implemented by 3 February 2016 and should be advised to the HFEA.	(medicines management) carried out in October 2015 (April – September data) was 100% compliant. The out of date medication, which was not a controlled drug, was not in the audit. The Infection Prevention and Control audit was carried out by an external auditor, generated an action plan which was monitored as part of the centre's governance procedure, has been documented on the QMS system and closed when the final action was carried out within the agreed timescales.	**Further action is required**
2) The following medical devices used by the centre are not CE marked: the supplement used in embryo culture media (SLC T30).	The PR should ensure that CE marked media supplements are used when required. This action should be implemented by 30 September 2016, the date agreed between the HFEA Executive and the CARE group by which this matter should be resolved.	Agreed. Ongoing with the CARE group.	The inspector acknowledges the PR's commitment to work with the CARE group on this matter to ensure the recommendation is implemented by 30 September 2016. **Further action is required.**

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
3) The centre is unlikely to meet the current multiple birth rate target (SLC T2).	The PR should ensure the centre continues to strive to reduce the multiple pregnancy rate. The inspection team notes the actions already taken by the centre, and consider that the centre is already addressing this non compliance. The inspection team therefore makes no recommendations at this time but will continue to monitor the centre's multiple pregnancy rate through the HFEA risk tool, to assess the effectiveness of the actions taken. Should these actions prove ineffective, recommendations for improvement will be made through the on-going monitoring system.	I would thank the inspectors for their guidance on MBMS. This is an area of concern for us and we are monitoring the situation regularly. We too, are aiming to control our multiple pregnancy rate without compromising the overall clinical pregnancy rate.	The inspection team will continue to monitor the centre’s multiple pregnancy rate through the HFEA risk tool.
4) Patients recover in single rooms with windowless	The PR should complete a risk assessment of the post	Procedures are carried out under conscious sedation. This means	The inspection team acknowledges the PR’s

doors. It was not clear that these doors remain open at all times during recovery and patients are not monitored at this time. If patients develop a medical problem and are in distress, the nursing staff may not be able to observe this if the doors are closed. This could delay assistance being provided (SLC T2; CoP 25.28).	procedure recovery area, including the type and frequency of nursing observation in place, to ensure patients are recovered safely. A copy of the risk assessment should be submitted to the inspector by 3 February 2016.	that patients are conscious at all times even during the procedure. Patients do not leave the procedure room until they have recovered and all observations are stable. Nurses carry out regular checks in the post operative room and there is an emergency call button next to the patient in all rooms. The nurse is always present in the immediate vicinity of the post operative rooms following the procedure. A risk assessment of the post operative rooms will be carried out and forwarded to you	response and his commitment to risk assess the situation. The PR should submit the risk assessment, including any proposed control measures, to the HFEA by 3 February 2016. **Further action is required.**
5) Two concerns were raised about infection control practices at the centre: • A review of records of procedure room cleaning indicated that the room had not been cleaned on the day before the inspection (SLC T26); • The floor in the first floor scanning room meets directly with the skirting board creating sharp angles which are difficult to clean.	The PR should conduct a review of infection control practice to ensure that the clinical environment meets infection prevention and control requirements. A report of this review with details of the actions taken should be provided to the HFEA by 3 February 2016.	The procedure room was cleaned on the evening before the inspection by the cleaning staff. This is a daily clean and part of the contract with the cleaning company. There was no non-conformance. In addition there is an additional weekly clean of drawers and cabinets carried out by the nursing staff. This was delayed due to clinical activity and carried out later than scheduled. This delay did not affect patient care. This practice will continue and will be audited over a three month period and non conformances will be shared.	The inspection team acknowledges the PR's response. We look forward to being provided with the infection control review and the cleaning audit, and being notified when the issues with the upstairs scanning room have been rectified. **Further action is required.**

Health Building Note 00-09: Infection control in the built environment (page 20). SLC T17.		Repair of the floor in the first floor scan room has now been actioned in December 2015 as planned and resolved.	
6) The centre's website content is not compliant with Chair's Letter 11(02).	The PR should review the website content and take actions to ensure that it is compliant with HFEA requirements. A report of this review, with proposed corrective actions, should be provided to the HFEA by the time this responds to this report. Corrective actions should be implemented by 3 February 2016 and a summary of the changes should be provided to the centre's inspector.	Website now compliant. Data is less than three years old. a link directing patients to the HFEA website (national success rates and advice on success rates) is to be found immediately below the 2014-15 figures	The inspection team is satisfied with the actions taken. No further action is required.
7) Two boxes of medicines stored in the controlled drugs cabinet had passed their expiry dates; nursing staff were not aware of this. Amendments within the controlled drugs book were	The PR should ensure that medicines are managed in a manner compliant with current medicines management regulations and best practice guidance.	These out of date 'non controlled drugs did not form part of the audit referred to above, They have been removed and destroyed. they were not for current use but had not been disposed of having reached expiry date.	The inspector acknowledges the changes already made at the centre. The PR should submit the report of the medicines management audit by 3 May

also not made in a manner compliant with requirements (SLC T2).	The PR should advise the centre's inspector of the actions taken to implement this recommendation by the time this report is considered 3 February 2016. Within three months of the implementation of corrective actions, the centre should conduct an audit of their medicines management practices, to ensure their compliance with current medicines management regulations and best practice guidance. A report of this audit should be provided to the HFEA by 3 May 2016.	A new checklist has been introduced to ensure nurses carry out regular checks of expiry dates of all medicines. At inspection and audit all medication available for current use are in date, On 1.1.16, A new Theatre Controlled Drugs Record Book was introduced enabling patient medical record numbers to be recorded together with the amount of drugs supplied, administered and disposed of	2016. **No further action is required beyond the audit.**

Additional information from the Person Responsible