Executive Licensing Panel Minutes

Centre 0364 (Semovo Glasgow)

Interim Inspection Report

Date:	27 July 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Helen Crutcher Anna Coundley	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Policy Manager
Executive:	Bernice Ash	Secretary
Observers	Catherine Burwood Julia Chain	Licensing Manager HFEA Chair (Induction)

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 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.

1.2. The panel noted that Semovo Glasgow has been licensed by the HFEA since 2017 and 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 the temporary storage of samples at the Glasgow clinic prior to transfer to Manchester Fertility.

1.3. 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.

1.4. The panel noted that, in March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

1.5. The panel noted that HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

1.6. The panel noted that the centre was last inspected in July 2019, therefore an on-site interim inspection should usually have been conducted by July 2021. Following the DBA/RBA, it was concluded that a shorter than normal on-site visit to the centre, with a smaller inspection team, could be undertaken. This reduced the risks to staff, associated with a full HFEA team attending the centre for an on-site inspection during the Covid-19 pandemic, while meeting the requirements of the HF&E Act 1990 (as amended).

1.7. The panel noted that a virtual inspection occurred on 26 May 2021, which included videoconferencing with key members of centre staff. An on-site inspection was conducted on 8 June 2021.

1.8. The panel noted that at the time of the inspection, there were no areas of practice which required improvement.

1.9. The panel noted the centre is well led and provides an acceptable level of donor support.

1.10. The panel noted that the inspection team recommends the continuation of the centre's storage only licence.

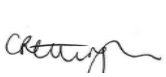
2. Decision

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

29 July 2021

Interim Licensing Report

Centre name: Semovo Glasgow
Centre number: 0364
Date licence issued: 20 December 2019
Licence expiry date: 19 December 2023
Additional conditions applied to this licence: None
Date of inspection: 26 May 2021 (virtual), 8 June 2021 (onsite)
Inspectors: Lesley Brown
Date of Executive Licensing Panel: 27 July 2021

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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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 interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in July 2019, therefore an on-site inspection should usually be conducted by July 2021. Following the DBA/RBA for this clinic, it was concluded that a shorter than normal on-site visit to the centre, with a smaller inspection team, could be undertaken. This reduced the risks to staff, associated with a full HFEA team attending the

centre for an on-site inspection during the Covid-19 pandemic, while meeting the requirements of the HF&E Act 1990 (as amended).

This inspection was therefore carried out by desk based assessment followed by a virtual inspection, which included videoconferencing with key members of centre staff, with a short onsite visit.

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 an acceptable level of donor support.

The Executive Licensing Panel is asked to note that that at the time of the inspection there were no areas of practice that require improvement.

Information about the centre

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, with the last renewal inspection taking place 30 July 2019. 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 the 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.

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[1]

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

Multiple births[2]

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 inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review the centre's own audit of witnessing practice. These activities indicated that witnessing procedures are 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.

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[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%.

During the inspection process, a report of the audit of consent records was reviewed. Sperm samples, procured and frozen on the premises, are transported on the same day to Manchester Fertility (centre 0033) for storage and future distribution under their licence. Therefore, the requirements of maintaining storage records and a 'bring forward' system are not relevant to this centre.

These activities indicate that the centre's processes for obtaining 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.

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 the following audits: infection control; witnessing; assessment, recruitment and selection of sperm donors.

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
- donor support
- implications of treatment and consent
- screening
- the use of CE marked medical devices

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

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.

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

Prescription of intralipid ‘off label’
Intralipid is an intravenous nutritional supplement sometimes prescribed to particular subset of women having IVF. These requirements are not relevant to the centre’s activities.

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 process, we reviewed infection control practices and audits 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 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 process: Sperm pots; pipettes. 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 patients, 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 patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

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

Patient feedback
The HFEA website has a facility on its ‘Choose a Fertility Clinic’ page enabling patients to provide feedback on their experience of their clinic. As this centre holds a storage only licence this facility is not available.

The centre does obtain feedback from donors. At the time of inspection, the most recent donor feedback audit was being collated, therefore raw data was reviewed. Nineteen donors provided mostly positive feedback to the centre. Centre staff reported that this represents a feedback rate of approximately 80 percent. Three donors provided negative responses regarding; production room comfort, frequency of visits and website information. Documents provided as part of the inspection process showed that actions are being taken to address these matters

No donors were available to speak to the inspector during this visit.

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;
- treats donors with empathy and understanding.

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 July 2019, a recommendation for improvement was made in relation to one 'other' area of non compliance.

The PR subsequently provided information and evidence that the recommendation was fully implemented within the required timescales.

On-going monitoring of centre success rates

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

Provision of information to the HFEA

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

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient 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 patient 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 patients.

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 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 identified.			

‘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 identified.			

‘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 identified.			

Additional information from the Person Responsible