Executive Licensing Panel - minutes

Centre 0300 (Fisher Bioservices UK) Interim Inspection Report

Friday, 6 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
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 Fisher Bioservices UK is located in Bishops Stortford, Hertfordshire and has held a storage only licence with the HFEA since August 2008. The centre offers a disaster recovery service to HFEA licensed centres, allowing centres to transfer cryopreserved gametes and embryos for continued storage in the event of an emergency. At the time of the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have ever been stored at the centre.

1.2. The panel noted that the centre's licence is due to expire on 31 July 2018.

1.3. The panel noted that the HFEA interim inspection took place on 8 March 2016.

1.4. The panel noted that the centre holds a Human Tissue Authority (HTA) licence to allow the storage of tissues and cells for human application. The centre was last inspected by the HTA in February 2016 and the inspection findings demonstrated that the centre had fully met all HTA standards with two minor observations identified. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility and is accredited to ISO standard 9001:2015. As the centre was inspected by the HTA prior to this inspection, the HTA inspection findings have been used to inform this report.

1.5. The panel noted that the HFEA inspectorate made no recommendations for improvement.

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

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

19 May 2016

Interim Licensing Report

Centre name: Fisher Bioservices UK
Centre number: 0300
Date licence issued: 1 August 2014
Licence expiry date: 31 July 2018
Additional conditions applied to this licence: none
Date of inspection: 8 March 2016
Inspectors: Louise Winstone
Date of Executive Licensing Panel: 6 May 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 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 with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The Executive Licensing Panel is asked to note that there are no recommendations for improvement. The inspector recommends the continuation of the centre's licence.

Information about the centre

Fisher BioServices UK is located in Bishops Stortford, Hertfordshire and has held a HFEA storage only licence since August 2008. The centre offers storage services to a wide portfolio of clients and a disaster recovery service to HFEA licensed centres. The latter would allow centres in an emergency to transfer cryopreserved gametes and embryos to Fisher BioServices UK for continued storage. At the time of the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have ever been stored at the centre.

The centre holds a Human Tissue Authority (HTA) licence to allow the storage of tissues and cells for human application. The centre was last inspected by the HTA in February 2016 and the inspection findings demonstrated that the centre had fully met all HTA Standards with two minor observations identified. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility and is accredited to ISO standard 9001:2015. As the centre was inspected by the HTA just prior to this inspection, the HTA inspection findings have been used to inform this report.

The centre varied their licence in February 2015 to appoint Mrs Lisa Forsyth as PR.

Details of inspection findings

ELP are asked to note that not all interim inspection themes were relevant to the inspection of this storage only facility.

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]

This inspection theme is not relevant as the centre does not offer treatment services.

Multiple births[2]

This inspection theme is not relevant as the centre does not offer treatment services.

[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%.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The proposed witnessing procedures were discussed with the PR during the inspection and were reviewed at the time of the renewal inspection. During the renewal inspection a 'walk through' of the receipt and dispatch processes which would be used if a HFEA licensed centre sent cryopreserved material to Fisher BioServices UK, was performed by centre staff and was observed by the inspection team. All steps are manually witnessed and were compliant 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.

No gametes or embryos are currently being stored at the centre, however the proposed procedures for ensuring effective consent to storage is in place were discussed with the PR during the inspection and were considered compliant with HFEA requirements at the time of the renewal inspection. The HFEA licensed centre sending cryopreserved material to Fisher BioServices UK will retain consent to storage documentation and remain responsible for the monitoring of storage consent expiry dates. The centre will ensure that stored gametes and embryos have effective consent by auditing their client's consent documentation annually or more frequently if required.

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 the inspection visit, staffing levels were discussed with the PR and she described the current level of recruitment to the centre in relation to the proposed expansion of services. The inspector considered that staffing levels in the centre appeared suitable for the proposed storage related activity.

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 findings from the recent HTA inspection report. The HTA inspection report findings as well as observations on this inspection confirm that the centre has a QMS in place that is compliant with HFEA 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 inspector was satisfied that the PR acts upon guidance issued in the Clinic Focus articles and disseminates the information to the rest of the team.

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.

This inspection theme is not relevant as the centre does not offer treatment services.

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.

This inspection theme is not relevant as the centre does not offer treatment services.

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'.

This inspection theme is not relevant as the centre only stores gametes and embryos as supplied by the HFEA licensed centre.

Patient experience
This inspection theme is not relevant as the centre does not offer treatment services.

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 May 2014, no recommendations for improvement were made.

On-going monitoring of centre success rates
This inspection theme is not relevant as the centre does not offer treatment services.

Provision of information to the HFEA
This inspection theme is not relevant as the centre does not offer treatment services.

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
None			

‘Other’ areas of practice that requires improvement

Other 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
With regards to our ISO9001 certification, we currently hold a 9001:2008 certificate, however our 9001:2015 certification audit was performed 03-04March 2016. Although no non-conformances were identified, we are currently awaiting confirmation in the form of our updated certificate.