Executive Licensing Panel - minutes

Centre 0159 (Royal Surrey County Hospital) Interim Inspection Report

Friday, 10 February 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Howard Ryan Jessica Watkin	Director of Strategy & Corporate Affairs Report Developer 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 Royal Surrey County Hospital is located in Guildford. The centre has held a licence with the HFEA since 1995. The centre currently holds a storage only licence providing a service to men wishing to store sperm before treatment that might cause them to become infertile.

1.2. The panel noted that the inspection took place on 29 November 2016.

1.3. The panel noted the centre stores sperm for two to three men per week. In relation to activity levels this is a small centre.

1.4. The panel noted that at the time of the interim inspection the centre had one major and three 'other' areas of non-compliance. The PR had already implemented two of the recommendations and had committed to implementing those remaining.

1.5. The panel noted that the inspectorate recommends the continuation of the centre's licence. The inspector notes the commitment of all staff to providing a quality service and regulatory compliance especially considering the limited, but important, service offered at the clinic.

2. Decision

2.1. The panel was satisfied that the centre was fit to have its 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

21 February 2017

Interim Licensing Report

Centre name: Royal Surrey County Hospital
Centre number: 0159
Date licence issued: 01 April 2015
Licence expiry date: 31 March 2019
Additional conditions applied to this licence: none
Date of inspection: 29 November 2016
Inspectors: Dr Douglas Gray
Date of Executive Licensing Panel: 10 February 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 announced 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, the inspector notes the commitment of all staff to providing a quality service and regulatory compliance especially considering the limited, but important service offered at the clinic.

The ELP is asked to note that there are recommendations for improvement in one major non compliance and three 'other' areas of practice as follows:

'Major' areas of non compliance:

- Gentlemen storing sperm should be assessed for their risk of Zika virus infection in accordance with HFEA guidance.

'Other' areas of practice that require improvement:

- The clinic's witnessing SOP and/or laboratory sheet used to record witnessing steps should be reviewed to ensure they are consistent and compliment each other.
- The PR should consider whether gentlemen storing sperm should be provided with the opportunity to consent to the use of their sperm in intrauterine insemination (IUI).
- Written information given to gentlemen should stress the importance of providing at a later date, consent to treatment with a named partner, if this consent is not provided when their sperm is first stored.

The PR has implemented two recommendations, and committed to implementing the remaining two recommendations.

Information about the centre

The Royal Surrey County Hospital is located in Guildford and has held a HFEA licence since 1995. It currently holds a storage only licence providing a service to gentlemen wishing to store sperm before treatment that might cause them to become infertile. The centre stores sperm for two to three gentlemen per week. In relation to activity levels this is a very small 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

Treatment services leading to pregnancies are not provided at this clinic.

Multiple births

Treatment services leading to pregnancies are not provided at this clinic.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of sperm and that identification errors do not occur. The inspector was able to discuss witnessing practices with staff and review witnessing in medical records. Witnessing procedures are compliant with HFEA requirements. It was however difficult in places to match the centre's SOP describing witnessing practices to the laboratory sheet used to record witnessing steps and the description of these steps provided by staff (recommendation 2).

Consent to the storage of cryopreserved material

The storage of sperm is an important service offered by fertility clinics. It enables patients 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 are stored in accordance with the consent of the gamete providers.

The inspector reviewed reports of audits of all stored gametes, the accuracy of storage and consent records and the 'bring-forward' system. Processes for storing sperm in line with the consent of the sperm provider 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 inspector considered that staffing levels in the clinic were suitable for the activities that take place.

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 audits was assessed by reviewing audits for witnessing, traceability, consent to storage, storage tank management and the quality management system. The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

The inspector 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
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles on screening for Zika virus.

Most guidance had been acted upon. However, gentlemen storing sperm are not assessed for their risk of being infected with Zika virus (recommendation 1).

Medicines management

The clinic does not offer treatment services.

Infection Control

The premises were visibly clear, and evidence of regular cleaning was seen.

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 used was discussed during the inspection and were considered compliant with HFEA requirements.

Patient experience

No feedback has been received from patients about this centre.

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

The following observations were made during the visit to the centre:

- Sperm can only be used posthumously if a gentleman has provided his consent to the use of his sperm, and the intended recipient is named on their consent form. Consent to use of sperm to create embryos (HFEA MT consent form) is only sought from gentlemen if they have a partner that they wish to name on that consent form. The HFEA MT form does not however allow sperm to be used posthumously for IUI; consent on a HFEA MGI form is required for this. Gentlemen providing consent on an MT form are not asked to consider whether they wish to also provide consent on an MGI form (recommendation 3). Written information provided to gentlemen also does not stress the importance of providing consent to treatment (on either an MT and/or MGI form) if a gentleman decides at a later date that he wishes his sperm to be available for use by a named partner (recommendation 4).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in three major areas of non compliance and one 'other' area of practice. The PR provided evidence that all recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Treatment services that result in success rates monitored by HFEA are not provided at this clinic.

Provision of information to the HFEA

The clinic are not required to provide information to HFEA.

Legal parenthood

Treatment services that might need a person to consider providing consent to legal parenthood are not provided at this clinic.

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. Screening Gentlemen are not assessed for their risk of Zika virus infection before their sperm is stored. SLC T50(d)	Gentlemen storing sperm should be assessed for their risk of Zika virus infection in accordance with HFEA guidance (http://www.hfea.gov.uk/10539.html and http://ecdc.europa.eu/en/publications/Publications/Zika-virus-safety-of-substances-of-human-origin.pdf (page 18)). It may not be necessary or appropriate to test for Zika before sperm samples are stored. However, the clinic might consider and record the gentlemen’s travel history so that the need for testing could be considered at a later date should their sperm be used in treatment services. A summary of actions taken should be provided by 29 February 2017.	PR will discuss with the nurses that when they are taking consent, they ask for a travel history over the past 6 months. The nurses will check the level of Zika virus risk (on gov.uk website) and note this down on the sperm banking form. The laboratory will add an additional section to the transfer of gametes form so any receiving centre can see that the	The PR has taken appropriate action. The PR should ensure their next audit of screening takes into account their assessment of the risk of infection with zika virus. This will be reviewed by the inspection team at the centre’s next inspection. No further action is required.

		sample may require testing for Zika. The laboratory will not be testing for the virus itself.	

‘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
2. Witnessing It was difficult in places to match the centre’s SOP describing witnessing practices to the laboratory sheet used to record witnessing steps and the description of these steps provided by staff. SLC T33(b)	The clinic’s witnessing SOP and/or laboratory sheet used to record witnessing steps should be reviewed to ensure they are consistent and compliment each other. Any documents revised in response to this recommendation should be provided to the clinic’s inspector by 29 May 2017.	The SOP will be amended to make the steps clearer. This will then be submitted to the inspector.	We await the revised SOP.
3. Consent Gentlemen storing sperm are not given the opportunity to provide their consent to the use of their sperm in IUI. SLC T58	The PR should consider whether gentlemen should be provided with the opportunity to consent to the use of their sperm in IUI. Should the PR decide to seek consent to IUI, they should ensure that staff are competent to seek this consent, and consider whether their written information needs updating. A summary of the PR’s considerations should be	PR has discussed this with the licence holder (Dr Stephen Whitaker) who is happy for the nurses to discuss this with the patient at consent taking.	The PR has taken appropriate action. No further action required.

	provided by 29 February 2017.		
4. Information Written information given to gentlemen does not stress the importance of providing consent at a later date to treatment with a named partner, if this consent is not provided when their sperm is first stored. SLC T58	Written information should be reviewed so that this important issue is clear to gentlemen storing sperm. A copy of the revised information should be provided to the clinic's inspector by 1 March 2017.	The sperm banking form will be amended to include a section saying 'patient has been informed and understands the importance that if his circumstances change, an MT form needs to be completed' and also include space for a signature.	The PR has taken appropriate action. We request a copy of the revised information is provided to their inspector by 1 March 2017.

Additional information from the Person Responsible