Executive Licensing Panel - minutes

Centre 0259 (Epsom and St Helier NHS Trust) Renewal Inspection Report

Friday, 11 March 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Ian Peacock Jessica Watkin	Director of Strategy & Corporate Affairs Analyst Programmer Policy Manager
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 a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that the centre holds a treatment (insemination using partner/donor sperm) and storage licence. The panel noted that the centre provides both secondary transport and satellite service for the Lister Fertility Clinic (centre 0006), The Bridge Centre (centre 0070) and King's Hewitt Fertility Centre (centre 0109). The centre performs approximately 250 egg collections per year. The three primary centres provide embryo culture, storage and use in treatment services.

1.3. The panel noted that the centre has been licensed by the HFEA since 2007.

1.4. The panel noted that the centre's licence is due to expire on 30 June 2016.

1.5. The panel noted that in the 12 months from August 2014 to July 2015, the centre provided one cycle of donor insemination treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.6. The panel noted that in 2014, the centre reported one cycle of partner insemination with one pregnancy which was consistent with the national average.

1.7. The panel noted that at the time of the inspection on 7 and 8 December 2015, six major and one other area of non-compliance was 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 within the prescribed timescales.

1.8. The panel noted that the inspectorate would usually recommend that the PR liaises with the PRs of the primary centres where areas of practice relating to transport activities require attention, to ensure that these recommendations are effectively implemented. However, as the PR has also submitted an application to vary the centre's licence to provide a full IVF service (application to be considered at a later date), it was considered proportionate that the PR of centre 0259 retains full responsibility for implementation. The panel noted that the findings of this renewal inspection report will be shared with the PRs of the primary centres to ensure that they understand their responsibilities for oversight and audit of all of their transport services.

1.9. The panel noted that significant improvement is required in order for the centre to reflect suitable practices. 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.

1.10. The panel noted that the inspectorate will continue to monitor the centre's performance.

1.11. The panel noted that the inspectorate recommended the renewal of the centre's treatment (insemination using partner/donor sperm) 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 was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR has discharged their duty under section 17 of the HFE Act 1990 (as amended).

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

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) and storage licence for a period of four years without additional conditions. The panel urged the centre to fully implement all of the outstanding recommendations 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

18 March 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: 7 and 8 December 2015

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner / donor sperm) and Storage

The centre has applied to add the following activities: The centre has made an application to vary its licence to include treatment and to reflect a change of premises. A second report regarding the variation of licence application will be submitted in due course.

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: Grace Lyndon (lead), Susan Jolliffe and Karen Conyers

Date of Executive Licensing Panel: 11 March 2016

Centre name	Epsom and St Helier NHS Trust
Centre number	0259
Licence number	L/0259/4/e
Centre address	Assisted Conception Unit, Womens Health, St Helier Hospital, Wrythe Lane, Carshalton, Surrey, SM5 1AA
Person Responsible	Ms Carolyn Croucher
Licence Holder	Mr Steve Simper
Date licence issued	1 July 2012
Licence expiry date	30 June 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Assisted Conception Unit (ACU) at Epsom and St Helier University Hospital NHS Trust has been licensed by the HFEA since 2007. The centre is licensed to provide intrauterine insemination (IUI) using partner/donor sperm and storage but has never had the facilities for, or intention to, store gametes.

In January 2012, an ELP agreed to renew the centre's licence for a period of four years with no additional conditions. Its licence at the time was for 'Treatment (insemination using partner sperm)'. In December 2013 the centre provided a single cycle of donor insemination (DI) treatment when it was not licensed to carry out this activity. Subsequently the Person Responsible (PR) reported this as an incident to the HFEA and the circumstances that led to the breach of licence were investigated. The PR applied for a variation to the licence to include insemination with donor sperm whereby donor sperm for insemination was obtained from Brighton Fertility Associates (centre 0322) then transported to Epsom and St Helier where it was used for insemination. An ELP agreed in May 2014 to vary the centre's licence to 'Treatment (insemination using partner/donor sperm) and Storage', in accordance with Section 18A of the HFE Act 1990 (as amended).

An application to vary the centre's licence was made to change the PR to Mrs Carolyn Croucher; this was granted by an ELP in May 2015. An application to change the centre's Licence Holder was approved in May 2015.

The centre provided one cycle of donor insemination treatment (excluding partner intrauterine insemination) in the 12 months from August 2014 to July 2015. In relation to activity levels this is a small centre.

In November 2015, an application was made to vary the licence to both include a change to current premises and to provide a full range of fertility services. A report of the inspection observations and desk based assessment relating to this application will be submitted to ELP for consideration in due course.

The centre provides both secondary transport and satellite service for three licensed centres: The Lister Fertility Clinic (centre 0006), The Bridge Centre (centre 0070) and King's Hewitt Fertility Centre (centre 0109). The centre informed the inspection team that it performs approximately 250 egg collections per year. The three primary centres provide embryo culture, storage and use in treatment services.

Pregnancy outcomes

In 2014, the centre reported one cycle of partner insemination with one pregnancy which is consistent with the national average.

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 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 six major and one 'other' area of non compliance or poor practice.

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

Major areas of non compliance:

- The PR should ensure CE marked medical devices are used where possible.
- The PR should ensure that all critical equipment used during the procurement of gametes is validated.
- The PR should ensure that the centre's counsellor is accredited by the British Infertility Counselling Association (BICA) or be able to demonstrate equivalent accreditation.

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

Major areas of non compliance:

- The PR should review the quality management system (QMS) to ensure that standard operating procedures (SOPs) and quality indicators (QIs) are in place and audits are undertaken for all activities authorised by the centre's licence and other activities carried out in the course of providing treatment services.
- The PR should ensure that witnessing checks are recorded at the time the relevant clinical or laboratory procedure takes place.
- The PR should ensure that all diagnostic tests are carried out by laboratories which are accredited by Clinical Pathology Accreditation (UK) (CPA) or another body accrediting to an equivalent standard.

'Other' areas that requires improvement:

- The PR should ensure compliance with medicines' management regulations.

Where areas of practice that require attention relate to transport activities, it would usually be recommended that the PR should liaise with the PR's of the primary centres to ensure that these recommendations are effectively implemented. However, because the centre is in the process of varying its licence to provide a full IVF service, it was considered proportionate that the PR of centre 0259 retain full responsibility for implementation. However, the executive will share the findings of this inspection report with the PR's of the primary centres to ensure that they understand their responsibilities for oversight and audit of all of their transport services. Once considered by ELP you can then ask the primary centre inspectors to share this report with them and follow up as a kind of ongoing monitoring.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have six major areas of concern.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a 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 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 the patient or donor to whom they relate are partially compliant with HFEA requirements.

What the centre could do better

During an audit of five records, two did not have documentation of the witnessing checks undertaken at the time of sperm preparation. Staff described the witnessing steps undertaken, providing assurance that witnessing steps are performed. The inspection team noted that the risk of mismatch is low given that the centre only performed six treatments in 2014 (recommendation 1, SLC T71 and CoP 18.8).

Prior to egg collection (for the transport service) appropriate witness steps to verify patient identification is undertaken by staff, and although these are documented, the time that witnessing takes place is not recorded (recommendation 1, SLC T71and CoP 18.8).

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 does not recruit donors therefore this area of practice is not applicable to this inspection.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not recruit donors therefore this area of practice is not applicable to this inspection.

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)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to process gametes 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 their gametes or any material removed from them, are partially 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 compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly 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 provides insemination with partner sperm and donor sperm treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births.

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes 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;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes 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 are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if the gametes are appropriately labelled and has enough information to permit the gametes 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 import or export gametes or embryos therefore this area of practice is not applicable to this inspection.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place 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 provides secondary satellite and secondary transport services to three centres but does not act as a primary centre for satellite or transport services with other centres. All three centres have a third party agreement (TPA) in place, but have not carried out an audit of Epsom and St Helier ACU in the last two years.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements.

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 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 adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Laboratory accreditation (Guidance note 25)
The centre had accepted screening test results from abroad for one patient (undergoing egg collection) but had not evaluated the accreditation status of all the laboratories that had conducted those tests (recommendation 2, SLC T51a).

Medicines management
All controlled drugs are stored safely and used only in the theatre area. The number of ampules taken out to be administered to the patient is recorded in the controlled drug register. The drug wastage is not recorded in the register and when the register was cross referenced with the patient drugs chart within their records, the documented amounts of drug administered to the patient was different from that recorded in the controlled drugs register (recommendation 7, SLC T2).

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place but this has not been used effectively to evaluate and continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's CoP. The centre has not established QIs for, or audited, the following activities within the last two years; consent, welfare of the child, confidentiality and privacy, record keeping (recommendation 3, SLC T35 and T36).

The centre does not have documented SOPs covering the following areas; clinical and non-clinical emergency situations (recommendation 3, SLC T33b).

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked: serological pipettes used for semen preparation and tubes used for egg collection (recommendation 4, SLC T30).

The suction pumps used for egg collection have not been validated (recommendation 5, SLC T24).

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 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 (T/1285/82).

Staff (Guidance note 2)
The centre is partially 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
Staff (Guidance note 2)
The counsellor is not accredited by the British Infertility Counselling Association (BICA) and does not have equivalent accreditation (see 'Counselling' section below and recommendation 6).

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 does not create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.

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 inspector spoke to four patients who provided feedback on their experiences. The feedback given by these patients was positive. A further nine patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with six of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

The centre conducts its own 'friends and family' patient survey and the feedback from this was positive.

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 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 are compliant with requirements to ensure that prospective and current patients 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 partially compliant with HFEA requirements. This

is important to ensure that counselling support is offered to patients receiving donor gametes providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg and sperm sharing arrangements and therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments and therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Counselling (Guidance note 3)
The centre's counsellor is not accredited under the BICA accreditation scheme, and does not have the equivalent qualification (recommendation 6, SLC T14 Cop 2.12(a), 12 (b)). The inspection team was informed that patients having transport IVF do have access to a BICA accredited counsellor at the primary centres. The inspection team is concerned that patients attending the centre for donor insemination treatment only have contact with the centre's counsellor.

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 are compliant with HFEA requirements. This ensures that the centre gives prospective and current 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.

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 have provided all relevant consents before carrying out any licensed activity.

Legal Parenthood
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.
The centre's procedures for obtaining consent to legal parenthood are compliant with HFEA requirements.

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. This centre was not included in that request because at that time they were not offering donor insemination. However, in May 2014 the centre provided evidence that they had completed a legal parenthood audit that was comprehensive and that their current procedures for obtaining consent to parenthood are 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. The centre's procedures 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' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

This area of practice is applicable to patients undergoing treatment with donor gametes but is not relevant to basic partner IUI services. Due to the small number of donor treatments provided by the centre, this was not assessed during this 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 does not create embryos therefore this area of practice is not applicable to this inspection.

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 and processing of gametes.

Storage of gametes and embryos (Guidance note 17)
Although the centre has a licence to store gametes and embryos, they do not do so currently. Therefore this area of practice is not applicable to this report.

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 does not use embryos for training staff therefore this area of practice is not applicable to this inspection.

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 centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register**.**

The centre provided an annual return for IUI treatments undertaken in 2014 within the required timeframe (General Direction 0005).

What the centre could do better
Nothing identified at this inspection

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

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.

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 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 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	Executive Review
1. Witnessing During an audit of five records, two did not have documentation of the witnessing checks undertaken at the time of sperm preparation. Prior to egg collection (for the transport service), appropriate witness steps to verify patient identity are undertaken by staff and although these are documented, the time that witnessing step takes place is not recorded. SLC T71 and CoP 18.8.	The PR should ensure that witnessing checks are appropriately recorded at the time the relevant clinical or laboratory procedure takes place. The PR should review the centre's witnessing procedures to determine why the documentation of witnessing was not recorded and to ensure that procedures are compliant with regulatory requirements. A summary of the findings of the review including corrective actions and the timescales for implementation should be	Whilst witnessing checks had occurred on all laboratory procedures the witnessing form for the receipt of sperm from donor banks has now been changed to provide separate documentation for the receipt of the sperm as per inspector's recommendation. A further training day into witnessing and consent was provided to all clinical staff Dec 2016 Witnessing procedures were in place but our new forms have clarified timing of signatures at egg collection. The corrective action is the new document	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The Executive acknowledges the PR's summary of her review of witnessing practices and corrective actions taken. Further action is required

	provided to the centre's inspector by 8 April 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. A copy of this audit should be submitted to the centre's inspector by 8 July 2016.	which is already in place Jan 2016[see attached] An audit of witnessing will be undertaken in May 2016 and sent to the centre's inspector Previously submitted audits include an IUI audit in Dec 2014, DI audit April 2015.	
2. Accreditation The centre has not evaluated the accreditation status of all the laboratories conducting blood screening tests. SLC T51a.	The PR should ensure that all diagnostic tests are carried out by laboratories which are appropriately accredited. The PR should conduct a review of the mechanism in place for assessing the suitability of screening results provided by laboratories other than that used by the centre to ensure that the provenance of all screening tests is known by the primary centre prior to treatment or donation taking place.	All laboratories used by our staff for diagnostic tests for IUI and DI are CPA certified, these labs are Epsom & St Helier (certificate attached) and TDL The accreditation referred to in this report is for chromosome analysis on an egg donor for an IVF cycle which is not part of our DI or IUI assessment. Following advice from our inspectors we have a new policy to check the accreditation of any external laboratories which patients	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The Executive acknowledges the PR's summary of her review of the centre's processes of assessing the accreditation status of the laboratories and corrective actions taken. Further action is required.

	The outcome of this review and any actions implemented should be provided to the centre's inspector by 8 April 2016. Three months after the implementation of any changes, the PR should conduct an audit of patient records to ensure that corrective actions have been effective. This audit should be submitted to the centre's inspector by 8 July 2016	may have used. Where accreditation cannot be found, samples will be repeated within our accredited laboratory. [see attached lab accreditation policy] Audit planned for June 2016	
3. Quality Management System. There is no SOP to direct the following procedures; • a clinical emergency. • a non clinical emergency. SLC T33(b) The centre has not established QIs for the following activities: • consent • welfare of the child	The PR should review the QMS and ensure the development of documented SOPs and QIs and conduct audits for all relevant activities undertaken in the centre. Copies of the SOPs and QIs noted should be provided to the centre's inspector by 8 April 2016. Copies of the audits should be	The PR has reviewed the QMS with new SOPs written for both clinical and non clinical emergencies (available and seen on second day of inspection). QIs for consent and welfare of the child, Audits of the welfare of the child and consent to disclosure have been undertaken and are attached including learning points	The Executive acknowledges the PR's response and commitment to fully implement this recommendation. Further action required

SLC T35. The centre has not audited the following activities; • welfare of the child • consent • confidentiality and privacy • record keeping SLC T36.	provided to the centre's inspector by 8 July 2016.	 Welfare of child now audited Consent now audited Confidentialiality & privacy Record keeping Both being audited this month and I will send results to HFEA inspector on completion	
4. CE marked devices The following medical devices used by the centre are not CE marked: serological pipettes used for semen preparation, and tubes used for egg collection. SLC T30.	The PR should ensure CE marked medical devices are used where possible. The PR should provide the centre's inspector with an action plan indicating the proposed timescale for the introduction of alternative products. Full introduction of all CE marked devices should be implemented by 8 June 2016.	Following manufacturers' advice we had been using MEA marked equipment in keeping with earlier guidance and producing excellent pregnancy rates until CE medical device versions are available as HFEA recommendations stating "where possible" Having taken the advice of our inspectors we now purchased CE marked equipment [repromed ref 113411 CE0535 serological pipettes, repromed ref 113521 round bottomed tubes for IVF CE0535]	The Executive acknowledges the PR's response. No further action required.
5. Validation	The PR should ensure that all	Suction pumps are not used	The PR has provided the

The suction pumps used for egg collection have not been validated. SLC T24.	critical equipment used during the procurement of gametes is validated. The PR should ensure that validation of the egg collection suction pumps is completed and evidence submitted to the centre's inspector by 8 April 2016.	within IUI and DI Please find attached our validation document for the suction pumps used for IVF egg collections	requested validation document. No further action is required.
6. Counselling The centre's counsellor is not accredited by BICA or able to demonstrate equivalent accreditation. SLC T14	The PR should ensure the centre's counsellor is suitably qualified and accredited, or that the centre can access a suitably qualified counsellor for patients and donors providing relevant consent. The PR should provide a summary of action to be taken when responding to this report.	The centres counsellor [redacted] has been an Information Officer for BICA and is working towards her BICA accreditation In addition, during the time of the inspection we appointed a further accredited & established BICA counsellor [redacted] to the team [CV attached]	The inspection team viewed the counselling as a non compliance as the inspection team were not assured that the counsellor was effectively working towards the BICA or equivalent accreditation. The PR has confirmed that a BICA accredited counsellor has been appointed. 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
7. Medicines management There is no record in the controlled drugs register of the wastage of any unused portion of a controlled drug and the usage documented in the patients drug chart was different from that documented in the controlled drugs book. SLC T2.	The PR should ensure compliance with medicines' management regulations. The PR should review procedures for the management of medicines at the centre and ensure that they are compliant with relevant regulatory requirements, and in line with the centre's own 'disposal of medicines' policy. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 8 April 2016. Three months after the implementation of corrective actions, the centre should	No controlled drugs are present or used within our DI and IUI service. No controlled drugs are present or used within the assisted conception unit. The Trusts medicine management policy, theatre and an interview with the Senior Pharmacist occurred on the second day of the inspection. The controlled drugs are recorded in CQC inspected theatres A controlled drug book which details a column for discarded drugs is being implemented within theatre by pharmacy	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Within three months of using the new controlled drug book, the PR should audit as requested and send a copy of this to the centre's inspector by 8 July 2016. Further action is required.

	perform an audit to ensure that these corrective actions have been effective. This audit should be submitted to the centre's inspector by 8 July 2016.		

Reponses from the Person Responsible to this inspection report