Executive Licensing Panel - minutes

Centre 0151 (Gloucestershire Hospitals NHS Trust) Interim Inspection Report

Friday, 30 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard 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 the centre is part of Gloucestershire Hospitals NHS Foundation Trust, located within the Gloucestershire Royal Hospital. The centre has held a storage only licence with the HFEA since 1995.

1.2. The panel noted that the inspection took place on 3 May 2017.

1.3. The panel noted that at the time of the inspection, one major and two 'other' areas of non-compliance or poor practice were identified regarding screening of patients, staff and equipment and materials. The panel noted that since the inspection, the Person Responsible (PR) had fully implemented the recommendation regarding minimising hazards to lone working staff and had given a commitment to fully implement the remaining non-compliances within the prescribed timescales.

1.4. The panel noted that there were positive comments made by patients in relation to their experiences at the centre.

1.5. The panel noted that the inspectorate recommends the continuation of the centre's Storage only licence.

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 Storage only 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: Gloucestershire Hospitals NHS Trust
Centre number: 0151
Date licence issued: 1 November 2015
Licence expiry date: 31 October 2019
Additional conditions applied to this licence: None
Date of inspection: 3 May 2017
Inspectors: Karen Conyers (lead), Polly Todd
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 a short notice 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.

The ELP is asked to note that at the time of the inspection there were three areas of practice that required improvement; one major and two 'other' areas of non-compliance.

Since the inspection visit the PR has confirmed that the following recommendation has been fully implemented:

'Other' areas of practice that require improvement:

- The PR should ensure that processes are in place to minimise hazards to lone working staff.

The PR has given a commitment to implementing the following recommendations in the prescribed timescales:

Major areas of non-compliance:

- The PR should ensure that there are processes in place for considering when and what additional testing may be necessary prior to storage of semen samples, in line with current professional guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that the semen sample collection containers are appropriately CE marked as medical devices.

Information about the centre

The centre is part of Gloucestershire Hospitals NHS Foundation Trust within the Gloucestershire Royal Hospital, and has held a storage only licence since 1995.

The centre offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire areas. 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

The centre does not provide any treatment services therefore this is not relevant to this centre.

Multiple births

The centre does not provide any treatment services therefore this is not relevant to this centre.

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 processes with staff. These discussions indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes is an important service offered that 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 provider.

On inspection, reports of audits of all stored gametes and the 'bring-forward' system was discussed with staff. These discussions indicated that the centre's processes for storing gametes in line with the consent of the gamete 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. During discussions with staff, the inspection team was able to conclude that staffing levels were suitable for the activities that take place.

We found the centre to be broadly compliant with HFEA requirements with the following exceptions:

- The centre does not have a process for staff lone working (recommendation 2). It is acknowledged that most licensed activities are carried out during working hours and staff rarely work alone in these duties. However, the inspection team was concerned that should staff be called in out of hours to attend to a cryo-storage tank alarm there is no process to ensure the safety of the lone worker.

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, consent to storage, provision of information and counselling. 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 records, witnessing and consent to storage
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding: changes to interpretation of storage regulations, additional screening requirements

Overall, the inspection team considers that the centre has been effective in ensuring compliance with guidance issued by the HFEA. However, gentlemen storing sperm are not assessed for their risk of being infected with Ebola and/or Zika virus in accordance with professional guidance (recommendation **Error! Reference source not found.**). The inspection team acknowledges that oncology patients are unlikely to be in a positon to defer storage for fertility preservation due to their circumstances. However, if the sperm provider has been exposed to a pathogen there could be an impact in the future, should the samples be used for treatment.

Medicines management

The centre does not provide any treatment services therefore this is not relevant to this centre.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a subset of women. The centre does not provide any treatment services therefore this is not relevant to this centre.

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 the following medical devices were reviewed during the inspection: sperm cryopreservation medium, serological pipettes, cryovials and specimen containers used to collect the semen samples.

The centre was broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical device is not CE marked: specimen containers used to collect the semen samples (recommendation 3). The inspection team noted that the containers that were in use were CE marked (not as a medical device) and are sperm toxicity tested prior to use.

Patient experience

During the inspection, no patients were available to speak with the inspectors. The centre's most recent patient survey responses were reviewed. Feedback was positive about the care that they received with 13 responses from patients commenting that they were treated with dignity and respect and were given sufficient information.

Based on this feedback and observations made during 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 and
- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

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 compliant with HFEA requirements.

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, three major and three 'other' areas of non-compliances or poor practice.

The PR provided information and evidence that the recommendations had been fully implemented within the prescribed timescales, except for establishing contact with all patients with stored samples. The timescale to compete this was extended due to the need to seek legal advice on the content of the letters. The PR was in regular contact with the centre's inspector regarding progress with this action.

On-going monitoring of centre success rates

The centre does not provide any treatment services therefore this is not relevant to this centre.

Provision of information to the HFEA

The centre is not required to provide information to the HFEA register as does not provide any treatment services, therefore this is not relevant to this centre.

Legal parenthood

The centre does not provide any donor gamete treatment services therefore this is not relevant to this centre.

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	Executive review
None identified during this inspection.			

‘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	Executive review
Screening of patients 1. Gentlemen storing sperm are not assessed for their risk of being infected with Ebola and/or Zika virus in accordance with professional guidance. SLC T50d and https://portal.hfea.gov.uk/knowledge-base/news-archive/hfea-zika-and-ebola-update-april-2017/	The PR should review and risk assess the centre’s processes for considering when and what additional testing may be necessary prior to storage of semen samples, in line with current professional guidance. A copy of the findings of the review should be provided to the centre’s inspector by 3 August 2017.	Agreed.	The executive acknowledges the PR’s response and his commitment to fully implement this recommendation. The review due by 3 August 2017 is awaited. **Further action is required**.

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
Staff 2. The centre does not have a process for staff lone working. SLC T2 and CoP 25.17.	The PR should ensure processes are in place to minimise hazards to lone working staff. The PR should provide a summary of the actions to be taken when responding to this report.	Existing relevant procedures and risk assessments will be reviewed and updated so as to minimise hazards to lone working staff.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a summary of the measures in place to minimise hazards to lone working staff. Further actions in relation to this issue will be followed up by the centre’s inspector through the ongoing monitoring process. No further action is required.
Equipment and materials 3. The following medical device used by the centre is not CE marked: specimen containers used to collect the semen samples.	The PR should ensure that the semen sample collection containers are appropriately CE marked as medical devices.	Agreed and we have identified a suitable container.	The executive acknowledges the PR’s response and his commitment to fully implement this recommendation. The executive acknowledges

The inspection team noted that the containers that were in use were CE marked (but not as a medical device) and are sperm toxicity tested prior to use. SLC T30.	We would not recommend precipitous changes that might impact on the quality of treatment, however, the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre's inspector by 3 August 2017. The PR should ensure compliance with this requirement by 3 November 2017.		the actions being taken and awaits confirmation of compliance with this requirement by 3 November 2017. **Further action is required**.

Additional information from the Person Responsible
We will work to address the identified major area of non-compliance and areas of practice that require improvement within the required timescales.