Executive Licensing Panel - minutes

Centre 0080 (Androlgy Unit, Hammersmith Hospital) – Interim Inspection Report

Friday, 27 November 2015

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

Panel members	Juliet Tizzard (Chair) Joanne Anton Jessica Watkin	Director of Strategy & Corporate Affairs Policy Manager Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Trisram Dawahoo	Digital Communications Manager

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 Andrology Unit, Hammersmith Hospital, centre 0080, has held a licence with the HFEA since 1992. The centre has a storage only licence and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment.

1.2. The panel noted that the centre's licence is due to expire on 28 February 2018.

1.3. The panel noted that the inspection took place on 29 September 2015.

1.4. The panel noted that at the time of the interim inspection on 29 September 2015, one critical and one major area of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented the inspectorate's recommendations for the critical area of non-compliance and has committed to fully implementing the recommendations for the major area of non-compliance within the prescribed timescales.

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

2. Decision

2.1. The panel had regard to its decision tree and 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

7 December 2015

Interim Licensing Report

Centre name: Andrology Unit, Hammersmith Hospital
Centre number: 0080
Date licence issued: 01 March 2014
Licence expiry date: 28 February 2018
Additional conditions applied to this licence: None
Date of inspection: 29 September 2015
Inspectors: Susan Jolliffe (Lead) Vicki Lamb Polly Todd
Date of Executive Licensing Panel: 27 November 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 at the time of the inspection, there were two recommendations for improvement in relation to one critical and one major area of practice that required improvement.

The PR has implemented the following recommendation:

'Critical' areas of non compliance:

- **The PR should ensure that no gametes are kept in storage for longer than the consented period.**

The PR has given a commitment to fully implement the following recommendation in the prescribed timescale:

'Major' areas of non compliance:

- For each patient the centre must maintain a record that is clear and legible, containing the consent, including the purpose for which their gametes may be used, and any specific instructions for use and/or disposal.

Information about the centre

The Andrology Unit, Hammersmith Hospital is located in London and has held a licence with the HFEA since 1992.

The centre provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment.

A new Licence Holder (LH) Mr Johnathon Ramsay was appointed by the ELP in September 2015 following the retirement of the previous post holder.

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

This does not apply to this centre as it holds a storage only licence.

Multiple births

This theme does not apply to this centre.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: sperm preparation. The procedure was observed a number of times and was witnessed using a manual witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes 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 are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and of the accuracy of storage logs and consent records were reviewed, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes in line with the consent of the gamete providers are partially compliant because there were 10 patients that had samples in storage beyond the consented period. All of the patients with gametes in store beyond the consented storage period have appointments arranged at the centre before 21 October (see recommendation 1).

The centre had already addressed the problem which led to 10 patients having samples in storage beyond the consent date and has introduced an audit system that identifies samples one year before the expiry of storage so this situation does not occur in future. It

should be noted that the centre has made significant progress in managing a large number of samples that were outside the consented storage period at the last inspection.

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 following audits: witnessing and consent to storage. The centre had evidence of ongoing audits that were compliant, however, the HFEA;s review of consent forms in 10 sets of patient records chosen at random on inspection, showed that in two records the declaration of consent was not signed and two records had corrections in the yes/no section of the consent form making interpretation difficult. These anomalies were not detected by the centre's own audit and therefore it is concluded that the centre's procedures for auditing are therefore only broadly compliant with requirements (see recommendation 2).

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 audit of storage, witnessing and consent.
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- 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.

Medicines management

This does not apply to this centre as it holds a storage only licence and does not have or store any medicines.

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 was reviewed in the course of the inspection: serological pipettes, preparation tubes and media. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection we were unable to speak with any patients at the centre. Four patients provided feedback directly to the HFEA in the time since the last inspection, and feedback was positive. A further 21 patients had provided feedback directly to the centre with 20 of the individuals giving compliments about the care 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 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 fully compliant with HFEA requirements.

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 one critical, four major and three 'other' areas of non compliance.
The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales, with one exception.
The following recommendation was implemented by August 2014 instead of April 2014.

- The centre does not have written effective consent for the storage of all cryopreserved sperm.HF&E Act (1990, as amended) 17(1) (c) and Schedule 3(8) (1).

As noted above there is still some improvement to be made to achieve full compliance but significant progress has been achieved.

On-going monitoring of centre success rates

Since the last renewal inspection in September 2013 the centre has not received any performance related risk tool alerts.

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
1. Consent to storage The centre has sperm samples for 10 patients in storage after the expiry of the consented storage period. HF&E Act as amended Schedule 3 paragraph 8 (1).	The PR must ensure that gametes are stored only when valid consent for storage is in place. The PR needs to take appropriate action regarding these samples. The PR should provide an update on the number of samples remaining in storage	At the time of inspection 10 patient's gametes remained in storage awaiting a consultation with the clinical lead, Mr Ramsay. These 10 patients have now been seen, 4 of them continue to have a valid medical reason to store gametes, he completed a medical practitioner statement and the patients completed LGS forms. The remaining patients agreed to discard their gametes as their fertility was restored. None of these samples are now stored without valid consent.	The Executive acknowledges the PR's response and progress addressing this matter. No further action is required.

This was non-compliance at the last inspection.	beyond the consented storage period when responding to this report.		

‘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
2. **Patient records.** During an audit of patient records, the consent form was not clear and legible in two records and the consent forms were not completed in full in two records. SLC T46 and T47	The PR must ensure that for each patient the centre holds a record of consent that is clear and legible. The PR should review the procedure for taking consent and checking the forms with the patient, as well as the audit procedures used to check patient consent forms, to identify and address the reasons for the incomplete forms. A summary report of this review including corrective actions and the timescale for their implementation should be provided to the centre’s	The requirement to double check that every page has been signed has been added to the checklist used by the clinical scientist during counselling, It has also been explained to them that any changes on the forms must be initialled by the patient. The audits previously performed were with the pre April 2015 forms and no errors were found. A further audit with the new forms will be performed. A summary report and confirmation that the corrective action has resolved this non compliance will be provided to	The Executive acknowledges the PR’s response and the commitment to fully implementing the recommendation. Further action is required

	inspector by 29 December 2015. Six months after implementing any corrective actions the PR should audit consent forms to confirm that the actions have been effective. A summary report of the audit should be provided the centre's inspector by 29 March 2016.	the inspector in the time frame 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	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible