Executive Licensing Panel - minutes

Centre 0345 (Semovo, Leeds)

Interim Inspection Report

Friday, 22 September 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Hannah Verdin (Chair) Howard Ryan Jessica Watkin	Head of Regulatory Policy 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 Semovo Leeds is located within Thorpe park Clinic, Leeds, a private medical practice. Semovo has use of two rooms, one day per week: Staff meet with potential donors and donors produce their samples in one room and sperm is processed and frozen in the second room. Sperm samples frozen on the premises are then transported on the same day to Manchester Fertility (centre 0033) for storage under their licence. A storage licence is required to cover the temporary storage of samples at the Thorpe Park Clinic prior to transfer to Manchester Fertility.

1.2. The panel noted that an initial storage only licence was granted in November 2016 for the standard period of new licences, for two years.

1.3. The panel noted that the inspection took place on 21 July 2017. The inspection was not unannounced or short notice as is the usual practice for interim inspections, due to the model of service with licensed activity and relevant staff only being available on site one day per week.

1.4. The panel noted that at the time of the inspection on 21 July 2017, there were no areas of non-compliance. Following an initial inspection in 2016, recommendations for improvement were made in relation to two major and one 'other' area of non-compliance and the recommendations were fully implementation within the prescribed timescales.

1.5. The panel noted that the inspectorate recommends the continuation of the centre's storage licence and there are no recommendations for improvement.

2. Decision

2.1. The panel was satisfied the centre was fit to have its storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Hannah Verdin

Date

4 October 2017

Interim Licensing Report

Centre name: Semovo Leeds
Centre number: 0345
Date licence issued: 28 November 2016
Licence expiry date: 27 November 2018
Date of inspection: 21 July 2017
Inspector: Douglas Gray
Date of Executive Licensing Panel: 22 September 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. The Executive Licensing Panel is asked to note that there are no recommendations for improvement.

Information about the centre

Semovo Leeds is located within Thorpe Park Clinic, Leeds, a private medical practice. Semovo has use of two rooms one day per week: Staff meet with potential donors and donors produce their samples in one room and sperm is processed and frozen in the second room. Sperm samples frozen on the premises are then transported on the same day to Manchester Fertility (HFEA centre 0033) for storage under their licence. A storage licence is required to cover the temporary storage of samples at the Thorpe Park Clinic prior to transfer to Manchester Fertility.

An initial storage only licence was granted in November 2016 for the standard period for new licences of two years. This is a report of a routine interim inspection. The inspection was not unannounced or short notice as is the usual practice for interim inspections, due to the model of service with licensed activity and relevant staff only being available on site one day per week.

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 gametes or embryos and that identification errors do not occur. The inspector was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

It is important that the centre has measures in place to ensure that sperm is stored in accordance with the consent of the donor.

On inspection, 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 donor 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: staff in the laboratory are able to carry out their activities without distraction and are 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 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 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 use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding: screening requirements for Zika and Ebola.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management
The clinic does not offer treatment services.

Infection Control
The premises were visibly clean 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 the following medical devices was reviewed in the course of the inspection: sperm pots, tubes, cryovials, pipette tips. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
No feedback has been received about this centre from donors. No donors were available during the inspection to speak with inspectors.

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 including an audit of three donor records, indicate that the centre is fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following an initial inspection in 2016, recommendations for improvement were made in relation to two major and one 'other' area 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

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

Provision of information to the HFEA

The centre has not yet needed to submit 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
None			

‘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
The PR has confirmed that as there are no recommendations for improvement, no further response is required.