Executive Licensing Panel Minutes

Centre 0367 (The Evewell)

Renewal Inspection Report

Date:	4 May 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Yvonne Akinmodun Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Human Resources Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Niamh Marren	Licensing Manager Regulatory Policy 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 four years.

1.2. The panel noted that The Evewell is located in central London and has held a licence with the HFEA since 2018. The centre provides a full range of fertility services including embryo testing.

1.3. The panel noted that, in the 12 months to 31 January 2021, the centre provided 352 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

1.4. The panel noted that, HFEA register data, for the period 1 November 2019 to 31 October 2020, show the centre's success rates for IVF and ICSI are in line with the national averages with the following exception:

- success rates following frozen embryo transfer cycles (FET) in all age groups are higher than average at a statistically significant level.

1.5. The panel noted that, in 2020, the centre reported 112 cycle of partner insemination, with 21 pregnancies. This represents a clinical pregnancy rate of 19% which is comparable to the national average.

1.6. The panel noted that, HFEA register data, between 1 November 2019 and 31 October 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.8. The panel noted that, due to the pandemic, the Person Responsible (PR) applied to extend the duration of the centre's initial licence; the duration of the licence was extended to three years.

1.9. The panel noted that the centre's interim inspection occurred in September 2019 and a renewal inspection was scheduled to be undertaken by September 2021. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted. Following this, it was established that any items of concern identified could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.10. The panel noted that a virtual inspection was conducted on 9 March 2021, which included telephone conversations with key members of staff.

1.11. The panel noted that, at time of the virtual inspection, there was one major area of non-compliance concerning laboratory accreditation. There were also four 'other' non-compliances regarding payment of donors, medicines management, the quality management system (QMS) and obligations and reporting requirements. Since the inspection, the Person Responsible (PR) has implemented the recommendations surrounding laboratory accreditation, medicines

management and the QMS. The PR has given a commitment to fully implementing the recommendations concerning payment of donors and obligations and reporting requirements.

1.12. The panel noted that the centre is well led and provides a good level of patient support.

1.13. The panel noted that, as a result of the UK's departure from the European Union (EU), a relicensing exercise is currently in progress. This follows approval by the Licence Committee of a variation without application on 4 March 2021, meaning that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

1.14. The panel noted that the renewal for this centre is being considered during that relicensing period. However, since this renewal licence (if approved) will commence on 17 September 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new, varied, licence.

1.15. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence, for a period of four years, without additional conditions, subject to the recommendations in the report being implemented in the prescribed timescales.

1.16. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

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 licensed activity.

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 his 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 treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.5. The panel endorsed the executive's recommendation to renew the ITE's import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

10 May 2021

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 report provides information on the centre's application to renew its existing licence. 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 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: 9 March 2021

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

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

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 September 2019; therefore, an on-site inspection should usually be conducted by September 2021. Following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

Inspectors: Louise Winstone (lead), Karen Conyers, Nicola Lawrence, (Karen Campbell, Sarah Stedman and Bernadette O'Leary; HFEA observers)

Date of Executive Licensing Panel: 4 May 2021

Centre name	The Evewell
Centre number	0367
Licence number	L/0367/1/b
Centre address	61 Harley Street, London, W1G 8QU
Person Responsible	Christian Ottolini
Licence Holder	James Kafton
Date licence issued	17 September 2018
Licence expiry date	16 September 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Evewell is located in central London and has held a licence with the HFEA since 2018.

The centre provides a full range of fertility services including embryo testing.

The centre provided 352 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2021. In relation to activity levels this is a small centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

This centre was due a renewal of licence inspection during the period of suspension of fertility treatments. In April 2020, the Person Responsible (PR) applied for a variation to extend the duration of the centre's current Treatment (including embryo testing) and Storage licence by one year. The centre's initial licence was issued for a period of two years and following the grant of the licence variation, the centre's licence duration was extended to three years.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2019 to 31 October 2020 show the centre's success rates are in line with national averages with the following exception:

- success rates following frozen embryo transfer cycles (FET) in all age groups are higher than average at a statistically significant level.

In 2020, the centre reported 112 cycles of partner insemination with 21 pregnancies. This represents a clinical pregnancy rate of 19%, which is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 November 2019 to 31 October 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target.

[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%.

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 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 his 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 were a number of areas of practice that required improvement, including one major and four 'other' areas of non compliance.

Since the inspection visit, the following recommendations have been fully implemented:

Major area of non compliance:

- The PR should ensure that diagnostic semen analyses are undertaken in a laboratory that is accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard.

'Other' areas that require improvement:

- The PR should ensure that medicines management practice is compliant with regulatory and best practice requirements.
- The PR should ensure that the quality management system (QMS) and audit process is coordinated across all aspects of the centre's activities.

The PR has given a commitment to fully implementing the following recommendations:

'Other' areas that require improvement:

- The PR should ensure that the import of donor gametes is compliant with General Direction 0006(GB) and General Direction 0001.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have one major area of concern. The inspection team notes that the success rates are consistent with the national average, with the exception of FET in all age groups which are significantly above the national average and their multiple clinical pregnancy rates are well below the target at a statistically significant level.

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

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Centre 0367 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

As a result of the UK's departure from the EU, there is currently a relicensing exercise under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

This renewal is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 17 September 2021, which is after 1 July 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new, varied, licence.

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 at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos 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 embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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 and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are broadly 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 or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos 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

Payments for donors (Guidance note 13; General Direction 0001)
The centre imports donated gametes from overseas sperm banks with which they have established contractual agreements. The agreements include confirmation that the donors are compensated in accordance with HFEA requirements which are taken as evidence by the centre that it can satisfy the requirements of General Direction 0006(GB) when undertaking these imports. The centre does not actively review the compensation provided to gamete donors either at the time of import or as part of the centre's auditing processes.

See recommendation 2.

General Directions 0001 and 0006(GB).

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

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 patients 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 and/or embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are partially 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)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

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 and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside 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 or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements, with the exception noted in 'Payments for donors' above.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs),

from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is broadly 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, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not undertake transport and satellite activities. Therefore, requirements related to the agreements are not relevant to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity 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 or embryos 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. The centre reports all incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred.

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

Laboratory accreditation (Guidance note 25)
The centre undertakes diagnostic semen analyses however the laboratory is not accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard. Whilst several requirements of accreditation to an equivalent standard are in place (e.g. appropriate premises to carry out the testing; a quality management system; staff who are suitably qualified to interpret the results), the inspection team noted that the laboratory does not currently participate in an interlaboratory comparison programme (such as an external quality assessment programme) for semen analysis. In addition, the centre's process validation for this activity did not provide sufficient detail to enable robust evaluation by the inspection team.

See recommendation 1.

SLC T21.

Medicines management (Guidance Note 25)
The centre occasionally provides unsigned electronic copies of prescriptions for patients to take to a pharmacy to check the cost of medication. The prescriptions carry the centre's letterhead, prescriber's information and GMC number. They do not ask for the unsigned prescriptions to be returned therefore the inspection team was concerned that this could lead to unauthorised use.

See recommendation 3.

SLC T2; British National Formulary (BNF)/National Institute for Care and Health Excellence (NICE) Guidance 'Prescription Writing': computer-issued prescriptions (2021) https://bnf.nice.org.uk/guidance/prescription-writing.html.

Quality management system (QMS) (Guidance note 23)
The following issues were noted with the centre's QMS.

- Whilst the inspection team was assured that the centre's audits of practice are conducted appropriately, the documentation of the audit criteria, scope and methods in the centre's audit reports are inadequate. For example:
    - The centre's audit report of Third Party Agreements (TPA) was provided. The report looked at three TPA agreements and confirmed 'Compliance with TPA conditions' and 'Documents checked for compliance'. However, the report does not provide any information of what the criteria should be or that relevant regulatory requirements were assessed.
    - The centre's audit of consent to legal parenthood was provided but this gave no information on the sample size audited, whether it included all patients who had received treatment using donor sperm, or the time period covered by the audit.
- When reviewing the performance of the QMS to ensure continuous and systematic improvement, the centre should document its review of whether the centre is meeting all its quality indicators (QIs). For example, one of the QIs set by the centre for their embryo testing programme is to evaluate the results from 'third party' (genetic testing laboratory) per blastocyst biopsied. Detailed records are

kept and monitored however it is not clear how this is formally reviewed against the QI.
- The PR performs detailed ongoing analysis of all treatment outcomes. Whilst the inspection team did not have any concerns with the key performance indicators (KPIs) being assessed, they noted that these were not the same QIs as those documented in the centre's QMS.

See recommendation 4.

SLC T36; CoP Guidance 23.20.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
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.

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.

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)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients 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)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only seven patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. This was discussed during the virtual inspection and the PR was asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were also reviewed. Between January 2020 and December 2020, 130 patients had provided written feedback with a patient satisfaction score of 98.5%. Feedback was comparable to that provided to the HFEA.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients 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 patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Patient support (Guidance note 3)

Recent HFEA guidance strengthens the requirement for 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 patient support procedures are compliant with HFEA guidance.

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 patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not offer treatment using egg or sperm sharing arrangements therefore requirements related to these arrangements are not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre does not offer treatment involving surrogacy therefore requirements related to surrogacy treatments are not relevant to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient 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 patients and donors.

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

Information

What the centre does well

Information (Guidance note 4
The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and 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 patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
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.

While the focus on legal parenthood consenting has been in place since February 2014, this centre only opened in 2018. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing in 2018.

At the interim inspection in September 2019, we reviewed the centre's audit and a number of issues were identified, for example: it was difficult to ascertain the marital status of the patients in the records audited and the centre had a blanket policy of completing the WP and PP legal parenthood consent forms for all patients where legal parenthood consent applies. Actions were taken in response to the inspection findings.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team reviewed the centre's own legal parenthood audit and discussed these procedures with staff. Some issues in relation to the documenting of the centre's audit were noted and are discussed in the 'Quality Management system' section above. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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 patients' consent, so that it only releases the patients 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

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

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)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

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)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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 broadly 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.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
A sample of 108 IVF and 10 donor insemination (DI) treatments obtained from the centre's record of licensed activity between 1 January 2019 and 31 December 2019 was reviewed against the HFEA's Register data. Of this sample, 6% (7/108) of the IVF and 20% (2/10) of the DI treatments had been reported to the HFEA outside the period required by General Direction 0005.

The centre had also reported two treatments using unregistered donors. The PR advised during the virtual inspection that this had been corrected shortly after the audit had been performed.

See recommendation 5.

General Direction 0005; SLC T41.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2019, recommendations for improvement were made in relation to three major and two 'other' areas of non compliance or poor practice.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

The centre has not received any risk tool alerts relating to success rates in the last year.

Areas of practice requiring action

This 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 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 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 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 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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Laboratory accreditation The centre undertakes diagnostic semen analyses however the laboratory is not accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard. Whilst several requirements of accreditation to an equivalent standard are in place (e.g. appropriate premises to carry out the testing; a quality management system; staff who are suitably qualified to interpret the results), the inspection team noted that the laboratory does not currently	The PR should ensure that diagnostic semen analyses are undertaken in a laboratory that is accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard. The PR should ensure that the centre's laboratory participates in an interlaboratory comparison programme (such as an external quality assessment programme) for semen analysis, and that a robust process validation (such as using data from published studies) is	The Evewell enrolled in the NEQAS as an external quality assurance program for diagnostic semen analysis. The process validation dicumented has been revised to include this action. See document VAL-PV-001 and copy of NEQAS enrolment. Please see our comments in the 'general comments' section.	The executive acknowledges the PR's response and commitment to implementing this recommendation. A copy of the centre's process validation document has been provided. The executive notes the PR's comments in the section 'Responses from the Person Responsible to this inspection report' below. The centre's andrology laboratory is not accredited by UKAS or another accreditation body recognised as accrediting to

participate in an interlaboratory comparison programme (such as an external quality assessment programme) for semen analysis. In addition, the centre's process validation for this activity did not provide sufficient detail to enable robust evaluation by the inspection team. SLC T21.	completed for semen analysis methods used in the laboratory. The PR should advise the centre's inspector of actions to be taken when responding to this report. A copy of the centre's process validation document should be provided to the centre's inspector by 9 June 2021.		an equivalent standard therefore this is classified as a major non compliance as per the HFEA's Compliance Assessment Framework. Participation in an interlaboratory comparison programme for semen analysis such as NEQAS is necessary to be able to demonstrate a status of accreditation to an equivalent standard and provides assurance of the reproducibility and accuracy of the diagnostic andrology test conducted in the laboratory. The PR has confirmed that the centre is now enrolled in an external quality assurance programme for semen analysis. No further action is required.

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice 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
2. Payment of donors The centre imports donated gametes from overseas sperm banks with which they have established contractual agreements. The agreements include confirmation that the donors are compensated in accordance with HFEA requirements which are taken as evidence by the centre that it can satisfy the requirements of General Direction 0006(GB) when undertaking these imports. The centre does not actively review the compensation provided to gamete donors either at the time of import or as part of the centre's auditing processes.	The PR should ensure that import of donor gametes is compliant with General Direction 0006(GB) and General Direction 0001. The PR should undertake an audit of records of the compensation provided to donors by overseas sperm banks. A summary report of the findings of the audit including corrective actions identified and the timescales for implementation should be provided to the centre's inspector by 9 June 2021. The PR should review the centre's processes to consider what further actions need to be put in place to ensure compliance	PR to undertake audit of all TPA's, including overseas donor sperm providers as per FM-QM-002 Third Party Agreement Audit (see attached). As discussed and agreed with HFEA Lead Inspector and Scientific Inspector, evidence will be obtained from one to two sperm donors per provider to demonstrate compliance with General Direction 0006 (GB). We have amended our TPA audit to reflect this. Audit to be provided by 9 June 2021	The executive acknowledges the PR's response and commitment to implementing this recommendation. Audit and summary report of the review is to be provided by 9 June 2021. Further action is required.

General Direction 0001 and 0006(GB).	with General Direction 0006(GB) and General Direction 0001 for future imports of gametes or embryos from any overseas donor banks. A summary report of this review should be provided to the centre's inspector by 9 June 2021.		
3. Medicines Management The centre occasionally provides unsigned electronic copies of prescriptions for patients to take to a pharmacy to check the cost of medication. The prescriptions carry the centre's letterhead, prescriber's information and GMC number. They do not ask for the unsigned prescriptions to be returned therefore the inspection team was concerned that this could lead to unauthorised use. SLC T2; BNF/NICE Guidance 'Prescription Writing': computer-issued prescriptions (2021)	The PR should ensure that medicines management practice is compliant with regulatory and best practice requirements. The PR should review the centre's medicines management practices and provide a summary report of the findings including corrective actions and the timescales for implementation to the centre's inspector by 9 June 2021. Three months after the review the PR should audit medicines management practices to ensure that any	From the day of inspection the practice of forwarding unsigned PDF prescription documents has stopped. If patients wish to obtain quotes external to the Evewell we utilise the 'snipping tool' on the computer to take a snapshot of just the medication in order for the patient's to be able to get a quote without being able to potentially utilise the unsigned prescription to obtain medication inappropriately. Medicines management is now complaint, no audit required as this practice no longer occurs.	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action is required.

https://bnf.nice.org.uk/guidance/prescription-writing.html.	corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 9 September 2021.		
4. Quality management system (QMS) The following issues were noted with the centre's QMS. • Whilst the inspection team was assured that the centre's audits of practice are conducted appropriately, the documentation of the audit criteria, scope and methods in the centre's audit reports are inadequate. • When reviewing the performance of the QMS to ensure continuous and systematic improvement, the centre should document its review of whether the centre is	The PR should ensure that the QMS and audit process is coordinated across all aspects of the centre's activities. The PR should review the centre's processes for documenting audits performed, ensuring they clearly define the audit criteria, scope, methods used and compliance with the regulatory requirements, the centre's approved protocols and quality indicators. A summary of the findings of the review including corrective actions and the timescales for implementation should be	All audit templates updated to include the audit criteria, scope and methods. Quality Indicators SOP-QM-003 updated - see attached The Quality Indictors have been bought in line with the treatment data assessed by the centre.	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action is required.

meeting all its quality indicators (QIs). For example, one of the QIs set by the centre for their embryo testing programme is to evaluate the results from 'third party' (genetic testing laboratory) per blastocyst biopsied. Detailed records are kept and monitored however it is not clear how this is formally reviewed against the QI. • The PR performs detailed ongoing analysis of all treatment outcomes. Whilst the inspection team did not have any concerns with the key performance indicators (KPIs) being assessed, they noted that these were not the same QIs as those documented in the centre's QMS.	provided to the centre's inspector by 9 June 2021. The PR should review and update the centre's QI's to ensure that they capture and accurately reflect the laboratory KPIs and centre's audits. A copy of the revised QI's should be provided to the centre's inspector by 9 June 2021.		

SLC T36; CoP Guidance 23.20.			
5. Obligations and reporting requirements A sample of 108 IVF and 10 donor insemination (DI) treatments obtained from the centre's record of licensed activity between 1 January 2019 and 31 December 2019 was reviewed against the HFEA's Register data. Of this sample, 6% (7/108) of the IVF and 20% (2/10) of the DI treatments had been reported to the HFEA outside the period required by General Direction 0005. The centre had also reported two treatments using unregistered donors. The PR advised during the virtual inspection that this had been corrected shortly after the audit had been performed. General Direction 0005; SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the centre's procedures used to submit licensed treatment data to the HFEA. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's	Given the planned change to data submission (PRISM) we would politely request a reconsideration that a review of our processes to submit data to the HFEA is not required. The findings of the registry audit were not in our oppinion in a range that would be considered critical and and any chages we implement now will be invalid before the time of the requested next audit. We would happily provide the HFEA with an updated process for data submission (and an audit if requested) following the implematation of PRISM. It was discovered that we have not used unregistered donors. The data error report from the HFEA we believe was due to a misinterpretation of how to complete the form. The donors originated from an	The executive acknowledges the PR's response and accepts that a review of the process of data submission following the implementation of PRISM should instead be performed. The executive will remain in contact with the PR to ensure that this is completed in due course. Further action is required.

	inspector by 9 September 2021.	overseas clinic and were registered by another UK clinic before being transferred to us. The person inputting the data interpretted the origin question as being where the sperm was originally from and not where that particualr sample was transferred from in order to come to the clinic. This was a brief misunderstanding with no further evidence of ongoing concern about the inputting of this data therefore no audit performed relating to this.	

Responses from the Person Responsible to this inspection report
Thank you for the comprehensive report following the recent virtual inspection, as always we value the guidance of the HFEA and are reassured that the changes suggested will improve our services provided to our patients. My only comment would be that we are a little disappointed that we have an area of major non-conformance in relation to diagnostic semen analysis. We have not seen any HFEA guidance that mandated enrollment in an external QA program. Your report references T21, which states that we should be equivalent to UKAS accreditation but it is not clear what is meant by this. We feel confident that our diagnostic semen analysis is both robust and accurate, given the corresponding high success rates that we demonstrate. We acknowledge that an external QA system is of value and as above have joined as recommended but feel strongly that this is not an area of major non-conformance and would request that this is reclassified as a 'Other areas of practise that require improvement'. We do however understand that there may be a framework that does not allow for this. We look forward to meeting with the inspection team in person next time.