Executive Licensing Panel - minutes

Centre 0061 (CARE Sheffield) – Interim Inspection Report

Friday, 18 September 2015

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

Panel members	Paula Robinson (Chair) Hannah Verdin Ian Peacock	Head of Business Planning Head of Regulatory Policy Analyst Programmer
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
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 Sheffield, centre 0061, has held a licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 31 December 2017.

1.3. The panel noted that the inspection took place on 21 July 2015.

1.4. The panel noted that in the 12 months to 30 April 2015, the centre provided 635 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 January 2015 showed the centre's success rates, in terms of clinical pregnancy, were in line with national averages.

1.6. The panel noted that HFEA-held register data for the year ending 31 January 2015 showed the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 15%. This means that the centre's multiple live birth rate is not likely to be statistically different to the 10% maximum multiple live birth rate target.

1.7. The panel noted that at the time of the interim inspection on 21 July 2015, two major and one other area of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing all of the recommendations within the prescribed timescales.

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

2. Decision

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

3. Chair's signature

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

Signature

Name

Paula Robinson

Date

29 September 2015

Interim Licensing Report

Centre name: CARE Sheffield
Centre number: 0061
Date licence issued: 01 January 2014
Licence expiry date: 31 December 2017
Additional conditions applied to this licence: None
Date of inspection: 21 July 2015
Inspectors: Lesley Brown (Lead), Victoria Lamb, Janet Kirkland MacHattie.
Date of Executive Licensing Panel: 18 September 2015

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 Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to two major and one 'other' area of non compliance or poor practice.

Since the inspection the PR has given a commitment to fully implementing all the following recommendations within the prescribed timescales.

'Major' areas of non compliance**:**

- The PR should ensure that there is consent in place for all embryos that are in storage.
- The PR should ensure that CE marked medical devices are used wherever possible.

'Other' areas of practice that require improvement:

- The procedures used to submit licensed treatment data to the HFEA should be reviewed to identify and address the reasons that have resulted in both delayed and poor quality donor related data submissions.

Information about the centre

CARE Sheffield has held a licence with the HFEA since 16 July 1992.

The centre provides a full range of fertility services.

The centre provided 635 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2015. In relation to activity levels this is a medium 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 January 2015 show the centre's success, in terms of clinical pregnancy rates are in line with national averages.

Multiple births[2]

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

HFEA held register data for the year ending 31 January 2015 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%: This means that the centre's multiple live birth rate is not likely to be statistically different to the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. An egg collection was observed in the course of the inspection. This procedure was witnessed using both a manual and an electronic witnessing system, at appropriate stages of the process, in accordance 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, the audit of all stored gametes and embryos, consent records and the 'bring-forward' system were discussed with staff. These reviews indicate that 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%.

processes for storing gametes and embryos in line with the consent of the gamete providers are only partially effective.

The inspection team were advised of one set of embryos held in storage without effective written consent. The centre uses an IT based 'bring forward' system to identify stored gametes and embryos where the consent to store is due to expire in the next four months. In this instance this set of embryos was not identified by the 'bring forward' system. The centre also carries out regular reviews of the cryobilling system, which highlights expired consents. During a review of the cryobilling system in July 2015, the centre discovered one set of embryos stored without effective written consent. The centre has taken steps to obtain effective consent from the patient involved. An investigation by the centre has highlighted that the IT based 'bring forward' system may not be effective when embryos have been created for surrogacy treatment. At the time of inspection this issue was still under investigation to confirm the root cause, before implementation of corrective actions (see recommendation 1).

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 are following 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 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 consent to storage audit and the storage of gametes and embryos audit.

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:

- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- the follow-up actions taken following one of the centre's own recent incidents (reported to the HFEA)
- the centre's screening procedures for patient and partner treatment

- guidance issued in 2012 related to the use of non CE marked medical devices.

The centre is broadly effective in implementing learning from their audits and from guidance from the HFEA. However, they had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical device (see below and recommendation 2).

Medicines management

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

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

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 medical devices in use at the centre was reviewed in the course of the inspection. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices. The following medical devices are not currently CE marked: Microm Ferticult medium, insemination tips, 5ml tubes and flush medium used during egg collection (see recommendation 2). Although the Ferticult medium is not currently CE marked, the PR has provided assurance that the centre are working with the manufacturer to provide data that will support CE marking, which is expected in the near future.

Patient experience

During the inspection, we spoke to a couple about their experiences at the centre. Additionally, four patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with two of the individuals providing written feedback giving compliments about the care received.

Although it is acknowledged that this is based on feedback from only a very small cohort of patients, 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 not fully compliant with the following HFEA requirement:

- Egg collection tubes are not labelled with the full patient name and further identifier or a uniquely identifying donor code. The inspection team notes that this policy has been risk assessed; the area where egg collection takes place is checked after the procedure to ensure no tubes remain in the area both prior and subsequent to the procedure and patient notes are signed to confirm this step has taken place. The inspection team are assured that the clinic has assessed the risks of this practice and has implemented measures to mitigate the risks. As a result no recommendation has been made with respect to this non-compliance.

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 eight major areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in 2013 the centre has received two risk tool alerts related to multiple pregnancy rates, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is broadly complaint with requirements to submit information to the HFEA. The centre currently has a number of donor–related data submission issues that the HFEA's information team is working with the centre to address (see recommendation 3).

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 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. On the day of the inspection the inspection team were informed that the centre does not have written effective consent for the storage of one set of cryopreserved embryos (Schedule 3, 8(2) HF&E Act). Although the compliance assessment framework would normally classify a non compliance of this nature as a ‘critical’ area of non compliance, due to the single example that was identified through the centres own robust procedures this non compliance has been re-	The PR should ensure that written effective consent is obtained for the continued storage of these embryos. The PR should confirm that this action has been implemented when responding to the report. The PR should ensure the IT system is corrected to include all stored gametes and embryos in the ‘bring forward’ system. Confirmation of corrective action should be provided to the centre’s inspector by 21 October 2015.	Consent received Signed by patient 30.7.15 for continued storage for 10years. Investigation and corrective actions - report conclusion will be submitted by 21.10.15	The Executive acknowledges the PR’s response and her commitment to fully implementing the recommendation. Further action required.

classified as 'major'.	The PR should immediately conduct an audit to identify further patients who may be affected before such a time that the IT system can be corrected. A summary of the audit should be provided when responding to this report.	Audit completed 1 patient identified Pt128746 expiry of consent on 8.9.15. Patient due to return for treatment will contact to update consent before expiry.	
2. The following medical devices used by the centre are not currently CE marked: insemination tips, 5ml tubes,Microm Ferticult medium and the flush medium used during egg collections (SLC T30). The PR failed to take action with respect to guidance provided in 2013 on expectations with respect to the use of CE marked medical devices.	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. The PR should provide the centre's inspector with a list of all medical devices including disposable plastic ware, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate the proposed timescale for sourcing alternatives by 21 October 2015. The PR should review whether	We are fully aware of the products that do not have CE marking and are currently working towards finding alternatives or working with the manufacturer to achieve CE status. A full list will be provided with the action plan and timeline for replacement on products that are available by 21st October I will provide evidence of the progress made since 2013 on the sourcing and replacement of products in line with the HFEA guidelines for CE marking and evidence of our continual monitoring of the situation by 21st October 2015	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action required, in particular to review the barriers to implementation of learning from guidance issued by the HFEA..

	there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources. The PR should provide feedback on this review to the centre's inspector by 21 October 2015.		

‘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 currently has a number of donor–related data submission issues (General Direction 0005 and SLC T41)	The PR should review the procedures used to submit treatment data to the HFEA to identify and address the reasons for the delayed and poor quality of donor related data submissions. A summary report of this review including corrective actions and the timescale for their implementation should be provided to the centre’s inspector by 21 October 2015. Six months after implementing any corrective actions the PR should audit procedures used to submit licensed treatment data to the HFEA to confirm that the actions have been effective. A summary report of the audit should be provided the centre’s inspector by 21 July 2016.	This will be completed in line with these recommendations by 21st October 2015 An audit will be completed 6 months following any corrective actions.	The Executive acknowledges the PR’s response and her commitment to fully implementing the recommendation. Further action required.

Additional information from the Person Responsible