Executive Licensing Panel - minutes

Centre 0307 (Complete Fertility Southampton) Interim Inspection Report

Friday, 30 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Anna Coundley Anna Quinn	Director of Strategy & Corporate Affairs Information Access and Policy Manager Scientific 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:

- 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 Complete Fertility Centre Southampton is located within the Princess Anne Hospital. The centre has held a licence with the HFEA since 2008 and provides a full range of fertility services.

1.2. The panel noted that the inspection took place on 23 May 2017.

1.3. The panel noted that in the 12 months to 28 February 2017, the centre provided 677 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.4. The panel noted that HFEA held register data showed that for the period December 2015 to November 2016, the centre's success rates for IVF and ICSI, are in line with national averages.

1.5. The panel noted that between December 2015 and November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that at the time of the inspection on 23 May 2017, two major and one 'other' area of non-compliance or poor practice were identified relating to medicines management, equipment and materials and record keeping. Since the inspection, the Person Responsible (PR) has given a commitment to fully implementing the recommendations.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's licence, particularly noting the positive comments made by patients in relation to treatment experiences.

2. Decision

2.1. The panel noted the non-compliances and the PR's engagement in addressing them.

2.2. The panel 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

Juliet Tizzard

Date

11 July 2017

Interim Licensing Report

Centre name: Complete Fertility Centre Southampton
Centre number: 0307
Date licence issued: 1 November 2015
Licence expiry date: 31 October 2019
Additional conditions applied to this licence: None
Date of inspection: 23 May 2017
Inspectors: Polly Todd (lead), Sara Parlett
Date of Executive Licensing Panel: 30 June 2017

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. In particular, we note the positive comments made by patients in relation to their experiences at the centre.

The ELP is asked to note that there are recommendations for improvement in relation to two major and one 'other' areas of non-compliance or poor practice.

Since the inspection visit the PR has given commitment to fully implement the following recommendations:

'Major' areas of non-compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.
- The PR should ensure that appropriately CE marked medical devices are in use where available.

'Other' areas of practice that require improvement:

- The PR should ensure that proper records are maintained.

Information about the centre

Complete Fertility Centre Southampton is located within the Princess Anne Hospital and has held a licence with the HFEA since 2008.

The centre provides a full range of fertility services.

The centre provided 677 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. 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 period December 2015 to November 2016 show the centre's success rates are in line with national averages.

In 2016, the centre reported 13 cycles of partner insemination with two pregnancies, performance which is in line with the national average.

Multiple births[2]

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

Between December 2015 and November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure 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: thawing of embryos; preparation for embryo transfer and placing embryos in storage dewars. All the procedures observed were witnessed using an electronic witnessing system 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.

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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, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed, 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 centre has had a significant reduction in staffing levels recently due to sickness and absence which has required an adjustment of their activity levels accordingly. The PR is committed to the regular assessment of staffing levels to ensure they are appropriate for the activities undertaken. The inspection team therefore, considered that staffing levels in the clinic appeared suitable for the activities being carried out; 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 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: witnessing, legal parenthood, and consent to treatment and 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:

- the centre's audits of consent to storage;
- the use of CE marked medical devices;
- 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.

The centre has been effective in ensuring compliance with guidance issued by the HFEA except for the use of CE marked medical devices described later in this report.

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 partially compliant with guidance because:

- a review of the controlled drugs register showed that the time of administration of the drug had not been recorded in several entries;
- a recent controlled drugs audit conducted by the pharmacy department, had noted that the controlled drugs cupboard keys are kept in a locked cupboard when not required, rather than being held by the nurse in charge when on duty. Other designated staff members may obtain the keys when access to controlled drugs is required, however the nurse in charge, if working in another area may not be informed of their whereabouts. Statutory regulations and best practice guidance do not specifically state that this practice is prohibited, however, they do require that the registrant in charge knows the whereabouts of the controlled drugs cupboard keys at all times. Whilst it is acknowledged that the registrant in charge can delegate holding of the controlled drug cupboard keys to another registered nurse or midwife, this does not abdicate responsibility for always knowing their whereabouts. The centre is awaiting further guidance from pharmacy to see whether this was an acceptable practice. 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. In addition, the centre has achieved a Trust accreditation for their infection control practices.

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'.

In a random sample of medical devices reviewed in the course of the inspection, two medical devices (specimen containers used to collect semen samples and 14ml tubes used for egg collection) were not appropriately CE marked. See recommendation 2.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. However, the centre's most recent patient survey responses were reviewed and feedback was extremely positive with all eight of the individuals providing written feedback giving compliments about the care they had 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 broadly compliant with HFEA requirements because:

- in a review of five patient records, one record did not contain the patient's consent for the surgical procedure undertaken and two records did not contain a World Health Organisation (WHO) surgical safety checklist (or equivalent). See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in 2015 recommendations for improvement were made in relation to one critical, one major and five 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

Since the last licence renewal inspection in May 2015, 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.

There have been several data submission errors from the centre which have not been addressed as efficiently as would be expected. These errors are not considered serious enough to warrant a recommendation at this time, but the PR is asked to liaise with the HFEA registry department to resolve the discrepancies.

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 three couples were affected by legal parenthood consent anomalies. All three couples have subsequently had their legal parenthood status established by the courts.

In May 2016, one case involving Complete Fertility was heard in the Family Division of the High Court by Sir James Munby regarding the legal parenthood status of one couple in which the centre was heavily criticised by the court. Following the judgement, the HFEA held a meeting with the PR, Licence Holder (LH) and key members of staff on 27 July 2016 to ascertain the details of the case and review the centre's actions since the incident and the judgement. As a result of the meeting, the centre was required to conduct a full root cause analysis of the case, to consider the criticisms made by Sir James Munby and audit the corrective actions taken. This was completed to the satisfaction of the Executive. In addition, a full re-audit of the centre's legal parenthood processes is also required to be performed and a report of the findings submitted to the Executive by 27 November 2017.

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

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

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		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.

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 During the inspection, the following were noted: • a review of the controlled drugs register showed that the time of administration of the drug had not been recorded in several entries. • a recent controlled drugs audit conducted by the pharmacy department, had noted that the controlled drugs cupboard keys are kept in a locked cupboard when not	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should conduct a review of the centre’s medicines management practices and procedures. This should include staff training requirements and corrective actions taken to ensure compliance. A summary report of the review should be provided to the centre’s inspector by 23 August 2017.	This review will be provided by the date requested. Going forward a sheet will be kept next to the key cupboard that whoever holding the key will sign. In this manner the nurse in charge knows who holds the key at any point. Only nurses have access to this key cupboard.	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

required, rather than being held by the nurse in charge when on duty. Statutory regulations and best practice guidance do not specifically state that this practice is prohibited, however, they do require that the registrant in charge knows the whereabouts of the controlled drugs cupboard keys at all times. DH 2007 'Safer Management of Controlled Drugs: a guide to good practice in secondary care (England). NICE Guidance [NG46] April 2016 'Controlled drugs; safe use and management'. NMC Standards for Medicines management 2010 (standards 8, 26).	Three months after the implementation of corrective actions the PR should audit practice to ensure the actions taken have been effective in achieving and maintaining compliance with regulatory requirements and best practice guidance. A summary report of this audit should be provided to the centre's inspector by 23 November 2017. The PR should ensure that there are procedures in place that ensures the nurse in charge is aware of the location of the controlled drug cupboard keys at all times when on duty. The PR should inform the centre's inspector of the actions taken when responding to this report.		
2. Equipment and materials In a random sample of medical devices reviewed in the course of the inspection, two medical devices	The PR should ensure that appropriately CE marked medical devices are in use where available.	This review will be provided by the date requested.	The Executive acknowledges the PR's response and commitment to implementing this recommendation.

(specimen containers used to collect semen samples, and 14ml tubes used for egg collection) were not appropriately CE marked. SLC T30.	We would not recommend precipitous changes that might impact on the quality of treatment. In consideration of this, the PR should provide the centre's inspector with a list of all medical devices currently in use in the clinic together with their CE mark status. Where devices are not CE marked for medical use, the PR should ensure that a plan is developed and implemented so that appropriately CE marked products are in use. The list of devices and the plan should be provided to the centre's inspector by 23 August 2017. Dependent on the number and type of devices identified by this review, the centre's inspector will liaise with the PR to agree a time line for full implementation of the requirement to use		Further action required.

	appropriately CE marked devices.		

‘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. **Record keeping** In a review of five patient records, one record did not contain the patient’s consent for the procedure undertaken and two records did not contain a WHO surgical safety checklist (or equivalent). SLC T37.	The PR should ensure that proper records are maintained. The PR should investigate why the documents identified in this report are absent in the patients’ records and implement processes that ensure patient records are complete. A summary report of this investigation together with corrective actions taken and timescales for their implementation should be provided to the centre’s inspector by 23 August 2017. Three months after the implementation of the corrective actions, the PR should conduct an audit of	A full investigation of this will be undertaken and a summary report supplied by the date requested.	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

	patient records to ensure that the corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 23 November 2017.		

Additional information from the Person Responsible
The requested actions are all appropriate and reasonable and will be supplied within the requested timescales.