Executive Licensing Panel - minutes

Centre 0061 (CARE Sheffield)

Interim Inspection Report

Tuesday, 17 September 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Danielle Vincent Niamh Marren	Director of Strategy and Corporate Affairs Communications Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	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:

- 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 Sheffield has held a licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 30 April 2019, the centre had provided 710 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the year ending 31 March 2019, show the centre's success rates are in line with the national averages.

1.4. The panel noted that, in 2018, the centre reported 16 cycles of partner insemination, with 2 pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, between 1 April 2018 and 31 March 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 2 July 2019.

1.7. The panel noted that at the time of inspection there was one major area of non-compliance concerning premises and facilities. Since the inspection visit, the Person Responsible (PR) has given a commitment to fully implement the recommendation, regarding premises and facilities, within the required timescales.

1.8. 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 centre's improvement, since the renewal inspection was conducted in June 2017, alongside the low multiple birth rate.

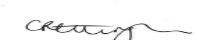
2.2. The panel also noted that, in the last 12 months, only one patient had provided feedback on their experiences at the centre, through the 'Choose a Fertility Clinic' facility, available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

2.3. 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

23 September 2019

Interim Licensing Report

Centre name: CARE Sheffield
Centre number: 0061
Date licence issued: 1 January 2018
Licence expiry date: 31 December 2021
Additional conditions applied to this licence: None
Date of inspection: 2 July 2019
Inspectors: Lesley Brown (lead), Polly Todd, Victoria Brown (HFEA observer)
Date of Executive Licensing Panel: 17 September 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. In particular we note the centre's low multiple pregnancy rate of 6%.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major area of non compliance or poor practice.

The PR has given a commitment to fully implementing the following recommendation:

Major area of non compliance:

- The PR should ensure storage of clinical waste and medical gases is in line with relevant Health and Safety regulatory requirements.

Information about the centre

CARE Sheffield has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 710 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2019. In relation to activity levels this is a medium centre.

This centre is part of the CARE group of centres.

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 31 March 2019 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 16 cycles of partner insemination with two clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

Between 1 April 2018 and 31 March 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be lower than the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review the centre's most recent audits of practice. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

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

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[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%.

On inspection, the 'bring-forward' system was discussed with staff and reports of audits of all stored gametes and embryos, and storage records were reviewed. These activities indicated 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.

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:

- leadership
- patient support
- information provision
- implications of treatment and consent
- counselling
- extension of storage consent
- screening
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- data submission to the HFEA
- the use of CE marked medical devices
- the content of the centre's website
- the centre's audit of legal parenthood

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

Medicines management

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

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

Prescription of intralipid 'off label'

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

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

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

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

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

Infection Control

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

During the inspection, we reviewed infection control practices and found them to be partially compliant with guidance because:

- The centre's clinical waste, including sharps, is stored in large bins that are unlocked, within a compound that is locked. The inspection team did not consider that the compound was sufficiently secure to house unlocked bins, and that lockable clinical waste bins should be used to ensure clinical waste is stored safely (see recommendation 1).

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: culture media; media supplements; vitrification kits; sperm preparation kits; culture dishes; tubes and pipettes used to handle gametes and embryos. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only one patient has provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. Although the PR described promoting the HFEA feedback facility when seeking their own patient feedback, the PR is asked to consider ways to increase patient engagement with this facility. This will be followed up at the next inspection.

The centre's own most recent patient survey responses was reviewed. The centre surveys patients both post-consultation and post-treatment, with results reviewed on a monthly basis. From a response rate of between 30% and 50% per month, approximately 80% of patients rate the clinic as good or excellent.

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

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is partially compliant with the following HFEA requirements:

- There was no safety signage outside or inside the compound in which medical gases were stored (see recommendation 1).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in June 2017, recommendations for improvement were made in relation to three major and four 'other' areas 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 June 2017, the centre has received one risk tool alert related to performance of pregnancy rate per cycle of ICSI in patients less than 38, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed.

Provision of information to the HFEA

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

The clinic is compliant with requirements to submit information to the HFEA. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 17 June 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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the renewal inspection in June 2017, legal parenthood consenting processes were found to be robust.

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

Action required and timescale for action	Area of practice and reference	PR Response	Executive review
None		N/A	

‘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	Executive review
1. **Premises and Facilities** • The inspection team did not consider that the compound was sufficiently secure to house unlocked bins, and that lockable clinical waste bins should be used to ensure clinical waste is stored safely • There was no safety signage on or inside the compound in which medical gases were stored. SLC T2. Environment and sustainability Health Technical Memorandum	The PR should ensure storage of clinical waste and medical gases is in line with relevant Health and Safety regulatory requirements. The PR should inform the centre’s inspector of the actions taken to comply with this recommendation when responding to the report. It is expected that suitable clinical waste arrangements and required signage on the medical gas store are in place by 2 October 2019, and the PR	Guidance requires correct labelling for Hazardous substances. Signage for the medical gases store will be ordered and fixed in place identifying the risks. We expect to be compliant for this by the deadline of 2nd October. The clinical waste bin that does not lock will be replaced by the company that supplies the bins on their next visit to the clinic. The bins will be checked as part of the infection control	The executive acknowledges the PR’s response, and her commitment to fully implementing the recommendation. The PR should provide confirmation, to the centre’s inspector, that the signage has been fitted by 2 October 2019. To ensure proposed actions to address the clinical waste bin are successful, the PR should provide a copy of the infection control audit by end October 2019.

07-01: Safe management of healthcare waste (2013). Section 5. DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006). Section 8.	should provide confirmation of this to the centre's inspector. The LH should consider if learning from this recommendation is relevant to other licenced centres within the CARE group.	audit to ensure the bins are locked. At the next C+G meeting staff will be advised to report any unlocked clinical bin on datix so this can be monitored and the bin replaced if reoccurs. All actions to be completed prior to 2nd October deadline	Further action 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.

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
none.		N/A	

Additional information from the Person Responsible