Executive Licensing Panel - minutes

Centre 0336 (Simply Fertility)

Renewal Inspection Report

Variation Change of Person Responsible (PR)

Tuesday, 15 October 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Finance and Resources Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel 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 Simply Fertility is situated in a purpose-built fertility clinic adjacent to Baddow Hospital in Chelmsford, Essex.

1.3. The panel noted that the centre initially commenced activity in August 2013 under a HFEA treatment (Insemination using partner / donor sperm) and storage licence and provided a limited range of fertility treatments. The centre subsequently became a member of the Fertility Partnership group, upgraded the clinical and laboratory facilities and varied their licence in May 2017 to a full treatment and storage licence. Simply Fertility now provides a full range of fertility services including the storage of gametes and embryos.

1.4. The panel noted that the centre reported a grade A incident to the HFEA in October 2018. This incident was investigated by the centre and a HFEA inspection team; a report of the incident investigation and inspection was presented to the Licence Committee on 7 March 2019. No regulatory sanctions were recommended or imposed, however the committee expected the centre 'to provide clear evidence, when it applies to renew its licence, that it has learned the lessons from this incident and embedded them into its procedures.'

1.5. The panel noted that, in the 12 months to 31 July 2019, the centre provided 451 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.6. The panel noted that, HFEA register data, for the year to 30 April 2019, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.7. The panel noted that, in 2018, the centre provided 16 cycles of partner inseminations, with no pregnancies, and this is in line with the national average.

1.8. The panel noted that, between 1 May 2018 and 30 April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to produce a multiple live birth rate statistically different from the 10% multiple live birth rate target.

1.9. An inspection was carried out at the centre on the 11 and 12 June 2019.

The panel noted that at the time of the inspection, there were three major areas of non-compliance concerning the Quality Management (QMS), third-party agreements (TPAs) and imports of sperm, alongside the consent to use of embryos in training. There was also one 'other' non-compliance regarding medicines management. Since the inspection visit, the Person Responsible (PR) has fully implemented all the recommendations made in the report. At the next interim inspection, in relation to the QMS, the inspector will consider the required audits and quality indicator monitoring. The inspector will also follow up with the centre, to ensure actions concerning TPAs and imports of sperm are complete and robust.

1.10. The panel noted that, with regards to the A grade incident, reported to the HFEA in October 2018, the inspection team confirmed that the centre has taken full learning from this incident and has implemented appropriate changes in processes to prevent recurrence. The Licence Committee minutes stated that the committee 'is happy to consider an application to renew the licence'. The inspection team considered this unnecessary in the absence of any compliance issues in areas of practice related to the incident, so to prevent further delay decided to progress the report and licence renewal application for consideration by the Executive Licensing Panel (ELP).

1.11. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve clinical pregnancy/live birth rates and the centre's compliance, and thus the service provided to patients.

1.12. The panel noted that the inspector will continue to monitor the centre's performance and implementation of the outstanding actions.

1.13. The panel noted that the inspection team recommends the renewal of the centre's treatment 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

1.14. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team 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 the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the current 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 congratulated the centre on the positive patient feedback, provided through the 'Choose a Fertility Clinic' facility on the HFEA's website; 52 patients had given feedback in the last 12 months, giving an average five-star rating to the centre.

2.5. The panel noted the centre's progress since the grade A incident was reported to the HFEA in October 2018, particularly acknowledging that the inspection team considered it unnecessary to present the renewal report to the Licence Committee for assessment, in the absence of any compliance issues.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment 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.

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

3. Change of Person Responsible

3.1. The committee considered the papers, which included a completed application form and the CV of and confirmation of acceptance from the proposed new PR.

3.2. The committee noted that the proposed PR, Mrs Sarah Glew, is willing to assume the responsibility of the role of PR. The committee noted that the proposed PR has satisfactorily completed the PR Entry Programme (PREP) and the certificate number was provided.

3.3. The committee noted that Mrs Sarah Glew has suitable qualifications for the role of PR.

3.4. The committee noted from the information provided, that the character, qualifications and experience of the proposed PR, Mrs Sarah Glew, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).

3.5. The committee noted that all information required under General Directions 0008 had been provided.

3.6. The committee noted the inspectorate's recommendation to vary the centre's licence to appoint Mrs Sarah Glew as the PR.

4. Decision

4.1. The committee agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of PR.

4.2. The committee endorsed the inspectorate's recommendation and agreed to vary the licence of Simply Fertility (centre 0336), with immediate effect to reflect the change of Person Responsible to Mrs Sarah Glew, in accordance with Section 18A of the HFE Act 1990 (as amended).

5. Chair's signature

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

Signature

Name

Richard Sydee

Date

17 October 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: 11 and 12 June 2019

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

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: Andrew Leonard (lead), Janet Kirkland MacHattie (clinical), Sara Parlett (scientific), Victoria Brown (training) and Neil McComb (register)

Date of Executive Licensing Panel: 15 October 2019

Centre name	Simply Fertility
Centre number	0336
Licence number	L/0336/2/b
Centre address	Baddow Hospital, West Hanningfield Road, Great Baddow, Chelmsford, Essex, CM2 8HN, UK.
Person Responsible (PR)	Mr Andrew Glew
Licence Holder (LH)	Mr Subrata Gangooly
Date licence issued	27 November 2015
Licence expiry date	26 November 2019
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The centre is situated in a purpose-built fertility clinic adjacent to Baddow Hospital in Chelmsford, Essex.

Simply Fertility initially commenced activity in August 2013 under a HFEA Treatment (Insemination using partner / donor sperm) and Storage licence, under which the centre provided a limited range of fertility treatments. The centre subsequently became a member of the Fertility Partnership group, upgraded the clinical and laboratory facilities and varied their licence in May 2017 to a full Treatment and Storage licence. The centre now provides a full range of fertility services including the storage of gametes and embryos. The licence has not been varied since this time.

The centre reported a grade A incident to the HFEA in October 2018. This incident was investigated by the centre and a HFEA inspection team and a report of the incident investigation and inspection was present to the Licence Committee on 7 March 2019. No regulatory sanctions were recommended or imposed, however the committee expected the centre 'to provide clear evidence, when it applies to renew its licence, that it has learned the lessons from this incident and embedded them into its procedures.'

The centre provided 451 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2019. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year to 30 April 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 16 cycles of partner insemination with no pregnancies. This is in line with the national average.

Multiple births[2]

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

Between 1 May 2018 and 30 April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be statistically different from 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 three major and one 'other' areas of non compliance which required this inspection report to make recommendations.

The following recommendation has been fully implemented:

'Other' area of non compliance:

- The PR should ensure drugs are immediately removed from use and are destroyed when they reach their expiry date.

The following recommendations have been implemented in part and the PR has committed to complete the actions necessary for full implementation within the timescales specified:

Major areas of non compliance:

- The PR should ensure that the quality management system (QMS) functions effectively.
- The PR should ensure that: third party agreements include all HFEA requirements relevant to the services provided; the compliance of third party suppliers with HFEA requirements is evaluated before supply commences and every two years thereafter; evidence is collected for the compliance with HFEA requirements of individual donor sperm samples imported under General Direction 0006.
- The PR should ensure that the storage and use of embryos in training is only undertaken when effective consent has been provided by the gamete providers.

Regarding the A grade incident reported to the HFEA in October 2018, the inspection team can confirm that the centre has taken full learning from this incident and has implemented appropriate changes in processes to prevent recurrence. The Licence Committee minutes stated that the committee 'is happy to consider an application to renew the licence'. The inspection team considers this unnecessary in the absence of any compliance issues in areas of practice related to the incident, so to prevent further delay has decided to progress the report and licence renewal application for consideration by the Executive Licensing Panel.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major and one 'other' areas of concern.

The inspection team notes that the success rates are consistent with the national average and the centre's multiple clinical pregnancy/live birth rates are likely to meet the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve clinical pregnancy/live birth rates and the centre's compliance, and thus the service provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team recommends the renewal of the centre's Treatment 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 0336 has only on 30 September 2019 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, however the executive requested that the certificate be issued to run until 26 November 2023 given the ongoing licence renewal process, as is standard practice. Therefore renewal of the centre's ITE import certificate is not necessary at this licence renewal.

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, notwithstanding the non compliance related to third party agreements and imported sperm discussed below. 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 compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos, notwithstanding the non compliance related to third party agreements and imported sperm discussed below. 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
Nothing identified at this inspection.

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 satellite/transport facilities and 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 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 note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements, notwithstanding the non compliance related to imported sperm discussed below. 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 partially compliant with HFEA requirements.

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 TCSs 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 partially 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 (TPAs) (Guidance note 24)
The centre's third party agreements including those associated with ITE/TCS import certificates, are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 actions taken by the centre in response to the Grade A incident reported in October 2018 were reviewed on inspection, as were the changes in processes to prevent recurrence. The inspection team considers the actions taken and changes made are thorough, suitable and appropriate.

The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has reported all adverse incidents (including serious adverse

events and reactions) to the HFEA. The centre has investigated 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

Medicines management (Guidance Note 25)
Recently expired drugs were stored in the laboratory refrigerator (SLC T2; recommendation 4).

QMS (Guidance note 23)
Non conformances in quality indicator (QI) monitoring (e.g. breaches of clinical pregnancy rate control limits by ICSI practitioners), their investigation and corrective actions, are not documented effectively. Furthermore, effective monitoring of some QIs was hindered because their control charts did not reflect data accurately due to calculation errors (SLC T35; CoP Guidance 23.20). It is noted that these issues will be addressed in the near future, because the centre is soon implementing the non conformance monitoring module in their electronic QMS support software and new QI control charts are being prepared.

Not all processes are subjected to observational audit every two years, for example the processes used to achieve gamete and embryo freeze/thaw; semen preparation; IVF insemination; and training use of embryos. In addition, where performed, observational audits do not state the person who was observed performing the process (SLC T36). It is noted that these issues will be addressed in the near future, because observational audits of all processes are being developed within new competence assessment frameworks for clinical and laboratory staff.

Three SOPs were out of date and had not been reviewed in the last two years, so were at risk of not reflecting current best practice guidelines and regulatory requirements. The SOP for administering the cryobank and monitoring storage consent, incorporating an effective bring forward system, is in preparation but needs to be implemented (SLC T33b).

Recommendation 1.

Third party agreements (Guidance note 24)
Imports and exports (Guidance note 16; General Direction 0006)
The TPAs with donor sperm banks in the European Union supplying the centre, contain non compliant donor reimbursement arrangements (General Direction 0001; SLC T116).

The centre has not effectively evaluated the compliance of services provided by third parties, including these suppliers of donor sperm, with HFEA requirements and the terms of the relevant TPAs (SLCs T36 and T112). For example, evidence was not available for the compliance of donor compensation and screening processes applied by donor banks generally (SLCs T36 and T112) or for each specific donor (General Direction 0001 and SLCs T52 and T53). Thus evidence was not present for the compliance of some imports of donor sperm with the requirements of General Direction 0006.

Recommendation 2.

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)
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 does not undertake embryo testing therefore these guidance notes were not relevant 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. Fifty two patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. A large majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff for being supportive, understanding and compassionate and praising the quality of the premises and treatment facilities at the centre. There were very occasional negative comments, which were already known to the PR and had led to management team reviews and corrective actions being implemented.

The centre's own most recent patient survey responses were also reviewed. Feedback was very good and comparable to that provided to the HFEA.

During the inspection the inspectors spoke to two patient couples who also provided positive feedback on their experiences, notably regarding the support provided to them by staff and the quality of the premises and facilities.

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, comfortable and well organised environment for patient treatment;
- has staff who are supportive and professional who treat patients with empathy, compassion and understanding;
- gives patients 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 patients fairly

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.

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 sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipients (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatments involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and 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, notwithstanding the concerns related to consent to the storage and use of embryos in training discussed below. 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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At those inspections in March 2017 and July 2018, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. 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 partially 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

Use of embryos for training staff (Guidance note 22)
The centre had transferred two sets of embryos to a storage dewar reserved for embryos to be used in training, after the gamete providers had indicated that they no longer wished to use the stored embryos in treatment. When doing this, the centre relied on the consent to use in training documented in the treatment consent forms (MT and WT) completed prior to treatment and before the embryos were stored. The gamete providers have not completed specific consents to the use of embryos in training.

In the absence of specific consents to the use of embryos in training, the inspection team questions whether the consents to use in training in the MT and WT forms are valid because:

- the MT and WT consents are provided prior to treatment and subsequent storage of 'spare embryos', while the potential use in training is occurring some time later at the end of storage;
- when patients are asked to consider their ongoing consent to storage, they are asked if they wish to consent to their embryos being removed from storage and allowed to perish, not to be used in training, and no information is provided to them regarding the use of embryos in training at this time.

It should be noted that the embryos, though allocated to and stored for training, have not actually been used in training. The original storage consents cover the period of storage in the 'training' dewar, though the validity of these storage consents is questionable given the gamete providers consented to their embryos being removed from storage and allowed to perish, albeit HFEA withdrawal of consent (WC) forms were not completed.

The inspection team is concerned that the centre is in breach of Schedule 3 of the HF&E Act 1990 (as amended) regarding the on-going storage of the embryos and would also be so if the embryos were to be used in training.

Recommendation 3.

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. The HFEA register audit team found no evidence of any systemic problems with the timeliness and accuracy of the centre's submission of data to the Register.
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in July 2018, recommendations for improvement were made in relation to three areas of major non compliance and two 'other' areas of non compliance.

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 PR has not been sent any risk tool emails concerning the centre's success rates in the last two years.

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			

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
1. QMS Non conformances in QI monitoring, their investigation and corrective actions, are not documented effectively. Furthermore, monitoring of some QIs was hindered because their control charts contained calculation errors (SLC T35; CoP Guidance 23.20). Not all processes are subjected to observational audit every two years, for example the processes used to achieve gamete and embryo freeze/thaw; semen preparation; IVF insemination; and training use of embryos. In	The PR should ensure that the QMS is functioning effectively. The centre is already implementing some plans to address this recommendation: • Activating the non conformance monitoring module in the electronic QMS support software; • new QI control charts are being prepared; • Implementation of a wider process audit schedule as part of new competence assessment frameworks for laboratory and clinical staff;	Non conformance monitoring module is live and functioning on electronic QMS support software (Q-Pulse). TFP Group QI schedule being implemented by the Group Quality Manager. Email being sent to lead inspector from Group Quality Manager to explain new schedule. Revised process audit shedule will be in place and	The inspector notes the PR's comments and the evidence provided by the centre and the Fertility Partnership Group Quality Lead, of actions which have addressed, or which will in future address, the multiple aspects of this non compliance within the timeframes specified in this report. The inspector notes that the completion date is close to the date on which this inspection report is to be considered by the ELP. This situation has been produced by the report being delayed in writing and

addition, where performed observational audits do not state the person who was observed performing the process (SLC T36). Three SOPs reviewed were out of date and had not been reviewed in the last two years. The SOP for administering the cryobank and monitoring storage consent, incorporating an effective bring forward system, remains to be implemented (SLC T33b).	• The SOP for administering the cryobank and monitoring storage consent, needs to be finalised and implemented. The PR should ensure these plans are implemented by 12 October 2019 and should report the actions taken, along with any actions still to be completed, to the centre's inspector on this date. The PR should ensure that SOPs are reviewed at an appropriate periodicity and are up to date by 12 October 2019. The centre's inspector should be advised of the actions taken to achieve this on 12 October 2019.	implemented by the 12th October. Administration of the Cryostorage Bank and the revised Bring forward system SOP (SF01-SOP-EMB-0098) will be activated and implemented by the 12th October. The three SOPs were to be made obsolete as were no longer in use. These were made obsolete on the date of the inspection as per PR's request. The document control system (Q-Pulse) alerts owners of documents to review on a yearly basis. The Quality Manager is now overseeing this by also running a monthly report of documents due for review and liasing with relevant staff members to ensure compliance.	the PR being ill. The inspector is confident that the actions will be implemented on time and will follow up with the centre to ensure this occurs. The inspection will monitor the centre thereafter to ensure the actions are effective and ensure compliance. **Further actions required**
2. TPAs and Imports of sperm The TPAs with donor sperm banks in the EU supplying the centre, contain non compliant donor	The PR should ensure that TPAs include all HFEA requirements relevant to the services provided. Before third party services are engaged,	TPA's being reviewed at Group level. There is now a TFP Group Procurement Manager in place who is ensuring all TPA's are included within	The inspector notes the PR's comments, discussions with the Fertility Partnership Group Quality Lead and other evidence provided by the

reimbursement arrangements (General Direction 0001; SLC T116). The centre has not effectively evaluated the compliance of services provided by third parties, including suppliers of donor sperm, with HFEA requirements and the terms of the relevant TPAs (SLCs T36 and T112). For example, evidence was not available for the compliance of donor compensation and screening processes applied by donor banks, generally (SLCs T36 and T112), or for each specific donor (General Direction 0001 and SLCs T52 and T53). Thus evidence was not present for the compliance of some imports of donor sperm with the requirements of General Direction 0006.	including suppliers of donor sperm, the PR should evaluate their compliance with HFEA requirements and the terms of the relevant TPAs. Evidence supporting the evaluation should be retained. On-going compliance should be audited at least every two years. For individual donor sperm samples imported under General Direction 0006, specific evidence for the compliance of the sperm with HFEA requirements (e.g. General Direction 0001 and SLCs T52 and T53) should be collected and stored by the centre. Evidence of the implementation of these recommendations should be provided to the centre's inspector by 12 December 2019.	Contracts. Email being sent to lead inspector from Group Quality Manager to explain this. An Auidit of all stored donor spem to be carried out to check compliance by the 12th October 2019 Our SOPs for importing gametes inside and outside of the EEA or Gibraltar have now been revised - please see attachments. All lab staff are fully aware of the recommendations and the revised SOP.	centre of actions taken which have addressed, or which will address, the multiple aspects of this non compliance, within the timeframes specified in this report. The inspector will continue to monitor the centre to ensure the recommendation is fully implemented and actions taken are effective and ensure compliance. **Further actions required**
3. Consent to use of embryos in training	The PR should ensure that the use of embryos in training is only undertaken when	We do accept that the consent form specific in the use of embryos in training needs to	The inspector notes the PR's comments and proposed actions, and further

The centre has two sets of embryos stored in a dewar allocated to storage for use in training, after the gamete providers indicated that they no longer wished to use the stored embryos in treatment. When doing this, the centre relied on the consent to use in training documented in the treatment consent forms (MT and WT) prior to treatment and before the embryos were stored. The gamete providers have not complete specific consents to the use of embryos in training and have in fact specified that their embryos should be removed from storage and allowed to perish. The inspection team questions whether there is valid consent for the ongoing storage and use in training of these embryos, for reasons discussed in the main body of the report. If there is no consent, the centre is in breach of Schedule 3 of the HF&E Act 1990 (as amended).	effective consent to this activity has been provided by the gamete providers. A consent form specific to the use of embryos in training should be completed by patients as part of the withdrawal of consent to storage process, if the patients wish their embryos to be used in this manner. Specific information regarding the use of embryos in training must be provided prior to the completion of this consent form The centre's inspector should be advised of the actions taken to implement this recommendation by 12 October 2019.	be completed as part of the withdrawal of consent to storage process. Revised Consent form will be in place and implemented by the 12th October.	communications, which will address this non compliance, within the timeframes specified in this report. The inspector notes that the completion date is close to the date on which this inspection report is to be considered by the ELP. The inspector will continue to monitor the centre to ensure the actions are implemented on time and are effective and ensure compliance. **Further actions required**

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
4. Medicines management: Recently expired drugs were stored in the laboratory refrigerator (SLC T2).	The PR should ensure drugs are immediately removed from use and are destroyed when they reach their expiry date. Evidence of the implementation of these recommendations should be provided to the centre's inspector by 12 October 2019.	We can confirm our Medicine Management SOP states that our Anaesthetic drugs are checked on a monthly basis - please see attached. A monthly checklist for Anaesthetic and emergency Anaesthetic drugs is now in place - please see attached. All nursing staff have been advised of new check list and change to SOP.	The lead inspector notes the PR's comments and the evidence provided of actions taken which will address this non compliance. No further actions are required.

Reponses from the Person Responsible to this inspection report
We felt that this inspection was very thorough and conducted in a professional manner. We welcome all the comments from the inspection team and will work to complete all the recommendations within the allocated time frame.