Executive Licensing Panel - minutes

Centre 0011 (London Sperm Bank) Interim Inspection Report

Friday, 15 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Anna Rajakumar	Director of Strategy & Corporate Affairs Technical Report Developer Scientific Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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 London Sperm Bank, centre 0011 has held a licence with the HFEA since April 2010. The centre recruits sperm donors and provides donated sperm to other fertility clinics. Laboratory activities are undertaken at the London Sperm Bank while sperm production and recruitment is undertaken under a third party agreement in nearby premises at the London Women's Clinic, centre 0105, another clinic in the JD Healthcare Group.

1.2. The panel noted that the centre's licence is due to expire on 31 March 2019.

1.3. The panel noted that the inspection took place on 10 May 2016.

1.4. The panel noted that at the time of this interim inspection two major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented all of the recommendations.

1.5. The panel noted how well organised, maintained and complete the paper donor records were.

1.6. The panel noted that the inspectorate recommends the continuation of the centre's storage only licence without additional conditions.

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

21 July 2016

Interim Licensing Report

Centre name: London Sperm Bank
Centre number: 0011
Date licence issued: 1 April 2015
Licence expiry date: 31 March 2019
Additional conditions applied to this licence: None
Date of inspection: 10 May 2016
Inspectors: Susan Jolliffe (Lead), Andrew Leonard
Date of Executive Licensing Panel: 15 July 2016

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 how well organised, maintained and completed the paper donor records were.

At the time of the inspection, there were recommendations for improvement in relation to two major and two 'other' area of practice that required improvement as follows:

'Major' areas of non compliance:

- The PR should ensure that CE marked medical devices are used wherever possible.
- The PR should ensure that audits of practice against documented procedures, CoP requirements and quality indicators are performed and documented.

'Other' areas of practice that require improvement:

- The PR should ensure that fire exits are clear to allow access and egress at all times.
- The PR should review the security for lone workers and access to health records in the centre.

The Executive Licensing Panel is asked to note that the PR has implemented all of the recommendations.

Information about the centre

The London Sperm Bank is located in London and has held a licence with the HFEA since April 2010.

The centre recruits sperm donors and provides donated sperm to other fertility clinics. Laboratory activities are undertaken at the London Sperm Bank while sperm production and recruitment is undertaken under a third party agreement in nearby premises at centre 0105, another clinic in the JD Healthcare Group.

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 activities were observed in the course of the inspection: sperm procurement, processing and cryopreservation. The procedures were observed using an electronic witnessing system, with manual witnessing where necessary, 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 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: donors attending to produce sperm 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.

Occasionally a member of staff will be working alone in the centre, which is housed on one of four floors in the building. There is no controlled access during the day to prevent unlicensed persons working on or visiting the three floors above the centre, from walking into the centre where lone workers and patient records are found, because the internal access door is not locked (recommendation 4). Access to the centre premises is controlled at night as doors to the cryostore and the laboratory office are locked.

The fire exit from the laboratory office to the external corridor was blocked by a stack of boxed supplies and a cleaner's trolley parked behind the fire door. The inspection team was informed that the boxed supplies had only recently been delivered, and the trolley is normally stored elsewhere. The exit was cleared before the inspection team left the building (recommendation 3).

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 (SOPs) 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 of witnessing; however these did not review the compliance of the witnessing SOP with CoP requirements and did not review all witnessing activities. There was good evidence of the review of consent to storage however the activities had not been formally documented into an audit report. Thus the centre's audit activities were considered partially compliant with requirements (recommendation 2).

The inspection team 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 content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- HFEA Clinic Focus articles regarding screening requirements and equipment failures;
- the use of CE marked medical devices.

Except for the one non compliance related to the use of a non CE marked sperm cryopreservation medium, discussed below, the centre has been generally effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

The centre 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, the inspection team 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 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 in the course of the inspection: serological pipettes, preparation tubes and cryopreservation media. The centre is partially compliant with the relevant HFEA requirements because one of the sperm cryopreservation media used is not CE marked (recommendation 1).

Patient experience
During the inspection there were no donors available to talk with and no donors had provided feedback directly to the HFEA in the time since the last inspection.

The centre captures feedback, where donors choose to comment or write to the centre. A donor questionnaire has also been used. No negative themes or trends were noted from the feedback.

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 donors in the clinic;
- provides a clean and well organised environment for donation;
- has staff who are supportive and professional;
- gives prospective and current donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to phone calls from donors.

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 2014, 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

The centre does not provide treatment therefore this does not apply.

Legal parenthood

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

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. CE marked medium The cryopreservation medium is not CE marked. SLC T30.	The PR should ensure that wherever possible only CE marked medical devices are used The PR should identify how this will be achieved in her response to this report, and should implement her proposed actions by 10 August 2016.	We have discarded the freezing medium from the day we got the confirmation form the supplier that the product is not CE marked. We will not be using this freezing medium moving forward to freeze any of our donor's semen samples.	The Executive acknowledges the PR’s response. No further action is required.
2. QMS - audits The witnessing and storage consent audits were not sufficiently robust. SLC T36.	The PR should ensure that audits of practice against the documented procedures, CoP requirements and quality indicators are performed and documented. A full audit of the witnessing process should be completed	LSB has Cryo-Element as an electronic witnessing system from Research Instruments. This system provides assurance and serves as a guarded point between processes. Moreover, crucial/key witnessing points are double witnessed on the	The Executive acknowledges the PR’s response. No further action is required.

	and the storage consent audit should be documented. The audits should be sent to the centre's inspector by 10 August 2016.	system. As each witnessing process/point is linked with the next one and without fulfilling the former, we are not allowed to move on to the next witnessing point/process, a blanket 'witnessing audit' was being performed so far. However, with a view to make it 'sufficiently robust', key witnessing areas have been broken into separate audit indicators and these audits have been performed. Please refer to audit references INTQALSB1635, INTQALSB1636, INTQALSB1637 & INTQALSB1638 completed and attached. The are now included as part of our audit schedule and will be performed regularly. Audit for storage consent has always been in place at LSB. Please refer to attachment INTQALSB1615 completed last year for the purpose. LSB's stock and slots database has a provision to log 'end of consent date.' Tentative end of	

		all donor's storage for a typical year is highlighted in red on the database at the beginning of every year & the same is noted on the calendar on Microsoft Outlook as a reminder to discard on the relevant date. Please refer to attachment INTQALSB1615 audit performed for the first half of this year for storage within the consented period.	

‘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. Premises - fire exits The fire exit from the laboratory office was blocked by recently delivered supplies and a cleaner’s trolley. This was addressed before the inspection had been completed leaving the fire exit and corridor clear. SLC T2.	No further action required.	N/A	Action resolved
4. Security Access to the laboratory and laboratory office, where donor records are stored, is not controlled during the day. There are occasions when lone workers will be in the centre and unlicensed persons will have access, leading to a risk to worker safety of breach of confidentiality.	The PR should review security at the centre regarding access to health records and dewars and the safety of lone workers. An action plan to strengthen security should be provided to the centre’s inspector by 10 August 2016.	It has been agreed with the maintenance/management to put up a digital lock on all glass doors as a security to staff and health records stored of sperm donors. A loan worker policy has been implemented at JD Healthcare (see attached).	The Executive acknowledges the PR’s response. No further action is required.

SLC T17.			

Additional information from the Person Responsible