Executive Licensing Panel - minutes

Centre 0364 (Semovo Glasgow)

Renewal Inspection Report

Tuesday, 29 October 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Helen Crutcher Howard Ryan	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Data Analyst
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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that Semovo is a registered company that recruits sperm donors at various locations in the UK. Semovo Leeds (centre 0345) and Semovo Liverpool (centre 0346) have been licensed by the HFEA since 2016. Semovo London (centre 0369) has been licensed since 2018.

1.3. The panel noted that Semovo Glasgow has been licensed by the HFEA since 2017 for the standard period for new licences of two years. The centre is located within Blythswood Health & Wellbeing, a clinic which provides a range of occupational health and private medical services. Sperm samples frozen on the premises, are transported on the same day, to Manchester Fertility (centre 0033) for storage and future distribution under their licence. A storage licence is required to cover this temporary storage of samples at the Glasgow clinic prior to transfer to Manchester Fertility.

1.4. The panel noted that documentation (such as information for donors), 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 three other Semovo clinics had occurred within the last year and demonstrated compliant practices. This was taken into consideration when determining the inspection methodology to ensure a proportionate regulatory approach.

1.5. An inspection was carried out at the centre on the 30 July 2019.

1.6. The panel noted that at the time of the inspection, there was one 'other' area of practice that required improvement regarding CE marking. Since the inspection visit, the Person Responsible (PR) has provided evidence that the recommendation has been implemented.

1.7. The panel noted that the inspection team recommended the renewal of the centre's storage only licence for a period of four years, without additional conditions.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

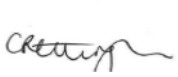
2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge her duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's storage only licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

4 November 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 30 July 2019

Purpose of inspection: Renewal of a licence to carry out Storage only

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Sara Parlett

Date of Executive Licensing Panel: 29 October 2019

Centre name	Semovo Glasgow
Centre number	0364
Licence number	L/0364/1/a
Centre address	Blythswood Health & Wellbeing, 1 Blythswood Square, Glasgow, G2 4AD
Person Responsible	Dr Deborah Falconer
Licence Holder	Mr Andrew Berkley
Date licence issued	20 December 2017
Licence expiry date	19 December 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Semovo is a registered company that recruits sperm donors at various locations in the UK. Semovo Leeds (centre 0345) and Semovo Liverpool (centre 0346) have been licensed by the HFEA since 2016. Semovo London (centre 0369) has been licensed since 2018.

Semovo Glasgow has been licensed by the HFEA since 2017 for the standard period for new licences of two years. It is located within Blythswood Health & Wellbeing, a clinic which provides a range of occupational health and private medical services. Sperm samples frozen on the premises are transported on the same day to Manchester Fertility (centre 0033) for storage and future distribution under their licence. A storage licence is required to cover this temporary storage of samples at the Glasgow clinic prior to transfer to Manchester Fertility.

Documentation (such as information for donors), 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 three other Semovo clinics had taken place within the last year and demonstrated compliant practices. This was therefore taken into consideration when determining the inspection methodology to ensure a proportionate regulatory approach.

Pregnancy outcomes
Treatment services leading to pregnancies are not provided at this clinic.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there was one 'other' area of practice that required improvement. Since the inspection visit, the PR has provided evidence that the following recommendation has been implemented:

'Other' areas that require improvement:

- The PR should ensure that appropriately CE marked sperm pots are used.

Recommendation to the Executive Licensing Panel

The centre has no critical or major areas of non compliance.

The inspection team recommends the renewal of the centre's Storage only licence for a period of four years without additional conditions.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment
2. The experience of donors at this centre
3. The protection of gametes (sperm) at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and the donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived

genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that donors and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of donors' samples, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)

The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
These requirements are not relevant to the centre's activities.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
These requirements are not relevant to the centre's activities.

Multiple births (Guidance note 7; General Direction 0003)
These requirements are not relevant to the centre's activities.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
These requirements are not relevant to the centre's activities.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
These requirements are not relevant to the centre's activities.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. All of the equipment and materials used in licensed activity, with one exception, are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. No adverse incidents have occurred at the centre since it was licensed, but discussions with centre staff demonstrated that any adverse incident would be appropriately managed. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Equipment and materials (Guidance note 26)
The sample pots used for the collection of sperm are not CE marked at the appropriate level (SLC T30).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting

relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
These requirements are not relevant to the centre's activities.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's donors and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
These requirements are not relevant to the centre's activities.

What the centre could do better
Nothing identified at this inspection.

2. The experience of donors

Donor feedback

What the centre does well

During the inspection visit, the inspector spoke to one donor. The donor was very positive about the clinic, including the flexibility with appointment scheduling and how useful the counselling session was.

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.

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.

What the centre could do better

Nothing identified at this inspection.

Treating donors fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating donors fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to donors providing relevant consent.

Egg sharing arrangements (Guidance note 12; General Direction 0001)

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

Surrogacy (Guidance note 14)

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

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek donor feedback and to be responsive to donor complaints. This is important to ensure that the centre uses feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current donors.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
These requirements are not relevant to the centre's activity.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of donors' consent, so that it only releases donor identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better
Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

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

What the centre could do better
Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)
These requirements are not relevant to the centre's activity.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers.

What the centre could do better
Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
These requirements are not relevant to the centre's activity.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority, are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the initial inspection in 2017, a recommendation for improvement was made in relation to one area of major non compliance.

The PR provided information and evidence that this recommendation was fully implemented.

On-going monitoring of centre success rates

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

Areas of practice requiring action

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, General 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 area 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of 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 identified.			

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 to a 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
- 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 identified.			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates 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
1. **CE marking** The sample pots used for the collection of sperm are not CE marked at the appropriate level. SLC T30.	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment. In consideration of this, the PR should inform the HFEA when responding to this report, either of the anticipated time by which appropriate CE marking is expected to be obtained or of the action that will be taken to ensure compliance within the next six months.	Alternative sperm collection containers were sourced from Repromed. These containers are CE marked for IVF use. Following satisfactory sperm survival testing the containers have been introduced for all donation samples across all Semovo sites.	The executive acknowledges the PR's response and implementation of the recommendation. No further action is required.

Reponses from the Person Responsible to this inspection report