Executive Licensing Panel - minutes

Centre 0346 (Semovo Liverpool)

Interim Inspection Report

Tuesday, 7 April 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Helen Crutcher	Director of Strategy and Corporate Affairs Communications Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing 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:

- 9th 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 Liverpool is located within Pall Mall Medical, Liverpool, a private medical practice. The centre has use of two consulting rooms, one or two days 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 and distribution under their licence. A storage licence is required to cover the temporary storage of samples at Pall Mall Medical, Liverpool prior to transfer to Manchester Fertility.

1.2. The panel noted that Semovo recruits sperm donors at various locations in the UK. Semovo Liverpool (centre 0346) and Semovo, Leeds (centre 0345) have been licensed by the HFEA since 2016. Semovo, Glasgow (centre 0364) has been licensed since 2017. Semovo, London (centre 0369) has been licensed since 2018. All the centres work to the same 'hub and spoke' model as described below.

1.3. The panel noted that documentation (such as donor information), processes and procedures are the same across all Semovo sites, with the exception of a small number of premises-specific differences. In view of the common structures and functioning of the centres within the group, a group approach was considered. Inspections at the four other Semovo clinics have taken place within the last two years and demonstrated compliant practices. This was therefore taken into consideration when determining the inspection method to ensure a proportionate regulatory approach.

1.4. The panel noted that an inspection took place on 27 February 2020.

1.5. The panel noted that at the time of inspection there were no areas of non-compliance.

1.6. The panel noted that the inspectorate recommended the continuation of the centre's storage only licence, particularly identifying the centre is well led and provides a good level of donor support.

2. Decision

2.1. The panel was satisfied 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

Clare Ettinghausen

Date

16 April 2020

Interim Licensing Report

Centre name: Semovo, Liverpool
Centre number: 0346
Date licence issued: 25 August 2018
Licence expiry date: 24 August 2022
Additional conditions applied to this licence: None
Date of inspection: 27 February 2020
Inspectors: Sara Parlett
Date of Executive Licensing Panel: 7 April 2020

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. The current foci for an interim inspection are:

- **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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

The centre is well led and provides a good level of donor support.

The ELP is asked to note that this report makes no recommendations for improvement.

Information about the centre

Semovo recruits sperm donors at various locations in the UK. Semovo, Liverpool (centre 0346) and Semovo, Leeds (centre 0345) have been licensed by the HFEA since 2016. Semovo, Glasgow (centre 0364) has been licensed since 2017. Semovo, London (centre 0369) has been licensed since 2018. All of the centres work to the same 'hub and spoke' model as described below.

Semovo, Liverpool is located within Pall Mall Medical, Liverpool a private medical practice. Semovo has use of two consulting rooms one or two days 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 and distribution under their licence. A storage licence is required to cover the temporary storage of samples at Pall Mall Medical, Liverpool prior to transfer to Manchester Fertility.

Documentation (such as donor information), processes and procedures are the same across all Semovo sites with the exception of a small number of premises-specific differences.

In view of the common structures and functioning of the centres within the group, a group approach was considered. Inspections at the four other Semovo clinics have taken place within the last two years and demonstrated compliant practices. This was therefore taken into consideration when determining the inspection method to ensure a proportionate regulatory approach.

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 and that identification errors do not occur. The inspector did not observe any laboratory activities during the inspection but reviewed witnessing in patient records. This 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 are suitable for the activities being carried out. Discussions with centre staff demonstrated effective management in ensuring each of the Semovo clinics are suitably staffed as 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 effectiveness of the centre's QMS was assessed by reviewing the reports of donor records audits which included: donor identification, provision of counselling, consent, witnessing and donor compensation.

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:

- leadership
- patient support
- the use of the most recently issued HFEA consent form versions
- changes to donor screening requirements

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

Medicines management

These requirements are not relevant to the centre's activities.

Infection Control

It is important that clinics have suitable arrangements in place so that donors experience care in a clean environment and to prevent donors 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 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 a selection of medical devices was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to donors, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to donors, before, during and after donation. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Donor feedback should be collected to enhance the donor support procedures.

The centre's donor support procedures are compliant with HFEA guidance.

Patient feedback

The centre does not provide fertility treatment so patient feedback to the HFEA is not available. The centre is committed to getting feedback from donors and centres that use Semovo donor sperm. Feedback received by the centre to date has been positive.

During the inspection, the inspector spoke to one donor who also provided positive feedback on his experiences.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats donors with privacy and dignity;
- provides a clean and well organised environment for donors;
- has staff who are supportive and professional;
- gives donors 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 licence renewal inspection in 2018, no recommendations for improvement were made.

On-going monitoring of centre success rates

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

Provision of information to the HFEA

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

These requirements are not relevant to the centre's activity.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves donor care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about donor care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or donors.

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 made.

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 non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None.			

‘Major’ areas 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None.			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas 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.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None.			

Additional information from the Person Responsible