Executive Licensing Panel - minutes

Centre 0259 (Epsom and St Helier NHS Trust)

Renewal Inspection Report

Variation of Premises

Variation of Name

Tuesday, 5 May 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Anna Coundley Yvonne Akinmodun	Director of Strategy and Corporate Affairs Policy Manager Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last five years.

1.2. The panel noted that the Assisted Conception Unit (ACU) at Epsom and St Helier University NHS Trust is in South London. The centre has been licensed by the HFEA since 2007, initially to provide intrauterine insemination (IUI) using partner sperm and, since 2014, donor sperm. It also functioned as a transport centre until 2016, providing approximately 250 cycles per year.

1.3. The panel noted that the centre's licence was varied to a full treatment and storage licence in 2016. Since this time, the centre has provided a full treatment and storage service and the IVF transport service has almost ceased except in very specific situations, using Kings Fertility and the Lister Fertility Clinic as primary centres.

1.4. The panel noted that, in the 12 months to 30 September 2019, the centre provided 220 cycles of treatment (excluding partner intrauterine inseminations). In relation to activity this a small sized centre.

1.5. The panel noted that, for IVF and ICSI, HFEA held register data, for the year to 31 October 2019, show the centre's success rates are in line with national averages.

1.6. The panel noted that, in 2019, the centre reported three cycles of partner insemination treatment, with no pregnancies, and this is in line with the national average.

1.7. The panel noted that, HFEA register data, between 1 November 2018 and 31 October 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles, for all age groups was 20%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.8. An inspection was carried out at the centre on the 12 and 13 November 2019.

1.9. The panel noted that at the time of the inspection, there was one major area of non-compliance concerning the quality management system (QMS). There were also two 'other' non-compliances relating to third party agreements (TPAs) and consent. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to fully implement to the non-compliance surrounding consent, with an audit due for receipt by 3 July 2020. The PR has also provided evidence that actions are being taken to implement the recommendations relating to the QMS and TPAs and has committed to fully implement them within the required timescales.

1.10. The panel noted that, in March 2020, the PR suspended fertility treatments at this clinic in accordance with HFEA requirements and professional body guidance issued in response to the Covid-19 pandemic. In view of this, the centre's inspector extended the timescales for implementation of the recommendations and will continue to liaise with the PR to ensure they remain appropriate.

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

1.12. The panel noted that the centre is well led and provides a good level of patient support.

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

1.14. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment)

Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

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

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

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

2.4. The panel noted that the centre provides a specific short survey to all patients which can be sent into the hospital patient feedback system. Responses are fed back to the centre by the hospital trust; these were said to be positive and, where negative, have been reviewed and actions taken to address concerns, if necessary. However, the panel noted that, in the last 12 months, only eight patients had provided feedback on their experience of the centre, through the 'Choose a Fertility Clinic' facility available on the HFEA website, giving it an average 5-star rating. The panel suggested that the centre actively encourages patients to provide feedback through the 'Choose a Fertility Clinic' facility on the HFEA website.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

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

3. Variation of Premises

3.1. The panel noted that the PR submitted an application to change the premises to include a new cryostore

3.1. The panel noted that, the inspector considered that they have sufficient information, drawn from documentation submitted by the centre, that the proposed new cryostore is suitable for the storage of gametes and embryos.

4. Consideration of application

4.1. The panel considered the papers, which included an application form and licensing minutes for the past three years.

4.2. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

4.3. The panel noted the inspectorate recommends the approval of the application to reflect a change of existing premises to incorporate a new cryostorage room.

5 Decision

5.1. The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

5.2. The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.

5.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

5.4. The panel endorsed the inspectorate's recommendation to vary the centre's licence to reflect a change of existing premises to incorporate a new cryostorage room.

6. Variation of Name

6.1. The panel noted that the centre's PR had also submitted an application to change the centre's name.

6.2. The panel noted that the centre's name is presently Epsom And St Helier NHS Trust and it now wishes to be known as Beginnings at Epsom & St Helier NHS University Trust.

6.3. The panel noted the inspectorate's recommendation to approve the variation of licence to change the centre name.

7. Decision

7.1. After considering the recommendation of the inspectorate and all supporting documentation, the panel changed the name of the centre to Beginnings at Epsom & St Helier NHS University Trust.

8. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

11 May 2020

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.

The centre has also applied to vary its licence to:

- Change the name of the centre to 'Beginnings at Epsom & St Helier NHS University Trust'; and
- Change the current premises to include a new cryostore

Date of inspection: 12 and 13 November 2019

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

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

Inspectors: Andrew Leonard, Nicola Lawrence and Louise Winstone.

Date of Executive Licensing Panel: 5 May 2020

Centre name	Epsom And St Helier NHS Trust
Proposed new centre name	Beginnings at Epsom & St Helier NHS University Trust
Centre number	0259
Licence number	L/0259/5/d
Centre address	Assisted Conception Unit, Women's Health, St Helier Hospital, Wrythe Lane, Carshalton, Surrey, SM5 1AA.
Person Responsible	Mrs Carolyn Croucher
Licence Holder	Mrs Kathryn Hughes
Date licence issued	1 July 2016
Licence expiry date	30 June 2020
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 is in South London. The centre has been licensed by the HFEA since 2007, initially to provide intrauterine insemination (IUI) using partner sperm and, since 2014, donor sperm. The centre also functioned until 2016 as a transport centre providing approximately 250 cycles per year.

The centre's licence was varied to a full Treatment and Storage licence in 2016. Since this time, the centre has provided a full treatment and storage service and the IVF transport service has almost ceased except in very specific situations, using Kings Fertility and the Lister Fertility Clinic as primary centres.

The centre varied the licence to change the Licence Holder shortly before this report was presented to the ELP.

The centre provided 220 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2019. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year to 31 October 2019 show the centre's success rates are in line with national averages.

In 2019, the centre reported three cycles of partner insemination with no pregnancies. This is in line with the national average.

Multiple births[2]

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

Between 1 November 2018 and 31 October 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the licence renewal application has been submitted in the form required;
- the licence renewal 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 licence renewal application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were one major and two 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to fully implement the following recommendation.

'Other' areas of non compliance:

- The PR should ensure that patient consent is recorded appropriately.

The PR has also provided evidence that actions are being taken to implement the following recommendations and has committed to fully implement them within the required timescales.

Major areas of non compliance:

- The PR should ensure that the quality management system (QMS) is robust and functions effectively.

'Other' areas of non compliance:

- The PR should ensure that the content of all third party agreements is compliant and that the ability of third party suppliers to comply with HFEA requirements is evaluated before supply commences and at least every two years thereafter.

In March 2020 the PR suspended fertility treatments at this clinic in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this, the centre's inspector extended the timescales for implementation of the recommendations and will continue to liaise with the PR to ensure they remain appropriate.

The ELP is also asked to note that the centre has also applied to vary its licence to:

- Change the name of the centre from 'Epsom And St Helier NHS Trust' to 'Beginnings at Epsom & St Helier NHS University Trust'; and
- To change the current premises to include a new cryostore.

In considering the compliance of the application to vary the licence, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre to conclude that:

- The centre's proposed new name is suitable;
- The cryostorage room to be added to the licence is suitable for storing gametes and embryos;
- The practices to be used for storing gametes and embryos are suitable;
- The centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licensed premises and to change the centre's name.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have one major area of non compliance.

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

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

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

The centre is well led and provides a good level of patient support.

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 0259 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 recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

The inspection team also recommends that the ELP approves the centre's application to vary its licence to:

- Change the name of the centre from 'Epsom And St Helier NHS Trust' to 'Beginnings at Epsom & St Helier NHS University Trust'; and
- Change the existing premises to include a new cryostore which has been produced by renovation of a staff changing room.

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. It is noted that the centre does not actively recruit gamete donors but uses donated sperm procured from donor banks.

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 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.

Specifically pertaining to the centre's application to vary the licence to change the existing premises to account for the conversion of a changing room to a cryostore, the inspection team reviewed the new cryostore and observed:

- The cryostore is on the same corridor as the centre's treatment room, laboratory, recovery area and other facilities. A floor plan has been provided detailing the room's location.

- The room is under the control of the PR, is secure and access to it is limited to specific members of the laboratory team authorised by the PR.
- The room has been refurbished to meet the requirements of the relevant health technical memoranda and health building notes.
- The room was clean, suitable and fitted with appropriate safety signage.
- The room has been equipped with an oxygen monitoring system, with displays and alarms inside and outside the room, and an extraction system to clear any nitrogen spillages.
- A dewar and temperature monitoring system, all validated, are present in the new cryostorage room, though no licensed material had been transferred to the room at the time of the inspection.
- Re-validation of further dewars and their monitoring devices will be undertaken when they have been transferred to the new cryostorage room.
- The centre's critical processes and documented procedures related to cryopreservation are not affected by the introduction of this new cryostore to the licensed premises, and were considered appropriate at this inspection.

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; notwithstanding the exception noted in 'Third Party Agreements' below. 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 compliant with guidance.

Prescription of intralipid 'off label'
The centre does not provide treatment involving the use of intralipid therapy therefore requirements pertaining to this area of practice 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 TCSs which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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

- to identify and locate gametes and embryos during any step from procurement to

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre is not the primary centre for any satellite or transport centres therefore this area of practice was not relevant at this inspection.

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

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has reported all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

QMS (Guidance note 23)
The inspection team was of the opinion that the audit programme was not robust (SLC T36) for several reasons. Audits of counselling, record keeping and of storage records (comparing digital records against the paper originals) have not been performed in the last two years. Audits generally consist of a retrospective review of a sample of patient records for evidence of compliance but do not, in general, include an active review of the activities and processes undertaken against the relevant SOPs, or assess the compliance

of SOPs with HFEA CoP requirements. In addition, audit reports do not generally document the corrective and preventative actions to be taken, the timescales for implementation or the completion of the actions; neither are these items recorded in the non conformance log. The scope and methodology used in some audits was not described in the audit reports, while for other audits, the methodology used was not robust: for example the legal parenthood consent audit reviewed from the records of only one patient couple who had been treated using donor sperm (SLC T36).

Quality indicator (QI) monitoring of laboratory processes is established at an appropriate frequency. QIs have also been established for clinical practice but these are assessed by the annual audit of patient records. It can be questioned whether QI monitoring is frequent enough for some activities, e.g. consenting, witnessing etc, where errors can have significant impact and need to be identified in a timely manner (SLC T35).

The centre does not have processes in place for reviewing the QMS at least annually, to ensure continuous and systematic improvement (SLC T34).

The inspection team concluded that the QMS itself was not suitably robust because of the compliance issues listed above (SLC T32).

Recommendation 1.

Third party agreements (Guidance note 24)
The TPAs reviewed on inspection did not meet the relevant SLC requirements. The TPAs with a donor bank and a courier company did not include a clause that the third party will comply with relevant HFEA licence conditions and other requirements, either generally or specifically. The TPA with the donor bank did not include clauses to ensure that the donor sperm provided is compliant with General Direction 0001 (regarding donor compensation) or SLC T117 (regarding the provision of a procurement report). The TPA with the courier company did not include the full address for the third party or that ‘validated’ dry shippers would be used. The TPAs with laboratories providing testing services did not include that tests performed should all be ISO15189 certified and evidence was not available to show which tests are appropriately certified (SLCs T21, T112, T114, T116 and T117).

The centre has evaluated the compliance of services provided by third parties, including suppliers of donor sperm, however the non compliances detailed above raise questions regarding the effectiveness of this audit (SLC T112).

Recommendation 2.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
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.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing therefore these guidance notes were not relevant at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Eight patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. A large majority of patients confirmed that they had paid what they expected to and provided comments complimenting staff for being supportive, understanding and compassionate.

The centre provides a specific short survey to all patients which can be sent into the hospital patient feedback system. Responses are fed back to the centre by the hospital trust. Responses were said to be positive and, where negative, have been reviewed and actions taken to address concerns, if necessary.

During the inspection the inspectors spoke to one patient couple who also provided very positive feedback on their experiences, notably regarding the support provided to them by staff and the quality of the information provided about treatments.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted

in a non discriminatory way.

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

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 does not undertake egg sharing treatments therefore these requirements were not relevant at this inspection.

Surrogacy (Guidance note 14)
The centre does not undertake treatments involving surrogacy arrangements therefore these requirements 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 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 broadly 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.

This centre has been inspected twice since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At those inspection in December 2016 and March 2018, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements, notwithstanding the inappropriate use of a PBR form by an unmarried couple discuss in 'Consent' below.

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

Consent (Guidance note 5;6)
In one record reviewed, a patient had changed the date of signing a consent form but

had not initialled the change; other corrections were also present and were not initialled. Another record contained completed legal parenthood WP and PP forms but also a PBR form; the marital status of the couple was not documented. The couple were in fact unmarried, so the PBR form should not have been completed. These observations lead to concerns that the quality of consent documented may not be robust in all cases (HF&E Act 1990 (as amended), Schedule 3).

Recommendation 3.

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, notwithstanding the failure to audit digital records of the consented storage period against the consent forms in patient records, as discussed in 'QMS' above. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are 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 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 team reported no significant 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 March 2018, recommendations for improvement were made in relation to one critical, three major and two 'other' areas of non compliance.

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

On-going monitoring of centre success rates

The PR has received two emails related to success rate from the HFEA risk tool in the two years prior to the inspection. The PR responded appropriately to the emails.

Areas of practice requiring action

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

Critical areas 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		N/A	

Major areas of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. QMS The QMS was not robust because, as is detailed in the main body of the text, non compliances were observed in: • the audit programme • the QI monitoring programme and • in annual review of the QMS. SLCs T32, T35 and T36; CoP guidance 23.12 and 23.15.	The PR should ensure that all areas of practice are audited at least every two years and that the centre's audit methodology is robust. Audits should include, where possible, a review of the activities and processes against the relevant SOPs (to ensure SOPs are adhered to), and a review of the SOPs against HFEA CoP requirements to ensure their documented compliant procedures. Corrective and preventative actions with timescales for implementation and completion dates, should also be documented in audit reports or in the non conformance log. Plans to	The QMS for the unit has been redesigned. The audit programme has been restructured with all audits following templates based on Licensing conditions & CoP guidelines. These are referenced in the report along with the background, frequency and scope of the audit. All audits now follow a revised template which includes both Corrective & Preventative Action plans with assigned ownership and time scales. Points raised through the audit	14-12-2019 and 12-01-2020: The PR informed the executive that the quality manager resource has been increased to 0.6 full time equivalents, with a plan to review workload/training. Time has been set aside for a thorough QMS review. The centre has permission to purchase QPulse to better organise the QMS and work it more efficiently. 16-04-2020: The PR's response shows good progress is being made in addressing this recommendation.

	implement this recommendation should be provided to the centre's inspector with the centre's response to this report. The recommendation should be fully implemented by 3 July 2020. This deadline, and other deadlines in this report, are extended to take into account the delayed production of this report and the impact of the covid19 pandemic on the centre's activities and staffing levels The PR should ensure QIs are established for all critical processes and are monitored at an appropriate frequency. Evidence of the implementation of this recommendation, for example a revised QI monitoring protocol documenting the frequency and methodology to be used to monitor each QI, should be provided to the centre's inspector by 3 July 2020. The PR should take immediate action to establish and implement a process for reviewing the performance of the QMS at least annually. A plan documenting the action to be taken including timescales for implementation,	process are addressed by the new reporting template (see attached for TPA & recently completed legal parenting audit) The QMS now provides more time to the role of QM, including training. The QM resource is now 0.6 WTE (22.5 hours/week) Approval, purchase and installation of new IT system called ipassport. The system is well supported, all licensed staff have individual passwords and have begun to use Following inspection 3 Senior Management Reviews of our QMS performance have occurred 18th Dec, Jan 15th & 25th Feb The work undertaken has included: QI monitoring programme planning in preparation for inspector for July 2020 ipassport implentation work force assessment including	The legal parenthood audit provided was suitably thorough and the audit templates which have been developed will ensure the compliance of the audit process. The centre's inspector will continue to work with the PR to further develop these tools and to monitor their introduction into a robust audit schedule, by 3 July 2020. The inspection team notes that QI monitoring across the centre's processes has been discussed by senior staff. Plans are being developed and the PR has committed to provide them to the centre's inspector by 3 July 2020. The inspection team notes the activities described by the PR to effect an annual QMS review, which seem robust in content and to satisfy requirements on this occasion. The centre's inspector expects however to be provided by 3 July 2020 with a documented summary of these review discussions, and also with standardised templates of an annual QMS review agenda

	should be submitted to the HFEA by 3 July 2020. The PR should provide monthly updates to the HFEA on progress in implementing proposed actions.	development needs for key staff groups future work planning (including fertility preservation) change of license holder departmental induction incidents /non conformity updates & remedial actions actions following verbal feedback from inspection audit templates redesign. pregnancy results review Further 6 monthly reviews are planned for the end of June, & Dec, The PR has discussed and agreed the necessary monthly updates with the inspector	and summary record, for use in future. The inspection team acknowledges the purchase of an electronic QMS package, the increase in time allocated to the Quality Manager (QM) role, the appointment of a new QM and the training to be provided to that person. These actions will support QMS compliance. The PR's response and evidence provided shows good progress is being made in addressing this recommendation. The PR has committed to complete actions within required timescales. **Further action is required**

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non compliance, but which indicate 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
2. TPAs The TPAs reviewed did not meet the relevant SLC requirements. The TPAs with a donor bank and a courier company did not include a clause that the third party will comply with relevant HFEA licence conditions and other requirements, either generally or specifically. The TPA with the donor bank did not include clauses to ensure that the donor sperm provided is compliant with General Direction 0001 (regarding donor compensation) or SLC T117 (regarding the provision of a procurement report). The TPA with the courier company did not include the	The PR should ensure the compliance of third party services provided to the centre. All TPAs should be audited against SLC and other HFEA requirements and necessary corrective actions taken to ensure the TPAs are compliant. All third party services should then be audited against the terms of the revised TPAs to ensure the compliance of the services provided. A report of the audit of TPA compliance, including non conformances, corrective actions and timescales for implementation, should be provided to the centre's inspector by 3 July 2020 along with an action plan for auditing the compliance of the third party services. It is expected that these service audits should be completed by 13 November 2020, after which a summary report should be	Attached to this response is our new audit template as being used for our TPAs It aims to clearly demonstrate the CoP sections and licensing conditions reviewed, the frequency and scope of the audit undertaken, clear findings with both correctional actions and preventative actions if necessary together with assigned responsibility, due dates and actual delivery dates The PR recognises that certain TPAs require change and as such work has already begun. The PR has discussed this with the inspector and would appreciate the inspectors comments on this template to confirm we are working	22-11-2019: Soon after the inspection the PR supplied evidence that the tests provided by third party laboratories are all ISO15189 certified. 16-04-2020: The PR's response shows good progress is being made in addressing this recommendation. The PR has committed to complete actions within required timescales. The centre's inspector considered the new audit tool and report template adapted for use in the TPA audit, to be robust. Minor changes only were suggested by the inspector. The new TPA template is also useful and will ensure compliance with TP requirements, as well as the ability to audit third party services

full address for the third party or that 'validated' dry shippers would be used. The TPAs with laboratories providing testing services did not include that tests performed should all be ISO15189 certified and evidence to show which tests are appropriately certified was not available (SLCs T21, T112, T114, T116 and T117). The centre has evaluated the compliance of third party service providers, including suppliers of donor sperm, with HFEA requirements. The non compliances detailed above raise questions however regarding the effectiveness of this audit (SLC T112).	provided to the centre's inspector. A sample of the actual audits performed will then be requested for review.	towards the correct goal. ISO 15189 certification as in executive review	against specific requirements in the TPA. The centre's inspector will continue to work with the centre to ensure compliant TPAs are developed with third parties, where necessary, by 3 July 2020, and third party services are audited against the requirements within those compliant TPAs, by 3 November 2020. **Further action is required**
3. Consent In one record reviewed, a patient had changed the date of signing a consent form but had not initialled the change; other corrections were also present and were not	The PR should ensure that corrections to consent forms are made in line with the centre's policy. The PR should also ensure that the correct consent forms are used to suit the specifics of each case.	As a result of the verbal feedback, further refresher consent training took place on a one to one basis with our nursing staff whilst we awaited the inspection report. All staff are aware of the consent policy	16-04-2020: The centre's inspector notes the PR's response, including that staff have been provided with further training regarding consent forms, and also the legal parenthood audit provided. This audit indicated no systemic problems

initialled. Another record contained completed legal parenthood WP and PP forms but also a PBR form; the marital status of the couple was not documented. The couple were in fact unmarried, so the PBR form should not have been completed. These observations lead to concerns that the quality of consents documented may not be robust in all cases HF&E Act 1990 (as amended), Schedule 3.	The PR should undertake an audit of a sample of patient records to investigate the prevalence of these problems and should take appropriate corrective and preventative actions if consents are undermined or inappropriate. A summary report of the audit, including corrective and preventative actions, with timescales for implementation, should be provided to the centre's inspector by 3 July 2020.	A legal parenting consent consent audit has already occurred and is attached Further consent audits will be sent to the inspector by 3rd July 2020	and included checks as to whether changes to consent forms had been made in accordance with the document correction policy. The centre's inspector considers that no further actions are required. The centre's inspector appreciates the PR's commitment to provide an audit of consent generally, by 3 July 2020, and will review this audit when provided.

Reponses from the Person Responsible to this inspection report
Thank you for this report, which whilst delayed, I consider to be balanced, accurate and fair. Following our inspection and prior to the report, our QM of many years sadly resigned from the post, in addition the world of healthcare as we knew it has been turned on its head by a new Corona virus. I would like to thank my dedicated team of NHS embryologists, clerical & management, nursing and medical staff for both supporting me with this response, keeping our patients (& their future offspring) informed, supported and safe and for their willingness to be redeployed to meet the needs of a busy district general hospital Despite unusual times our QM resource has been increased to 0.6 WTE and following extensive research & reviewing other healthcare systems we have purchased ipassport.Obviously a lot of work has gone into customising the system to our specific QM needs but the system is well supported and all Beginnings' staff are now logged in and have initiated utilisation. Ideally as many audits as possible will be conducted contemporaneously as possible as this is an excellent way to improve staff engagement, discussion & refresh knowledge. In view of the current suspension of activity whilst this will remain our goal retrospective audits will still occur. Funding has been found for CPD training for all staff groups and key courses identified As discussed with our lead inspector I will continue to monitor closely the multiple pregnancy rate, whilst not changing our startegy criteria for at least the next 12 months as recommended.