Licence Committee - minutes

Centre 0005 (Fertility Exeter)
Renewal Licence

Thursday, 7 November 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Bernice Ash (Observer)	Committee Secretary Committee Secretary
Legal Adviser	Alistair Robertson	DAC Beachcroft LLP
Specialist Adviser		
Observers	Darryn Hale (Induction)	DAC Beachcroft LLP

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Renewal inspection report
- Application Form
- Importing Tissue Establishment (ITE) Import Certificate
- Previous licensing minutes:
  - 7 September 2017 - Interim inspection report - Licence Committee
  - 4 May 2017 - Executive update - Licence Committee
  - 12 January 2017 - Renewal and Executive update - Licence Committee

1. Background

1.1. Fertility Exeter, centre 0005 is located in Devon. The centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The centre's ownership changed in 2014 from Peninsular Centre for Reproductive Medicine Ltd to Royal Devon and Exeter NHS Foundation Trust.

Licence

1.3. The centre's current licence was issued for a period of 3 years and is due to expire on 28 February 2020.

History of Non-Compliance

Licence Committee Decision - January 2017 - Licence Renewal

1.4. Due to concerns about the centre, the report of the renewal inspection carried out in September 2016 was presented to the Licence Committee for consideration at its meeting on 12 January 2017, rather than the Executive Licensing Panel (ELP). One critical, nine major and three other areas of non-compliance were identified. The Executive was particularly concerned about the centre's persistently low success rates for IVF in patients under the age of 38.

1.5. The committee requested to see the outcome of an external review of the centre's clinical and laboratory practices and procedures that could impact on success rates, and an action plan to implement the recommendations resulting from the review.

1.6. The committee agreed to renew the centre's licence for a period of three years rather than the standard four years. The committee also endorsed the inspectorate's recommendation to carry out an interim inspection within 12 months of the renewal inspection, focusing on the Quality Management System (QMS), surgical pathway and pregnancy success rates. The committee asked to see the report of this interim inspection.

Licence Committee Decision – May 2017 - Executive Update to Licence Renewal

1.7. At its meeting on 4 May 2017, the Licence Committee considered the Executive's update on the centre's progress in implementing the recommendations made at the renewal inspection. The Executive reported that the centre had an external review of clinical and laboratory practices and procedures that could impact on success rates, and the centre was developing an action plan. The centre had addressed the recommendations within the set timescales and the Executive was satisfied with the centre's progress.

Licence Committee Decision – September 2017 - Interim Inspection

1.8. At its meeting on 7 September 2017, the Licence Committee considered the report of the interim inspection carried out on 25 July 2017. The centre had addressed the recommendations within the set timescales and the Executive was satisfied with the centre's progress.

1.9. The committee was satisfied that considerable improvement had been made by the centre, following engagement with the inspectorate and continuous monitoring.

1.10. The committee noted, in particular, that the issues relating to legal parenthood and low success rates for IVF in patients under the age of 38 years had been addressed over time. However, the committee agreed that it was too early to assess the full results of the centre's actions and asked that the inspectorate shares with it future data from the centre for reassurance that improvements in the centre's practices are permanent.

1.11. The committee was satisfied that the centre was fit to have its licence continued.

1.12. The committee also requested that the centre's future inspection report is considered by the Licence Committee. The renewal inspection report has been submitted for the Licence Committee's consideration.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the treatment and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 30 April 2019, the centre provided 476 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period 1 May 2018 to 30 April 2019 showed the centre's success rates were in line with national averages with the following exception:

- pregnancy rate per cycle following frozen embryo transfer (FET) in patients under 40 years old is lower than average at a statistically significant level.

2.5. The committee noted that in 2018, the centre reported 82 cycles of partner insemination with 12 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

2.6. The committee noted that between 1 May 2018 and 30 April 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents a performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 30 and 31 July 2019. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there were three other areas of non-compliance identified:

Other areas of non-compliance or poor practice:

- The PR should ensure compliance with controlled drugs practice guidance and Trust policy.
- The PR should ensure that the centre's Quality Management System (QMS) and auditing processes are effective.
- The PR should ensure that appropriately CE marked medical devices are used where possible.

2.8. The committee noted that since the inspection visit, the PR has committed to implementing these recommendations within the required timescales.

2.9. The committee noted that some improvement is required in order for the centre to reflect suitable practices.

2.10. The centre has a Quality Management System (QMS) and the PR is encouraged to continue to use it to monitor and improve the centre's success rates and the quality of the service offered to patients.

Recommendations

Licence

2.11. The committee noted that the inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions, subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

Importing Tissue Establishment (ITE) import certificate

2.12. The committee noted that centre 0005 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The Executive recommends the renewal of the centre's ITE import certificate.

3. Decision

3.1. The committee had regard to its decision tree.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Dr Lisa Joels

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge her duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Royal Devon & Exeter NHS Foundation Trust

3.4. The committee was satisfied that the proposed LH is suitable.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – Royal Devon & Exeter Hospital (Heavitree), Gladstone Road, Exeter, Devon, EX1 2ED

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.7. The committee was satisfied that the third-party premises are also suitable.

Licence

3.8. The committee endorsed the Executive's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions, subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

Internal Review - Due 31 October 2019

3.9. The committee noted that the pregnancy rate per cycle, for frozen embryo treatments in patients under 40 years old, has remained lower than average at a statistically significant level since July 2018. The PR had informed the inspectorate that several actions have been implemented since October - November 2018 and some positive improvements have been observed.

3.10. However, since the corrective actions have not been as effective as expected, the PR had confirmed that an internal review was to be performed over the next few months. The PR has committed to keeping success rates for treatments using frozen embryos under review and has taken necessary action to seek a resolution. Therefore, the inspectorate considered that a recommendation was unnecessary and no further action is required other than for the PR to provide a summary of the internal review to the inspectorate by 31 October 2019.

3.11. The committee noted that the internal review was due outside of the Executive's deadline to submit papers to the Licence Committee scheduled on 7 November 2019. Therefore, details of this review were not provided for its consideration. The committee noted that the centre's success rates will be kept under review through normal post inspection monitoring. If the success rates continue to remain lower than average and the centre's planned action is ineffective, then the inspectorate will require a further external review to be completed.

3.12. The committee agreed that the Executive should review the centre's internal review in great detail and strongly suggested that, in the interest of patients, if the success rates continue to remain lower than average, the centre should have an external audit of clinical and laboratory practices and procedures that could impact on success rates.

Displaying information on success rates

3.13. The committee held a discussion on information available to patients on success rates, in particular information displayed on centre websites. The Legal Adviser referred the committee to the HFEA Code of Practice, reminding members that information displayed by centres should include the most recent data available from the past three years and that centres are encouraged to display live birth rate data per embryo transferred where relevant. The information should also provide raw numbers rather than just percentages.

3.14. The committee agreed that the centre should be transparent when providing information on its success rates in order for patients to make informed choice about their treatment and care of gametes and embryos.

Importing Tissue Establishment (ITE) import certificate

3.15. The committee endorsed the Executive's recommendation to renew the Importing Tissue Establishment (ITE) import certificate.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

3 December 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) 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: 30 and 31 July 2019

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

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

Inspectors: Sandrine Oakes (lead), Louise Winstone, Polly Todd, Janet Kirkland MacHattie, Victoria Brown (observing) and Neil McComb

Licence Committee Date: 7 November 2019

Centre name	Fertility Exeter
Centre number	0005
Licence number	L/0005/17/a
Centre address	Royal Devon & Exeter Hospital (Heavitree), Gladstone Road, Exeter, Devon, EX1 2ED, United Kingdom
Person Responsible	Dr Lisa Joels
Licence Holder	Royal Devon & Exeter NHS Foundation Trust
Date licence issued	1 March 2017
Licence expiry date	28 February 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Fertility Exeter is located in Devon and has held a Treatment and Storage licence with the HFEA since 1992.

The centre's ownership changed in 2014 from Peninsular Centre for Reproductive Medicine Ltd to Royal Devon and Exeter NHS Foundation Trust.

The centre provides a full range of fertility services (NHS and self-funding patients), including the storage of gametes and embryos.

The centre provided 476 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2019. In relation to activity levels this is a small centre.

A renewal inspection performed at the centre in September 2016 identified one critical, nine major and three 'other' areas of non-compliance or poor practice. Such was the executives' concern, in particular about the centre's persistently low success rates for IVF in patients under the age of 38, that the report was presented in January 2017 to a Licence Committee rather than to an Executive Licensing Panel (ELP).

The Licence Committee renewed the centre's licence for a period of three years rather than the usual four. The committee requested to see the outcome of an external review of the centre's clinical and laboratory practices and procedures that could impact on success rates and an action plan to implement the review's recommendations. The Licence Committee also endorsed the inspectorate's recommendation to carry out an interim inspection within 12 months of the renewal inspection, focussing on the Quality Management System (QMS), surgical pathway and pregnancy success rates, and required that the report of that interim inspection be presented to them.

An update of actions taken to implement the recommendations of the renewal inspection was presented to the Licence Committee in May 2017, at which time the centre's inspector was satisfied with the progress being made; recommendations had been addressed within the timescales specified, an external review had been performed and the action plan was in development. The committee requested another update focussing on the implementation of the recommendations of the renewal inspection. A report of the interim inspection of July 2017 was presented to the Licence Committee in September 2017, at which time the centre's inspector was satisfied with the progress being made; recommendations had been addressed within the timescales specified. The committee requested that the renewal inspection report in 2019 be presented to them rather than ELP. This is the report of the renewal inspection.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 May 2018 to 30 April 2019 show the centre's success rates are in line with national averages with the following exception:

- Pregnancy rate per cycle for frozen embryo treatments in patients under 40 years old is lower than average at a statistically significant level.

In 2018, the centre reported 82 cycles of partner insemination with 12 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

Multiple births[2]

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

Between 1 May 2018 and 30 April 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents a performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the 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 the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three 'other' areas of non-compliance, which have resulted in the following recommendations:

'Other' areas that require improvement:

- The PR should ensure compliance with controlled drugs practice guidance and Trust policy.

- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective.
- The PR should ensure that appropriately CE marked medical devices are used where possible.

The PR has committed to implement actions to address these recommendations within the required timescales.

Recommendation to the Licence Committee

The centre has no critical or major areas of concern.

The inspection team notes the centre's success rates are generally in line with national averages, except that for frozen embryo treatment in patients under 40 years old which is below the national average. The centre's multiple clinical pregnancy/ live birth rates meet the target. The PR should ensure that the QMS is used to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

At the last renewal inspection, such was the executives' concern, in particular about the centre's persistently low success rates for IVF in patients under the age of 38, that the inspection report was presented in January 2017 to a Licence Committee. The Licence Committee requested that the renewal inspection report in 2019 be presented to them rather than ELP.

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

Centre 0005 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

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

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body

recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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

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

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

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;

- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Satellite agreements (Guidance note 24; General Direction 0010)
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 transport and

satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. Most equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all 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

Medicines management (Guidance Note 25)
During the inspection, the following non-compliances were identified:

- the carry-over of drugs from one page to another was not consistently recorded, witnessed or signed;
- in one instance, additional stocks of controlled drugs had been received but the source of the stock was not recorded;
- an alteration in the controlled drugs (CD) register was not in line with Trust policy, which states that alterations are not to be crossed out.

SLC T2; Section 4.7 DH 'Safer Management of Controlled Drugs, A guide to good practice in secondary care (England)' (2007); recommendation 1.

Quality management system (QMS) (Guidance note 23)
During the inspection, the following non-compliances were identified:

- the legal parenthood standard operating procedure (SOP) has not been reviewed within its specified review date and does not refer to the use of the PBR consent form ('your consent to being registered as the legal parent in the event of your death') by patients who are married or in a civil partnership. On discussion, staff were able to provide assurance that the PBR form is correctly used in practice. A draft copy of a new version of the legal parenthood SOP was provided on day two of the inspection, albeit the document had not been ratified or finalised;
- a record keeping audit has not been performed within the last two years, contrary to HFEA requirements, and quality indicators have not been established.

SLC T34, T36; 'Consent forms: A Guide for Clinic Staff', HFEA (2019); recommendation 2.

Equipment and materials (Guidance note 26)
The sample pots used for the collection of sperm for use in treatment, are not CE marked at the appropriate level.

SLC T30; 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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

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

Welfare of the child and safeguarding

What the centre does well

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

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
This centre does not undertake embryo testing and therefore requirements related to their procedures were not relevant at 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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only seven patients provided feedback in the last 12 months, giving an average three-star rating to the clinic. This feedback suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it is important that every patient knows about the rating system. The inspection team discussed this with the PR. She felt the clinic was pro-actively seeking patients' feedback, a patient support champion has been appointed and a draft of the new patient support policy was seen on inspection. The inspection team was reassured that the PR is taking appropriate actions to remedy the low feedback rate to the HFEA website.

The centre's own most recent monthly patient survey responses (July 2019) were reviewed. The patient survey measured 'patient experience'. Of 15 patients who had returned it, 100% of patients would recommend the clinic to friends and family. The centre's own most recent annual counselling responses (2018) were also reviewed. The patient survey measured 'patient experience'. Of 51 patients who had returned it, 98% of patients would recommend the service and thought it was helpful.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

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

Surrogacy (Guidance note 14)

This centre does not offer surrogacy treatments, therefore requirements related to this area of practice were not relevant at this inspection.

Complaints (Guidance note 28)

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

Confidentiality and privacy (Guidance note 30)

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

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)

The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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 reported the findings of the audit to the HFEA within the required timeframe.

On inspection in 2014, the inspection team reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. In 2016, in re-visiting the audit results, it was noted that two anomalies had been identified in the original audit which the previous PR had considered minor; further action such as contacting the patients had not been taken.

The current PR has, since the renewal inspection in September 2016 and in compliance with a recommendation in the inspection report, reviewed the relevant patient records and ascertained that one of the couples affected was married at the time of treatment and therefore no further action was needed. The PR has met with the other affected couple and informed them of the anomalies identified in their consent to legal parenthood. The PR informed the inspection team at the interim inspection in July 2017 that the Trust would cover the cost of any legal proceedings that the couple may wish to pursue. The PR informed the centre's inspector in December 2017 that the case had been reviewed by the Family Division of the High Court and Judge Munby had ruled that the legal parenthood was no longer in question for the couple concerned. Judge Munby also noted the support offered by the centre to the couple throughout the legal process.

To provide further assurance of the ongoing effectiveness of the centre's procedures with regards to consent to legal parenthood, at this inspection the inspection team reviewed ten sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and an offer of counselling were seen to be in place prior to consent and treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements, with the exception noted in the QMS section of this report.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers to the exception of the findings below. 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

Storage of gametes and embryos (Guidance note 17)

Subsequent to HFEA guidance at the annual conference in June 2019, but prior to the renewal inspection, the centre audited the consents provided by patients who have gametes and embryos in storage. The centre identified three anomalies involving the Medical Practitioner's Statement (MPS) form. The PR reported these to the HFEA as an incident and has sought legal advice for one case. Each case requires to be reviewed individually as they may present with various complexities and the PR was advised on inspection to seek legal advice about each case from a specialist expert in this field, once all the evidence pertaining to each case has been collated. As the PR has taken necessary

actions to date to seek a resolution, no recommendation has been made requiring further action at this time.

Use of embryos for training staff

What the centre does well

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

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

4. Information management

Record keeping and Obligations and reporting requirements
What the centre does well **Record keeping and document control (Guidance note 31)** The centre's procedures for keeping records are compliant with HFEA requirements, with the exception noted in the QMS section of this report, 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.
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, no recommendations for improvement were made.

On-going monitoring of centre success rates

Since the last interim inspection in July 2017, the centre has received three risk tool alerts related to performance to which the PR has responded appropriately. These include:

- Pregnancy rate per cycle for frozen embryo treatment in patients under 40 years.
- Multiple Pregnancy rate per pregnancy all treatment cycles, 16 – 70 years.
- Pregnancy rate per cycle for fresh IVF treatment in patients over 38 years.

As the pregnancy rate per cycle for frozen embryo treatments in patients under 40 years old has remained lower than average at a statistically significant level since the last risk tool alert in July 2018, this was discussed with the PR on inspection. She informed the inspection team that several actions have been implemented since October-November 2018 and some positive improvements have been observed. However, since the corrective actions have not been as effective as expected, the PR has confirmed that an internal review is to be performed over the next few months. The PR has provided a commitment to keep success rates for treatments using frozen embryos under review and has taken necessary actions to seek a resolution. As such, the inspection team considers a recommendation to be unnecessary and no further action is required other than for the PR to provide a summary of the internal review to the centre's inspector by 31 October 2019. The success rates will be kept under review by the centre's inspector through normal post inspection monitoring. If the success rates continue to remain lower than average and the centre's planned actions are ineffective, then the centre's inspector will require a further external review to be completed.

Areas of practice requiring action

This section sets out matters which the Inspection Team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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

Major area of non-compliance

A major area of non-compliance is a non critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

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

Other areas of practice that requires improvement

Other areas of practice that require improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from statutory requirements or good practice.

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Medicines management During the inspection, the following non-compliances were identified: ▪ the carry-over of drugs from one page to another was not consistently recorded, witnessed or signed; ▪ in one instance stocks of controlled drugs had been received but source of the stock was not recorded; ▪ an alteration in the CD register was not in line with Trust policy. SLC T2, the DH 'Safer Management of Controlled Drugs, A guide to good practice in secondary care (England)' (2007).	The PR should ensure compliance with controlled drugs practice guidance and Trust policy. The PR should review practice and ensure staff are aware of their responsibilities for ensuring the safe custody of controlled drugs. The PR should audit practice in three months to ensure the non-compliances identified in this report have been resolved. A summary report of this audit should be provided to the centre's inspector by 31 October 2019.	The PR recognises the need to comply with controlled durgs guidance and Trust policy. The PR, the matron and the senior theatre nurse have had a meeting with the Deputy Chief Pharmacist who has agreed to provide further training to all relevant staff. The PR has shared the inspection report with all centre staff so that they are aware of their responsibilittes in relation to controlled drugs. The PR will audit practice in three months and will provide a summary to the centre's inspector by 31st October 2019.	The executive notes the PR's response and commitment to implement this recommendation. No further action is required beyond submission of a controlled drug audit by 31 October 2019.

2. QMS During the inspection, the following non-compliances were identified: ▪ the legal parenthood SOP has not been reviewed within its specified review date and does not refer to the use of the PBR consent form for patients who are married or in a civil partnership; ▪ the record keeping audit has not been performed within the last two years and quality indicators have not been established. SLC T34, T35, T36, 'Consent forms: A Guide for Clinic Staff', HFEA (2019).	The PR should ensure that the centre's QMS and auditing processes are effective. The PR should ensure that documents and SOPs are reviewed every two years to ensure they remain fit for purpose. The PR should provide a copy of a compliant SOP for legal parenthood to the centre's inspector by 31 October 2019. The PR should ensure that quality indicators are established for all activities. The PR should provide the quality indicators for 'record keeping' to the centre's inspector by 31 October 2019. The PR should ensure that the record keeping audit is conducted. A summary report of this audit should be provided to the centre's inspector by 31 October 2019.	The PR is aware that the QMS needs further development to ensure that it is effective. There has been a programme of work relating to this over the last year. There is currently a transition from spreadsheet based systems for the QMS to Q Pulse which will improve effectiveness. There is also a plan to recruit a Fertility Quality Officer to assist the Quality Manager and ensure that documents and SOPs are reviewed every two years. A job description has been created and is with the Trust's HR team for banding/approval. The SOP for legal parenthood has been updated and once ratified at Fertility Governance in Sept 2019, will be provided to the centre's inspector. The PR recognises the need for quality indicators for all activities and will ensure that quality indicators for record keeping are included in the centre's SOP for quality indicators. This will be provided to the centres' inspector by 31st October 2019	The executive notes the PR's response and commitment to implementing this recommendation. No further action is required beyond the submission of a compliant SOP for legal parenthood, evidence of quality indicator monitoring for 'record keeping', and a summary report of the 'record keeping' audit by 31 October 2019.

		A record keeping audit will be conducted and a summary of the findings provided to the Centre's Inspector by 31st October 2019	
3. Equipment and materials The sample pots used for the collection of sperm prior to treatment are not CE marked at the appropriate level. SLC T30.	The PR should ensure that appropriately CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment; however, the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre's inspector by 31 October 2019 and should include the timescales by which the product identified in this report will either be replaced with a suitably CE marked alternative or will obtain CE mark certification.	The pots currently used for sperm collection are CE marked for diagnostic purposes. The PR is aware that there are now pots CE marked for treatment purposes.Appropiately CE marked samples pots for treatment have been procured and since they have been mouse embryo tested their use has been implemented from 9th Sept 2019 for treatment samples. The PR will provide a summary of the plan and outcome of implementation of the treatment sample pots by 31st January 2020	The executive notes the PR's response and commitment to implement this recommendation. No further action is required beyond the submission of a plan of action to address CE marking issues by 31 October 2019.

	The plan should be fully implemented by 31 January 2020.		

Responses from the Person Responsible to this inspection report

The PR was very pleased that the inspection report and verbal feedback given during inspection recognises the huge efforts the Centre's team has made to correct the non-compliances identified in previous inspections and also the huge efforts made in making further improvements to the service which is borne out in the Centre's siginifcantly improved pregnancy rates for fresh IVF and ICSI cycles over the last two years.
The PR shares the ongoing concerns about the frozen treatment clinical pregancy rates which are lower than expected due to a high early pregnancy loss rates. A number of changes have been introduced and further investigations into this are ongoing.