Executive Licensing Panel - minutes

Centre 0057 (Wessex Fertility Limited) Renewal

Friday, 17 June 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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 a completed application form, inspection report, and licensing minutes for the last three years.

1.2. The panel noted that Wessex Fertility Limited, centre 0057 is located in Southampton, Hampshire. The centre provides a full range of fertility services including embryo testing. In relation to activity levels this is a medium-sized centre.

1.3. The panel noted that the centre has held a licence with the HFEA since July 1992.

1.4. The panel noted that in the 12 months to 31 January 2016, the centre provided 917 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period November 2014 to October 2015 showed the centre's success rates were in line with national averages with the following exception:

- success rates following ICSI in women under 38 years old were lower than average at a statistically significant level.

1.6. The panel noted that in 2015, the centre reported 27 cycles of partner insemination with two pregnancies. This success rate is likely to be in line with national averages.

1.7. Between 1 November 2014 and 31 October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 9%. This represents performance that will meet the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 23 and 24 February 2016, four major and three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has fully implemented some of the recommendations and has committed to fully implementing all of the outstanding recommendations.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices.

1.10. The panel noted that the centre has a Quality Management System in place and the PR is encouraged to use it to best effect to monitor and improve the service provided. The inspectorate will continue to monitor the centre's performance.

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

2. Decision

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

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

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

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

30 June 2016

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: 23 and 24 February 2016

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage

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

Inspectors: Vicki Lamb, Susan Jolliffe and Andrew Leonard

Date of Executive Licensing Panel: 17 June 2016

Centre name	Wessex Fertility Limited
Centre number	0057
Licence number	L/0057/17/b
Centre address	The Freya Centre, 72-74 Anglesea Road, Southampton, Hampshire, SO15 5QS
Person Responsible	Dr Sue Ingamells
Licence Holder	Dr Chantal Dominique Simonis
Date licence issued	1 August 2012
Licence expiry date	31 July 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Wessex Fertility Limited has held a treatment and storage licence with the HFEA since July 1992 and provides a full range of fertility services.

The centre provided 917 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a medium-sized centre.

On 16 August 2013 the ELP agreed to vary the centre's licence to add embryo testing, and thereby change the licence from treatment and storage to treatment (including embryo testing) and storage.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period November 2014 – October 2015 show the centre's success rates are in line with national averages with the following exception:

- success rates following ICSI in women under 38 years old are lower than average at a statistically significant level.

In 2015, the centre reported 27 cycles of partner insemination with two pregnancies. National data for this year has not yet been analysed but the centre's success rate for partner insemination is likely to be in line with national averages.

Multiple births[2]

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

Between 1 November 2014 and 31 October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 9%: this represents performance that will meet the 10% multiple live birth rate target for this period.

[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), the inspection team considers that it has sufficient information to conclude that:

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

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

Major areas of non compliance:

- The PR should ensure that gas cylinders are secured and stored safely, and clinical areas have appropriate floor coverings.
- The PR should ensure that all critical equipment is validated.

'Other' areas that require improvement:

- The PR should review the documentation used to ensure that imports and exports of gametes or embryos can be performed under General Directions 0006.

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

Major areas of non compliance:

- The PR should ensure all equipment and materials are traceable.
- The PR should ensure that all donors used in treatments are registered.

'Other' areas that require improvement:

- The PR should ensure that witnessing is recorded at all critical points during the clinical and laboratory processes.
- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms

Recommendation to the Executive Licensing Panel

The centre had no critical areas of concern but did have four major of areas of concern.

The inspection team notes that the centre's success rates are generally consistent with the national average and the multiple clinical pregnancy rates are below the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided. The inspector will continue to monitor the centre's performance.

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

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 broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Six sets of patient notes were reviewed. In one set a signature was missing for witnessing the receipt of sperm in the laboratory. The inspector was satisfied that the step had been witnessed and this was a documentation error only (SLC T71) (recommendation 5).

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

Donor assisted conception (Guidance note 20)

A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this 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)
It 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 partially compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

Laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are accredited and therefore considered 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 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 has systems in place to manage and monitor the prevention and control of infection that are partially compliant with guidance (see recommendation 1).

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
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;
- record in the gamete provider's records if the sperm is procured at home.

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. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and

has enough information to permit the gametes and embryos 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 broadly compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are partially 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 in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport centres but does have three satellite centres. The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by 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 of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share

the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities
Gas cylinders in the laboratory were not secured sufficiently to ensure that they remain in an upright position. Gas cylinders stored in the corridor restricted access to the fire exit. (SLC T17, Health Technical Memorandum 02-01: medical gas pipeline systems part B, Operational management) (recommendation 1).

The recovery area has an unsuitable floor covering (SLC T17, Health Building Note 00-09, page 11) (recommendation 1).

Imports and exports
The centre's documentation used to ensure an import of gametes or embryos can be performed under General Directions 0006 did not include all the requirements of General Direction 0006 schedule 3, although there was no evidence that any imports had occurred that were not compliant with General Directions 0006 (recommendation 6).

Traceability
Traceability training is not covered by the competence assessment and training framework for laboratory staff (SLC T12 and T15a) (recommendation 2).

Records are not kept of the flow hood and centrifuge used during gamete and/or embryo processing (SLC T22) (recommendation 2).

The batch recording system only records which day a batch of consumables was in use, so it was not possible to identify which batch of a consumable was used in a specific treatment if the batch was changed part way through the day of treatment (SLC T99) (recommendation 2).

Equipment and materials
The electronic witnessing system has not been fully validated through the normal centre procedures. Documents for primary validation are present, i.e. installation and functional qualification documentation, so the inspector was assured that a basic level of validation had been performed and was assured that regular maintenance of the system is planned through the suppliers (SLC T24) (recommendation 3).

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 medicine 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 (PREP

number T/1033/7).

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 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 are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

The centre ensures that people seeking embryo testing are given written information and every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further five patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with all five 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 and observations made in the course of the inspection 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;
- provides patients with satisfactory facilities for their care.

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 no longer offers egg sharing, therefore this guidance note is not relevant.

Surrogacy (Guidance note 14)
The centre's procedures for treatment 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. 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 are not married or in a civil partnership, both the woman and her partner must given 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 centres 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 complied with this request and took appropriate action with respect to the issues identified by the audit.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures to ensure on-going compliance with consent taking requirements are in place. The PR provided confirmation of this.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. No concerns were identified, therefore the inspection team concludes that the centre's procedures for taking consent to legal parenthood are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Disclosure of information, held on the HFEA register, for use in research
Two discrepancies from 17 records were found between completed patient/partner disclosure consents in patient files and the related consent data submitted for inclusion on the register. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent (CH(10)05 and General Directions 0005) (recommendation 7).

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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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 (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
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 HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information about licensed activities to the Authority are partially 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

Obligations and reporting requirements
At the time of the register audit inspection (8 December 2015) the centre had recorded four treatments using unregistered donors. By the time of the renewal inspection this had been reduced to two (General Directions 0005 and SLC T41) (recommendation 4).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, no recommendations for improvement were made.

On-going monitoring of centre success rates

Although in the last year the centre has not received any alerts regarding success rates, the PR is aware that success rates following ICSI in women under 38 years old are lower than average at a statistically significant level. She has performed a full review of practices and a potential cause was identified, along with acknowledgement that patient factors in recent months would be likely to reduce average pregnancy rates. The identified potential issue has been corrected and blastocyst development rates have improved. As the full cause of the reduction in pregnancy rates to levels below the national average is likely to be complex and multifactorial, the PR has also instigated a review of laboratory and clinical practice by an external expert. The PR has committed to keep the inspector informed of the results of this external review.

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 Direction 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.

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.

Area of practice and reference	Action required and timescale for action	PR response 22 April 2016	Executive review following an update from the PR received on 24 May 2016
1. **Safety and suitability of premises and facilities** Gas cylinders in the laboratory were not secured sufficiently to ensure that they remain in an upright position. Gas cylinders stored in the corridor restricted access to the fire exit (SLC T17, Health Technical Memorandum 02-01: medical gas pipeline systems part B: Operational management).	The PR should ensure that gas cylinders are secured and stored safely. The PR should provide confirmation of the action taken by 24 May 2016.	During March & April 2016 gas stocks will be run-down, to ensure only required supplies of gases are stored on-site. The Lab Team have discontinued using the large cylinders and they are being returned to BOC & the fixtures to secure the remaining smaller tanks are being fitted as soon as possible.	On 24 May 2016, the PR confirmed that the gas cylinders are now secured individually and the number of cylinders has been reduced.
The recovery area has an unsuitable floor covering (SLC T17 Health Building Note 00-09 page 11).	The PR should ensure that clinical areas have appropriate floor coverings. The PR should provide confirmation of the	A quote for the replacement flooring has been obtained and it will be fitted on the weekends of 24th April and 1st	The PR confirmed that new flooring has been installed in the recovery area.

	action taken by 24 May 2016.	May 2016	No further action required.
2. Traceability Traceability training is not covered by the competence assessment and training framework for laboratory staff (SLC T12 and T15a).	The PR should review training and competence assessments to ensure that all staff are appropriately trained and assessed to perform their designated tasks. A summary of the findings of this review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 24 May 2016.	The traceability audit is underway and will be ready for review by 24th May 2016	The PR had not completed the review of training and competence assessments by 24 May 2016. She has provided assurance that the review has been started and that it will be forwarded as soon as possible. The inspector will follow this up with the PR to ensure that the review is completed by 24 June 2016.
Records are not kept of the flow hood and centrifuge used during processing (SLC T22). As the batch recording system only records which day a batch of consumables was in use, it was not possible to identify which batch of a consumable was used in a specific treatment if the batch was changed part way through the day (SLC T99).	The PR should ensure that, for every critical activity, identifying information about all of the materials and equipment is documented. The PR should provide confirmation of the action taken by 24 May 2016. The PR should review the traceability systems for batch and equipment recording. A summary of the findings of this review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 24 May 2016. Within six months of the	Extra steps have been inserted into the paper documentation to record the centrifuge used and into the RI witnessing system to record the hood used at all stages already. The traceability of batches systems have been reviewed and are available for review. They will be sent to the inspector by 24th May 2016. The traceability audit to include these extra items has been programmed for completion by 24 September 2016.	The PR confirmed, at the time of responding to the report, that records are now kept of the flow hood and centrifuge used during processing. The PR has reviewed the traceability systems and provided a summary of that review. The traceability audit is due for submission to the inspector on 24 September 2016. Further action required.

	inspection the PR should carry out an audit of the traceability systems for batch and equipment records and a summary report of the findings of the audit should be provided to the inspector by 24 September 2016.		
3. Equipment and materials The electronic witnessing system has not been fully validated (SLC T24).	The PR should ensure that all critical equipment is validated. The PR should provide confirmation of the action taken, and provide evidence of validation, by 24 May 2016.	The company providing the electronic witnessing system has been contacted for the completion of the validation process within this timescale.	The completed validation documents for all the electronic witnessing systems at the centre were provided to the inspector on 24 May 2016. No further action required.
4. Obligations and reporting requirements At the time of the register audit inspection (8 December 2015) the centre had recorded four treatments using unregistered donors. By the time of the renewal inspection this had been reduced to two (General Directions 0005 and SLC T41).	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Directions 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting. This recommendation should be implemented by the time the PR responds to the inspection report and the inspector informed of the results of the	The two remaining donors are registered with HFEA as they are donors brought to our clinic from a registered London fertility clinic. The donor codes provided by the clinic in London to HFEA differed from those they provided to us. We registered the donors in good faith with HFEA using the codes provided to us and were unaware they were incorrect codes until this was identified by the inspection. Attempts to obtain the correct codes were not dealt with in a timely	The PR has reviewed the procedures used to submit this data and identified corrective and preventative actions. One of the registration issues has been resolved. The remaining registration issue has been more difficult to resolve, and the PR is continuing to correspond with the supplying centre to resolve this issue. The inspector will follow this up, with an expected resolution date of 24 June 2016. Further action required.

	review and actions taken. The PR should regularly check the 'treatments missing donors' report after implementing any corrective actions, to confirm that the actions have had the desired effect.	manner by the London clinic. Correcting the codes is now making progress and will be completed as soon as possible	

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
5. Witnessing Four sets of patient notes were reviewed. In one set a signature was missing for witnessing the receipt of sperm in the laboratory. The inspector was satisfied that the step had been witnessed and this was a documentation error only (SLC T71).	The PR should ensure that witnessing is recorded at all critical points of the clinical and laboratory process. The inspector should be advised of the measures taken to ensure that this happens by 24 May 2016. Within three months of the inspection the PR should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the inspector by 24 June 2016.	The SOP for witnessing has been reviewed and staff have received further training to ensure this does not occur again The audit to confirm this will be completed by 24th June 2016 as requested.	The PR has provided the inspector with information on the review, and measures taken to ensure this issue is not repeated. The signature error has been corrected. The PR is aware that the results of the audit are due for submission by 24 June 2016. Further action required.
6. Imports and exports The centre's documentation used to ensure an import of gametes or embryos can be performed under General Directions 0006 did not include all the requirements of General	The PR should review the documentation used to ensure that imports and exports of gametes or embryos can be performed under General Directions 0006. A summary of the findings of this review, any corrective actions and timescales for implementation	This action has been completed and has been closed out now.	The PR has provided the required information. No further action required.

Directions 0006 schedule 3. There was no evidence however that any imports had occurred that were not compliant with General Directions 0006.	should be provided to the centre's inspector by 24 May 2016.		
7. Disclosure of information, held on the HFEA register, for use in research Two discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent (CH(10)05 and General Directions 0005).	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time the PR responds to the inspection report and the inspector informed of the results of the review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the	A repeat audit will be undertaken as advised and corrective actions made with a report supplied by the deadline in November.	The PR has corrected the relevant data submitted to the HFEA. A review of procedures, with corrective actions has been provided. The PR is aware that the results of the audit are due for submission by 24 November 2016. Further action required.

	inspector by 24 November 2016.		

Reponses from the Person Responsible to this inspection report
The clinic has undergone a number of modernising processes in the last year including the introduction of an electronic witnessing system. Inevitably there are some processes which have taken longer to streamline with this system but it is now working well and the areas identified for improvement by the inspection have now been addressed. The clinic is also moving to a paperlight process that involves compliance checking all consents and enables any errors to be identified immediately. The commitment of the staff to complete the introduction of these modernising processes is leading to rapid benefits within the clinic and improvements in the processes outlined by the inspection team.