Executive Licensing Panel - minutes

Centre 0336 (Simply Fertility) Interim Inspection Report, Variation of Licensed Activities and Change of Premises

Friday, 19 May 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Anjeli Kara Hannah Verdin	Director of Strategic and Corporate Affairs Regulatory Policy Manager Head of Regulatory Policy
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

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:

- 8th 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 an application form, report and licensing minutes for the past three years.

1.2. The panel noted that Simply Fertility, centre 0336 is located in Essex. The centre has held a treatment (insemination using partner/donor sperm) and storage licence with the HFEA since August 2013. The centre is also a satellite centre to Boston Place (centre 0327). As part of The Fertility Partnership, a group of licensed centres, centre 0336 shares staff, experience and documentation, including Standard Operating Procedures (SOPs) and form templates.

1.3. The panel noted that the inspection took place on 22 March 2017.

1.4. The panel noted that in the 12 months to 31 December 2016, the centre provided one cycle of stimulated intrauterine insemination using partner sperm and thirteen cycles using donor sperm. The centre reported one pregnancy using partner sperm and one pregnancy using donor sperm. These success rates were in line with national averages. In relation to activity levels this is currently a small centre.

1.5. The panel noted that the Person Responsible (PR) wishes to vary the centre's licence to reflect a change of premises, to relocate to new, purpose-built premises. There will be no change to the centre's address as the new premises are located on the existing Essex Health Park site and adjacent to Baddow Hospital. The centre also wishes to vary the licensed activities, to provide a full range of fertility services.

1.6. The panel noted that the new premises are designed to accommodate up to 800 IVF/ICSI/FET and 200 DI/IUI treatment cycles per year. The PR plans to increase the centre's activities gradually, with staffing and other resource levels, after a licence is obtained. The PR anticipates that no greater than 150 to 170 treatment cycles will be conducted in the first year.

1.7. The panel noted that at the time of the interim inspection on 22 March 2017, eight major and two other areas of non-compliance were identified. Since the inspection the PR has fully implemented most of the recommendations and will provide an update summary of audits conducted, to ensure the corrective actions taken are effective, where required and within the set timescales.

1.8. The panel noted that most of the recommendations in this report address non-compliances relating to the proposed new activities and premises which are currently in development and not being used for licensed activity. The panel noted that the inspectorate considers that there is sufficient information available to recommend the approval of the centre's application to vary the licence to a full treatment and storage licence, subject to the recommendations made in this report being implemented within the timescales specified and before the commencement of the proposed new licensed activities.

1.9. The panel noted that this variation represents a significant change to the centre's licensed activities and therefore, the inspectorate recommends an interim inspection is conducted within one year of this licence variation coming into force.

1.10. The panel noted that, if this application is approved, there will be a short period after the licence is varied, during which time cryopreserved samples will remain at the existing premises. Special Directions have therefore been requested by the PR to be in force from the date this licence is varied for a period of one month, to allow for the storage of gametes at the existing premises which will no longer be licensed, until they are relocated to the new licensed premises. The inspectorate considers the storage facilities at the existing premises to be suitable and satisfactory arrangements have been made by the PR for ongoing security and suitability during the term of the Special Directions. The inspectorate also considers that the PR has made appropriate arrangements for the safe movement of stored material to the new licensed premises and recommended the approval of the application for Special Directions, under delegated powers, provided by Section 24 5A of the HF&E Act 1990 (as amended).

2. Decision

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

2.2. The panel agreed that the centre was fit to continue providing the services under its current licence and approved the centre's application to vary the licence to reflect a change of licensed activities to provide a full range of fertility services. However, the panel expects that the new activities will not commence until the non-compliances are fully addressed to the satisfaction of the inspectorate, to ensure the safety and suitability of the premises and facilities.

2.3. The panel approved the centre's application to vary the licence to reflect a change of premises to new, purpose-built premises, located on the existing Essex Health Park site, adjacent to Baddow Hospital.

2.4. The panel also endorsed the inspectorate's recommendation to issue Special Directions, under Section 24 5A of the HF&E Act 1990 (as amended), to be in force from the date the licence is varied for a period of one month, to allow for the storage of gametes at the existing premises, which will no longer be licensed, whilst they are relocated to the new licensed premises.

2.5. The panel endorsed the inspectorate's recommendation to conduct an inspection within one year of the licence variation coming into force.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

30 May 2017

Variation of licence and interim inspection report

Centre name: Simply Fertility
Centre number: 0336
Date licence issued: 27 November 2015
Licence expiry date: 26 November 2019
Additional conditions applied to this licence: None
Date of inspection: 22 March 2017
Inspectors: Grace Lyndon (lead) and Douglas Gray
Date of Executive Licensing Panel: 19 May 2017

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. Inspections may also be carried out when centres apply to vary their licence to add activities or to change their premises.

This centre has applied to vary its licence to change both its premises and licensed activities, the licence type being varied from a Treatment (insemination using partner / donor sperm) and Storage licence to a Treatment and Storage licence so that a full range of fertility services can be provided. The centre was due for an interim inspection when this application was submitted; it was therefore considered appropriate to combine the licence variation inspection with a standard interim inspection of the insemination and storage activities currently undertaken.

This report presents the findings of a desk-based review of documents provided in support of the licence variation application and an on-site inspection of the proposed new premises, to assess the compliance of the centre's licence variation application. An on-site interim inspection of the centre's current activities and premises was also performed and the findings are also presented.

The Authority's Executive Licensing Panel (ELP) uses the report to determine whether the current licence should continue. It will also use the licence variation application and this report to decide whether to grant the licence variation and, if so, whether any additional conditions should be applied to the licence.

Background

Simply Fertility has held a Treatment (insemination using partner / donor sperm) and Storage licence with the HFEA since August 2013 when a two-year licence was granted; this is the usual term for an initial licence. The centre is currently situated within, but operates separately from, Baddow Hospital, Chelmsford, which is a small independent hospital providing day case surgery. Treatments provided at the centre currently include: partner insemination, donor insemination and storage.

In the 12 months to 31 December 2016, the centre provided one cycle of stimulated intrauterine insemination using partner sperm (IUIp) and thirteen cycles of donor insemination (DI) and reported one IUIp pregnancy and one DI pregnancy from these treatments. These success rates are in line with national averages. In relation to activity levels this is currently a small centre.

Other licensed activities at the centre include storage of sperm and recruitment of sperm donors.

Simply Fertility is a satellite centre to Boston Place (centre 0327) and is part of The Fertility Partnership group of licensed centres, which includes Boston Place, Oxford Fertility, IVF Hammersmith, GCRM Glasgow and Nurture. Documents such as standard operating procedures (SOPs) and form templates are exchanged between the centres, as is experience via cross over and sharing of experienced staff.

The Person Responsible (PR) submitted an application in October 2016 to vary the centre's licence to reflect a relocation to new premises and to provide a full range of fertility services. The centre is relocating to new, purpose-built premises on the same site adjacent to Baddow Hospital.

The centre has applied to add the following licensed activities to its licence, thus varying the licence to a Treatment and Storage licence:

- Creation of embryos in vitro
- procuring embryos
- keeping embryos
- processing embryos
- storage of embryos
- placing any permitted embryo in a woman

The new premises are designed to accommodate up to 800 IVF/ICSI/FET and 200 DI/IUI treatment cycles per year. The PR suggests however that the centre's activity will increase gradually after a licence is obtained, commensurate with staffing and other resource levels, and he anticipates no greater than 150 to 170 treatment cycles will be conducted in the first year.

Summary and recommendations for the Executive Licensing Panel

In considering overall compliance, the inspection team considers that there is sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the current premises are suitable
- the current practices are suitable
- the new premises to be used if the licence is varied are suitable
- the proposed practices to be used if the licence is varied are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for the variation of their licence to change the premises and activities licensed
- 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 assessment there were a number of areas of practice that require improvement, comprising eight major and two other areas of non-compliance or poor practice.

Since the inspection visit, the following recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update summary of audits conducted, to ensure the corrective actions taken are effective.

Major areas of noncompliance:

- The PR should ensure that the emergency trolley is properly equipped and stocked.

- The PR should review the quality management system (QMS) to ensure processes are in place, and are documented in SOPs and monitored by quality indicators (QIs), for all activities undertaken, and that it contains an appropriate mechanism to act upon changes to regulatory requirements and best practice guidance to embed them in the centre's practices.

- The PR should consider the most recent guidance regarding the risk of Ebola virus infection in patients and their partners, and in donors, and should revise the centre's procedures and practices in line with the guidance.

- The PR should ensure that relevant staff are provided with training relating to their areas of practice;

- The PR should ensure that the processes and procedures for the management of medicines are compliant with all regulatory requirements and guidance.

- The PR should ensure that all critical equipment to be used in the proposed new activities is validated.

Other area of noncompliance

- The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority.

- The PR should ensure that action is taken to minimise any infection control risks posed by the observations cited in this report.

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

Major areas of noncompliance:

- The PR should ensure that all the critical processes to be used in the proposed new activities are validated.

- The PR should ensure that the proposed new premises are compliant, i.e. that the access control system is fully functional and a final deep clean and confirmatory air quality testing are undertaken.

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

The inspection team also considers that there is sufficient information available to recommend that the ELP approves the centre's application to vary the licence to a full Treatment and Storage licence. The inspection team notes that there will be no change to the centre's address as the new premises are located on the existing Essex Health Park site and adjacent to Baddow Hospital.

The inspection team notes that most of the report's recommendations address non compliances related to the proposed new activities and premises, which are the subject of the licence variation application and are currently in development and are not being used for licensed activity. The licensing recommendation is subject to the recommendations made in this report being implemented within the timescales specified and before the commencement of the proposed new licensed activities, as the PR has committed to do.

As this variation represents a significant change to the centre's licensed activities, the inspection team recommends an interim inspection to be conducted within one year of this licence variation coming into force.

Assuming the ELP approves this application, there will be a short period after the licence is varied during which cryopreserved samples will remain at the existing premises. A Special Direction has therefore been requested by the PR to be in force from the date this licence is varied for a period of one month, to allow for the storage of gametes at the 'old' premises until such time as they are relocated to the new premises. The inspection team considered the storage facilities at the 'old' premises to be suitable and note that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. The

executive also considers that the PR has made appropriate arrangement for the safe movement of stored material to the new premises. It is recommended therefore that the ELP approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended)).

Details of Inspection findings

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 current procedures for double checking the identification of gametes and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

The procedures to be used to double check the identification of gametes and embryos and the patient or donor to whom they relate, in future while performing the new activities proposed by the licence variation, are broadly compliant with HFEA requirements.

What the centre could do better

Witnessing (Guidance note 18)
The centre's witnessing SOP does not cover witnessing processes to be used while undertaking the proposed new activities (recommendation 5: SLC T33b).

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 practices for screening sperm and egg donors under their satellite arrangement with Boston Place were considered broadly compliant with HFEA requirements at the last renewal inspection. After that inspection, the executive was assured by the PR that recommendations were fully implemented. During this inspection, the inspection team considered the centre's practices for screening egg and sperm donors to be broadly compliant.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures for giving and receiving money or other benefits in respect of any supply of sperm were considered compliant with HFEA requirements at the

time of the last renewal inspection.

The centre's proposed practices for making payments to egg donors are also compliant with HFEA requirements.

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, should be 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.

What the centre could do better

Screening of donors (Guidance note 11)
The centre have not acted upon guidance issued by the HFEA regarding the need to consider the risk of Ebola virus infection in donors (recommendation 1: SLC T52).

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 current premises are suitable. The proposed new premises were partially suitable at the time of the inspection. Suitable premises are important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre's current and proposed procedures are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

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

The centre is currently compliant with HFEA requirements which ensure that gamete processing is performed in an environment of appropriate air quality. The proposed new premises are only partially compliant with these requirements.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which will 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 for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre's current systems to manage and monitor the prevention and control of infection are compliant with guidance. The proposed systems which will be used for this purpose if the licence is varied are broadly compliant with guidance.

Medicines management
The centre does not currently use controlled drugs. The proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of controlled drugs and other medicines, if the licence is varied, 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 is undertaken by a third party and was considered by the inspection team to be suitable. The centre's process for managing patients before and after intralipid therapy was partially compliant. These processes will also be used when necessary during the proposed new licensed activities.

Pre-operative assessment and the surgical pathway
The centre has procedures in place which will also be used for the proposed new licensed activities. These procedures are broadly 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 current and proposed procedures are compliant with HFEA multiple births minimisation strategy requirements, where relevant, 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 current and proposed new 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:
- to keep a record of home-based sperm procurement in the gamete provider's records.

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

- packaged and transported in a manner that minimises the risk of contamination and preserves their characteristics and biological functions;

- shipped in a container that is designed for the transport of biological materials and that maintains their safety and quality;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- transported in a secure container/package which ensures that they 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 the proposed procedures for the receipt of 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 supplied with 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 does not intend to import or export gametes or embryos, therefore this area of practice was not reviewed.

Traceability (Guidance note 19)
The centre's current and proposed additional 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,
- 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 in place which will support the proposed new activities 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 (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre currently provides a satellite service to Boston Place. The PR advised that this agreement will end when the licence variation is approved and that the centre has no immediate plans to enter into any further satellite or transport agreements.

Equipment and materials (Guidance note 26)
The centre currently uses equipment and materials that are compliant with HFEA requirements, including CE marking and validation.

The centre proposes to use equipment and materials that are compliant with HFEA requirements when undertaking the proposed new activities, however the centre at the time of the inspection was partially compliant with HFEA requirements to validate the critical equipment to be used in the proposed new activities, some of which has not yet been installed.

All of the equipment and materials to be used in licensed activity are and will be designated for the purpose and appropriately maintained in order to minimise any hazard to patients and/or staff.

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 current procedures are compliant with HFEA requirements to validate critical processes, however the procedures to be used to provide the proposed new activities are only partially compliant with these requirements. Process validation is important to ensure that 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 were considered compliant with HFEA requirements at the time of the last renewal inspection. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA and investigates them appropriately. 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

Safety and suitability of premises and facilities (Guidance note 25)
The proposed new premises are partially compliant because:

- The access control system on the main entrance and internal doors has yet to be activated so the premises are not secure.
- Air quality testing in the critical work areas and background in relevant rooms has not yet been undertaken.
- The premises have not been subjected yet to a final deep clean.

(Recommendation 2: SLCs T17, T20 and T26.

Infection control (Guidance Note 25)
Infection control practices in the proposed new premises are partially compliant because:

- The consultation rooms, which may be used for phlebotomy, contain chairs covered with absorbent cloth which are not appropriate for clinical activities and pose an infection control hazard.
- The metal skirting boards have ridges and grooves which are difficult to clean and pose an infection control hazard. There were no special cleaning arrangements to ensure the grooves are kept clean.

(Recommendation 9: SLCs T2 and T17)

Medicines management (Guidance Note 25)
The current and proposed medicines management practices are partially compliant because:

- The centre does not have a process to ensure the availability of drugs out of hours in a manner compliant with medicines management regulations and best practice guidance.
- The reasons for prescribing reproductive immunology treatments are not recorded clearly in the patient's medical records.
- The centre does not have a process to follow up patients after they have received intralipid treatment.

The proposed medicines management practices are partially compliant because:

- The centre does not have a controlled drugs record book in which to document the delivery, usage and disposal of controlled drugs.
- The controlled drugs cupboard has not yet been assessed by Home Office inspectors as secure.

(Recommendation 3: SLCs T2 and T33).

Pre-operative assessment and the surgical pathway (Guidance Note 25)
Both of the emergency trollies were missing a number of items recommended as contents by the Resuscitation Council including;

- Portable suction pumps
- Some emergency drugs
- Ambui-bags
- Spare batteries for the laryngeal scope
- Emergency intra venous fluids

(Recommendation 4: SLCs T2 and T17)

Quality management system (Guidance note 23)
The QMS which will support the current and proposed new activities was partially compliant because:

- Quality Indicators(QIs) have not yet been established for some critical processes.
- Processes have not been established and / or documented in SOPs for a number of important activities discussed elsewhere in this report, for example:
    i. Patient follow up after intralipid treatment

ii. Vitrification and warming of eggs and embryos
iii. Witnessing during the processes used to deliver the proposed new activities.
iv. Donor recruitment and assessment
v. Clinical practices used in the procedure room and during post procedure recovery

- The QMS failed to respond to changes in best practice guidance concerning Ebola virus infection risks in patients, their partners, and donors.

(Recommendation 5: SLCs T32, T33b, T35).

Equipment and materials (Guidance note 26)
The critical equipment to be used for the proposed new activities has not yet been validated (recommendation 6: SLC T24).

Process validation (Guidance note 15)
The critical processes to be used to provide the proposed new activities have not yet been validated (recommendation 7: SLC T72).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of science and embryology 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 T1191/8.

Staff (Guidance note 2)
The centre has suitably qualified and competent staff, in sufficient number, to carry out the current licensed activities.

The centre is partially compliant with the requirement to have suitably qualified and competent staff to undertake the proposed new activities in the licence variation application.

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

Staff (Guidance note 2)
The centre is partially compliant with the requirement to have suitably qualified and competent staff to undertake the proposed new activities because further training and / or competence assessment of staff in some of the proposed activities is required: e.g.: The donor recruitment and screening process; Clinical practice in the procedure room and during post procedure recovery; Use of the RI electronic witnessing system; Use of QPulse; Use of Embryo scope (recommendation 8: SLCs T12 and T15a).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's current and proposed procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided were considered compliant with HFEA requirements at the time of the last renewal inspection.

Safeguarding
The centre's procedures were considered compliant with HFEA requirements at the time of the last renewal inspection. 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 has not applied to conduct these activities as part of this variation and therefore not applicable.

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

2. The experience of patients

Patient feedback

What the centre does well

There were no patients attending the centre for the inspection team to speak to.

Four patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- 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 and sperm 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 to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way were considered compliant at the last renewal inspection.

Counselling (Guidance note 3)

The centre's current and proposed counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients undertaking licensed treatment activities, before they provide consents to treatment or legal parenthood.

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

The centre's egg and sperm sharing arrangements for use during the proposed new

activities 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 mentally suitable, and
- the benefit offered is the most suitable for the egg provider and recipients.

Surrogacy (Guidance note 14)
The centre's proposed procedures for surrogacy arrangements 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 to seek patient feedback and to be responsive to patient complaints were considered compliant at the time of the last renewal inspection. 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 current and proposed 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; CH(11)02)
The centre's current and proposed procedures for providing information to patients and donors are compliant with HFEA requirements. This is important to ensure 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 current and proposed procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided, and will provide, all relevant consents before carrying out any licensed activity.

Legal Parenthood (Guidance note 6)

When a couple to be treated with donated gametes are 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.

In February 2014, the HFEA asked all centre's to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre did not send an audit report but advised the centre's inspector that it had not undertaken any relevant treatments as it had only been licensed since November 2013. In October 2015, the HFEA requested a full statement from centres to be assured that all errors have been identified and that such errors will not occur in the future. The centre provided a response that they had completed a legal parenthood audit that was comprehensive and that their current procedures for obtaining consent to parenthood were robust.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. No errors were identified.

The inspection team consider the centre's procedures for obtaining consent to legal parenthood are compliant with legal parenthood requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

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

The centre's procedures for taking consent to disclosure to researchers were considered compliant with HFEA requirements at the last renewal inspection.

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 proposed procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting the proposed licensed activities:

- licensed activities will only take place on licensed premises;
- only permitted embryos will be used in the provision of treatment services;
- embryos will not be selected for use in treatment for social reasons;
- embryos will not be created by embryo splitting;
- embryos will only be 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 will only be 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
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's current and proposed procedures for screening patients and their partners are broadly 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 current procedures for storing gametes were considered compliant during the last renewal inspection and after assessment on this inspection.

The centre's proposed procedures for storing embryos were also reviewed at this inspection and were considered compliant with HFEA requirements.

These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. 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
Screening of patients (Guidance note 17)
The centre has not acted upon guidance issued by the HFEA regarding the need to consider the risk of Ebola virus infection in patients and their partners (recommendation 1: SLC T50).

Use of embryos for training staff (Guidance note 22)

What the centre does well
Use of embryos for training staff (Guidance note 22)
The centre's proposed procedures for using embryos for training staff are compliant with HFEA requirements. Embryos will only be used for the purpose of training staff in activities expressly authorised by the Authority.

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

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)

The centre's procedures for keeping records to ensure that accurate medical records are maintained were considered compliant at the last renewal inspection. 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 current and proposed procedures for submitting information, about licensed activities to the Authority, are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Nothing identified at this inspection.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in 2015, recommendations for improvement were made in relation to six major and one 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in September 2015, the centre has not been issued with any performance alerts related to their DI activities and are not subject to monitoring for the partner IUI treatments.

The centre has received nine risk tool alerts related to the late payment of fees. On average fees were paid 56 days after the invoice was issued. In discussions held during this inspection, the PR provided a commitment to ensure payments are made within the allotted timeframe (recommendation 10; SLC T9d).

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, 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 child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Screening of donors, patients and their partners The centre does not consider the risk of Ebola virus infection in patients and their partners, and in donors. SLCs T50 and T52	The PR should consider the most recent guidance regarding the risk of Ebola virus infection in patients and their partners, and in donors. The centre’s procedures and practices should be revised in line with the guidance and staff training in the revised procedures should be provided. This recommendation should be implemented by the time the report is returned to the centre’s inspector and definitely by the time the	The Group Screening Policy, Patient information leaflet and relevant checklists have all been updated and attached to this report. All staff are aware of the new Ebola Guidance.	The Executive acknowledges the PR’s response and actions taken in response to this recommendation. No further action required.

	inspection report is considered by a licensing committee. Evidence of the actions taken should be provided to the centre's inspector at the first opportunity.		
2. Safety and suitability of premises and facilities The proposed new premises are partially compliant because: • The access control system on the main entrance and internal doors has yet to be activated. • Air quality testing has not yet been undertaken. • The proposed new premises have not been subjected yet to a final deep clean. SLCs T17, T20 and T26.	The PR should ensure that the proposed new premises are suitable for the activities to be undertaken there. Actions should include the activation and validation of the physical security arrangements, such as the access control system, as well as air quality testing and deep cleaning of relevant areas. Actions should be implemented, if possible, by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee. Evidence of the implementation of actions	Activation of the Door Access has been purposely delayed for logistical reasons and will now be fully operational from 11 May 2017. A full deep clean with laboratory air quality testing for validation purposes will be completed by Friday 12 May 2017. The results of which will be presented to the Inspector. Previous lab validation testing post build qualified the whole lab space as compliant for Grade C at rest.	The Executive acknowledges the PR's response. The PR should provide confirmation that security measures are fully operational and provide evidence of appropriate air quality following the deep clean when completed. Further action required

	should be provided to the centre's inspector at the first opportunity.		
3. Medicines management The current and proposed medicines management procedures are partially compliant because: • The centre does not have a process to ensure the availability of drugs out of hours in a manner compliant with medicines management regulations and best practice guidance. • The reasons for prescribing reproductive immunology treatments are not recorded clearly in the patient's medical records. • The centre does not have a process to follow up patients after they have received intralipid treatment. The proposed medicines management practices are partially compliant because: • The centre does not have a	The PR should ensure that the current and proposed medicines management procedures are compliant with all regulatory requirements and guidance. The PR should review the medicines management procedures, seeking external advice if necessary, and should revise them to ensure compliance with all regulatory requirements. Focus areas should include, but not be restricted to, drug dispensing out of hours and practice around the use of intralipid therapy. The PR should also acquire an appropriate controlled drugs record book and ensure that the controlled drugs cupboard is inspected by the Home Office and signed off as	The Medicines Management SOP has been updated to include out of hours availability. The SOP is attached to this report. The PR can also confirm that all members of the nursing team have had external medicines management training. The nursing team have reviewed and amended the Intralipid Infusion SOP to include a section on documenting the reasons for prescribing in the patient records and to include the procedure for the follow up of patients where Intralipids have been administered. All staff are aware of the changes made. The Controlled Drugs license has been issued and a full inspection has been arranged by the home office on 31 May 2017. A full report will be issued to the HFEA and any recommendations will be	The Executive acknowledges the PRs response and actions taken to implement this recommendation. No further action required

controlled drugs record book in which to document the delivery, usage and disposal of controlled drugs. • The controlled drugs cupboard has not yet been assessed by the Home Office as secure. SLCs T2 and T33; The Misuse of Drugs (Safe Custody) Regulations 1973; NMC (2010) Standards for Medicines Management.	compliant. Actions should be implemented, if possible, by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee. Evidence of the implementation of actions should be provided to the centre's inspector at the first opportunity.	actioned immediately The cabinet style, location and relevant security has been deemed acceptable by the Home office inspector prior to the inspection (Previous verbal conversation with inspector). We do have a controlled drugs record book	
4. Pre-operative assessment and surgical pathway Both of the emergency trolleys were missing a number of items recommended as contents by the Resuscitation Council. SLCs T2 and T17	The PR should ensure that the equipment and materials on the emergency trolleys are as described by Resuscitation Council guidance This recommendation should be implemented by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee.	The emergency trolley is now fully complete as described by the Resuscitation Council and validated by one of the senior Anaesthetists who will be working with Simply Fertility. All known missing items reported on the day of inspection are now in place and daily checks are being recorded.	The Executive acknowledges the PR's response and implementation of this recommendation. No further action required

	Evidence of the implementation of actions should be provided to the centre's inspector at the first opportunity.		
5. The QMS The QMS was partially compliant because: • QIs have not yet been established for some critical processes. • Processes have not been established and / or documented in SOPs for a number of important activities discussed elsewhere in this report, for example: i. Patient follow up after intralipid treatment ii. Vitrification and warming of eggs and embryos iii. Witnessing during the processes used to deliver the proposed new activities iv. Donor recruitment and assessment v. Clinical practices used in the procedure room and	The PR should review the QMS and ensure its compliance with all CoP requirements. This should include the development of documented SOPs and QI monitoring where necessary for the proposed activities, and the implementation of an appropriate mechanism to act upon changes to regulatory requirements and best practice guidance to embed them in the centre's practices This recommendation should be implemented by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee.	QIs for all critical pathways have been established within the centre for all previous licensed activities and activities involved in the management of our satellite IVF patients. We have attached the QI SOP for your records. Also attached to this report are the new Laboratory KPIs. Attached to this report are the following SOPs: • Vitrification and Warming of eggs and embryos • Witnessing Process • Donor Recruitment and Assessment (this is an established SOP which was not asked for at the time of inspection) • Egg Collection • Moving and Safe Handling of Patients • Post Op Care Discharge • Admission of Patient to	The Executive acknowledges the PR's responses and implementation of this recommendation. No further action required

during post procedure recovery • The QMS failed to respond to changes in best practice guidance concerning Ebola virus infection risks in patients and their partners, and donors. SLCs T32, T33b and T35	Evidence of the actions taken should be provided to the centre's inspector at the first opportunity.	Recovery Suite • Operating Theatre The Screening SOP has been updated for Ebola inclusion and been added to the Zika Virus information leaflet. Both attached to this report.	
6. Equipment and materials The critical equipment to be used for the proposed new activities has not yet been validated SLC T24	The PR should ensure that all critical equipment is validated. This recommendation should be implemented by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee. Evidence of the actions taken should be provided to the centre's inspector at the first opportunity.	Critical equipment has been installed, calibrated and validated with relevant documentation. Individual validation documents can be requested for assessment A list of all critical equipment with the installation/calibration/validation dates is attached to this report	The Executive acknowledges the PR's response and implementation of this recommendation. The PR has submitted a spreadsheet confirming all but two items of equipment have been validated. The PR should provide confirmation the outstanding validation has been completed prior to proposed licensed activities commencing. Separate to this report, the centre's inspector will ask for copies of a sample of validation documents. No further action required

7. Process validation The critical processes to be used to provide the proposed new activities have not yet been validated. SLC T72	The PR should ensure that all the critical processes are validated. This recommendation should be implemented by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee. Evidence of the actions taken should be provided to the centre's inspector at the first opportunity.	Process validation will be an ongoing programme which begins once IVF and associated treatments commence. A process validation framework document has been developed and is attached to this report.	The Executive acknowledges the PR's response and commitment to fully implement this recommendation. For clarification, further confirmation has been provided by the PR that the centre will be using well established processing procedures which have been validated per published data. The centre will also perform a retrospective evaluation based on their own clinical results when they have sufficient treatment data to do so. The PR is to provide assurance that all critical processes have been validated against published studies or well established processing procedures prior to the commencement of the proposed licence activities. Further action required
8. Staff Relevant staff could not provide evidence of training or the assessment of their competence	The PR should ensure that relevant staff are provided with training relating to all the activities they undertake and	Staff training in a number of areas has been implemented on a daily basis and taken very seriously. To date all equipment has been	The Executive acknowledges the PR response and actions taken to implement this recommendation.

in certain areas of practice, specified in the main body of the report, which are required to deliver the proposed new activities. SLC T12/T15	that their competence to deliver those activities is assessed. This recommendation should be implemented by the time the report is returned to the centre's inspector and definitely by the time the inspection report is considered by a licensing committee. Evidence of the actions taken should be provided to the centre's inspector at the first opportunity.	demonstrated, offering a process for documented training and competency. In addition all processes involved in delivering an IVF service have been analysed and improved with an involvement of all staff. These structured meetings continue and are all documented. All staff employed by Simply Fertility have previous experience in IVF Programmes Competency of all staff has been considered by the PR and the PR is happy with the processes in place.	No further action 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
9. Infection control The following observations were made that could present an infection control risk: • The consultation rooms, which may be used for phlebotomy, contain chairs covered with absorbent cloth which are not appropriate for clinical activities and pose an infection control hazard. • The metal skirting boards have ridges and grooves which are difficult to clean and pose an infection control hazard. There were no special cleaning arrangements to ensure the grooves are kept clean. SLCs T2 and T17	The PR should ensure that action is taken to minimise any infection control risks posed by these observations, if necessary seeking independent expert advice. This recommendation should be implemented by the time the report is returned to the centre’s inspector and definitely by the time the inspection report is considered by a licensing committee. Evidence of the actions taken should be provided to the centre’s inspector at the first opportunity.	The additional chairs in the consulting rooms used for phlebotomy, other than the dedicated phlebotomy chair have been replaced. All infection control risks have been considered very carefully in the build The metallic Skirting with micro lines of less than 1mm are not considered to be a risk. Cleaning staff procedure has however been adapted to ensure that these are taken into consideration when cleaning consulting rooms	The Executive acknowledges the PR’s response and implementation of this recommendation. The cleanliness and efficacy of measures in place to minimise the risk of infection will be reviewed at the next inspection. No further action required

10. Person Responsible Fees payable to the HFEA are not always been paid within the required timeframe. SLC T9d.	The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescale specified by the Authority, and advise the centre's inspector of these actions when responding to this report.	The PR is aware that there have been delays in payment and will ensure that the finance department of the new facility has direct access to the portal to ensure timely payments.	The Executive acknowledges the PR's response and commitment to comply with HFEA requirement regarding the payment of fees. The efficacy of new arrangements will be monitored. No further action required

Additional information from the Person Responsible
The report is a fair representation of what was essentially three inspections in one day. I am sure that the inspection team were impressed with the state of the art facilities that we have built. As a team we were happy with report and believe that the responses made will satisfy the licensing committee.