Executive Licensing Panel - minutes

Centre 0162 (Fertility Unit, Nottingham University Hospital)

Renewal Inspection Report

Variation of Centre Name

Tuesday, 25 February 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Howard Ryan	Director of Strategy and Corporate Affairs Communications Manager Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Rachel Cutting	Licensing Manager Director of Information and Compliance (Induction)

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 Fertility Unit, Nottingham University Hospital has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is an NHS clinic, located within the Queen's Medical Centre campus, which is part of Nottingham University Hospitals NHS Trust.

1.3. The panel noted that the centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates the andrology department which provides a service for those wishing to donate sperm and for those wishing to store their sperm for the preservation of fertility.

1.4. The panel noted that, in 2018, the centre provided 197 cycles of partner inseminations, with 31 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

1.5. The panel noted that HFEA held register data, for the period between October 2018 to September 2019, for donor inseminations, show the centre's success rates are in line with the national average.

1.6. The panel noted that, between January 2018 and December 2018, the centre's multiple birth rate, for all IUI cycles for all age groups was 25%. This represents performance that is unlikely to be statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 3 December 2019.

1.8. The panel noted that at the time of the inspection, there were three major areas of non-compliance concerning witnessing, staff and counselling. Since the inspection, the Person Responsible (PR) has fully addressed the recommendation regarding counselling and has provided a commitment to implementing the recommendations concerning witnessing and staff, within the prescribed timescales.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The centre is well led and provides a good level of patient support.

1.10. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of the renewal report's recommendations, within the required timescales.

1.11. The panel noted that the inspection team recommends the renewal of the centre's treatment (insemination using partner/donor sperm) and storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

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

2.2. The panel 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 his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel noted that 100 patients have provided feedback through means of the centre's own patient survey, and many positive comments had been given regarding the standard of service received. However, the panel noted that, in the last 12 months, no patients had provided feedback on their experience of the centre, through the 'Choose a Fertility Clinic' facility available on the HFEA website. 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 (insemination using partner/donor sperm) 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.

3. Variation of Name

3.1. The panel noted that the centre's PR had also submitted an application to change the centre's name on the 27 January 2020.

3.2. The panel noted that the name is presently Fertility Unit, Nottingham University Hospital and the centre now wishes to be known as NUH Life Fertility Services.

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

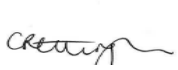
4. Decision

4.1. After considering the recommendation of the inspectorate and all supporting documentation, the panel changed the name of the centre to NUH Life Fertility Services.

5. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

3 March 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.

Date of inspection: 3 December 2019

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using partner/donor sperm) 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: Nicola Lawrence (lead), Polly Todd and Louise Winstone

Date of Executive Licensing Panel: 25 February 2020

Centre name	Fertility Unit, Nottingham University Hospital
Centre number	0162
Licence number	L/0162/15/e
Centre address	A Floor, West Block, Nottingham University Hospital, Derby Road, Nottingham, NG7 2UH
Person Responsible	Dr Mathew Tomlinson
Licence Holder	Mr Andrew Marshall
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 Fertility Unit, Nottingham University Hospital has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is an NHS clinic which is located within the Queen's Medical Centre campus which is part of Nottingham University Hospitals NHS Trust.

The centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates the andrology department which provides a service for those wishing to donate sperm and for those wishing to store their sperm for the preservation of fertility.

This current licence has been varied to reflect the following changes:

- Change of Licence Holder on 27 September 2018;
- Change of Person Responsible on 15 January 2019;
- Variation of licensed premises to include a new room for storing gametes on 21 May 2019;
- Change of premises on 13 November 2019. The premises relocated to 'A floor' of Queen's Medical Centre, which is a new, purpose-built department.
- Change of name on 13 November 2019. The centre changed its name from 'Queen's Medical Centre Fertility Unit' to 'Fertility Unit, Nottingham University Hospital'.

The centre has also submitted an application to change its name.

Pregnancy outcomes[1]

In 2018, the centre reported 197 cycles of partner insemination with 31 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

For donor insemination (DI), HFEA held register data from October 2018- September 2019 show the centre's success rates are in line with national averages.

Between January 2018-December 2018 the centre's multiple pregnancy rate for all IUI cycles for all age groups was 25%. This represents performance that is unlikely 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 – pre review of draft by PR

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 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 his 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 ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major areas of non compliance which have resulted in the following recommendations:

Major areas of non compliance:

- The PR should ensure that gametes are appropriately witnessed at all critical points of the clinical and laboratory processes.
- The PR should ensure that staff are suitably trained and assessed as competent to undertake their roles.
- The PR must ensure that a woman is not provided with treatment services using donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling.

Since the inspection visit, the following recommendation has been fully implemented:

Major areas of non-compliance:

- The PR must ensure that a woman is not provided with treatment services using donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling.

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

Major area of non-compliance:

- The PR should ensure that gametes are appropriately witnessed at all critical points of the clinical and laboratory processes.
- The PR should ensure that staff are suitably trained and assessed as competent to undertake their roles.

Recommendation to the Executive Licensing Panel

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve 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 (insemination using partner/donor sperm) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Centre 0162 does not import or export gametes and so has not applied for an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

The centre has also submitted an application to change its name. The centre wishes to change its name from 'Fertility Unit, Nottingham University Hospital' to 'NUH Life Fertility Services'.

The executive recommends that the application to reflect a change of premises name is approved.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better

Witnessing (Guidance note 18)
Patients are given the option of producing their sample at home. If they choose this option, they are given a 'chain of custody form' to complete. This form enables the male partner to sign to confirm that the details on the sample pot are his and that he is handing over custody of his sample to his partner. In two patient records reviewed during the inspection, where the male partner had produced his sample at home, this form was absent or had been completed incorrectly. The inspectors were concerned that for these treatment cycles, there was no verification from the male partner confirming that the sample was his. Confirmation from the female partner was present.

See recommendation 1.

SLC T71.

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.

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. 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 centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, 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 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 does not undertake surgical procedures therefore this area of practice is not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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 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, with exception to the observation noted above, see recommendation 1.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre does not transport or distribute gametes therefore this area of practice is not applicable to this inspection.

Receipt of gametes (Guidance note 15)
The centre does not receive distributed gametes from other centres therefore this area of

practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes or embryos therefore this area of practice is not applicable to this inspection.

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

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite arrangements therefore this area of practice is not relevant to this inspection.

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

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

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

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

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

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 biological sciences 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 partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

What the centre could do better

Staff (Guidance note 2)
Clinicians working at the centre have not had competencies formally assessed for the duties they perform. The PR has received verbal confirmation from senior clinicians in the Trust that the centre's clinicians are competent, however, there is no documented evidence that they are competent to undertake licensed activities.

See recommendation 2.

SLCs T12 and T15a.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's 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 provide preimplantation genetic screening or embryo testing and sex selection, therefore this area of practice is not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their centre. No patients have provided feedback in the last 12 months. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well it's important that every patient knows about the rating system. The centre has patients with underlying medical conditions using their services, including those storing sperm prior to commencing cancer therapies. It is important that the feedback of this group of patients is also sought to ensure that there is consideration of their needs.

The PR is asked to consider ways to promote the use of this facility and this will be followed up at the next inspection.

The centre's own most recent patient survey responses were reviewed. One hundred patients had completed a satisfaction questionnaire. Many had provided positive comments about the service they had received.

During the inspection the inspectors spoke to two patients who also provided positive feedback on their experiences.

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

Patient support
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.

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

Surrogacy (Guidance note 14)
The centre does not undertake surrogacy therefore this area of practice is not relevant to this inspection.

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

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

What the centre could do better

Counselling (Guidance note 3)
The centre's counsellor is not accredited by BICA or an equivalent body. Sufficient evidence to demonstrate that the counsellor meets full equivalence, or is working towards BICA accreditation, was not seen. This could call into question the validity of the consents that patients have provided when receiving donated gametes, or consents that donors have provided prior to donation.

The inspection team considers that the patients have to wait an excessive length of time to access counselling. At the time of the inspection patients have to wait until March 2020

for an appointment. This impacts on their treatment as clinic protocols require counselling before having treatment using donated gametes.

The centre's counselling audit was not robust in that it did not address findings of the audit relating to long waiting lists and did not implement any corrective actions to rectify this issue.

During the inspection, the PR confirmed that interviews were being held for two additional 'bank' counsellors who would work at the centre when required. Following the interviews, and prior to the report being sent to the PR, the PR confirmed that two counsellors with appropriate accreditation had accepted offers of employment.

See recommendation 3.

HF&E Act 1990 (as amended) schedule 3ZA.

SLC T12; T14; T60 and T61; CoP Guidance note 2.14; 2.15; 3.8.

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 sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies. The 2014 audit was reviewed at the licence renewal inspection in 2015. It had been performed according to the method specified by the HFEA.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in 2015 legal parenthood consent procedures were found to be compliant with requirements.

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

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.

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 does not create or store embryos therefore this area of practice is not relevant to this inspection.

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.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes 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 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 does not create or store embryos therefore this area of practice is not relevant to this inspection.

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 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 2018, recommendations for improvement were made in relation to two areas of major non compliance and one 'other' area 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

Since the interim inspection in 2018, the centre has not received any risk tool alerts related to performance.

Areas of practice that require the attention of the Person Responsible

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
1. Witnessing Patients are given the option of producing their sample at home. If they choose this option, they are given a 'chain of custody form' to complete. This form enables the male partner to sign to confirm that the details on the sample pot are his and that he is handing over custody of his sample to his partner. In two patient records reviewed during the inspection, where the male partner had produced his sample at home, this form was absent or had been completed	The PR should ensure that gametes are appropriately witnessed at all critical points of the clinical and laboratory processes. The PR should provide a summary of any immediate actions taken to prevent this recurring when responding to this report. The PR should risk assess the use of the sperm samples where there was no verification from the male partner that it was his sample. A summary of	The root-cause of this issue is the introduction of a new form which must accompany patients providing samples 'offsite'. The centre feels that it is draconian to insist that all men should produce onsite (especially if they have a history of failure due to anxiety). Therefore, a new 'chain of custody' form was introduced alongside a modified procedure to ensure traceability and ID were confirmed for men producing offsite. These 2 examples highlighted that that training in	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required.

incorrectly. The inspectors were concerned that for these treatment cycles, there was no verification from the male partner confirming that the sample was his. Confirmation from the female partner was present. SLC T71.	the risk assessment should be sent to the centre's inspector when responding to this report. The PR should also perform a root cause analysis to consider why the centre's processes for witnessing had failed in these two cases. This should include any staff training requirements. A copy of the report should be provided to the centre's inspector by 3 March 2020. The PR should audit patient records since the time of the last inspection to ensure that there are no further failures. A summary of this audit should be provided to the centre's inspector by 3 March 2020. Three months after the implementation of any changes the PR should carry out an audit of records to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be	both the procedure and the forms has not been as comprehensive as it should be. The unit will monitor and re-audit this over the coming weeks.	

	provided to the centre's inspector by 3 June 2020.		
2. Staff Clinicians working at the centre have not had competencies formally assessed for the duties they perform. The PR has received verbal confirmation from senior clinicians in the Trust that the centre's clinicians are competent, however, there is no documented evidence that they are competent to undertake licensed activities. SLC T12 and T15a.	The PR should ensure that staff are suitably trained and assessed as competent to undertake their roles. The PR should provide the centre's inspector with a plan of how he intends to address this non-compliance, including timescales for completion of actions when responding to the report. It is expected that all staff will have been suitably assessed as competent to carry out licensed activities by 3 June 2020. The PR should provide confirmation of this to the centre's inspector.	Meetings with the new lead for gynaecology have taken place in early January. He has given assurances that all of these records will be made available at the earliest opportunity. An ongoing piece of work will be ensuring that such assurances are written into honorary contracts where appropriate.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required.
3. Counselling The centre's counsellor is not accredited by BICA or an equivalent body and sufficient evidence to demonstrate that the counsellor meets full equivalence or is working	The PR must ensure that a woman must not be provided with treatment services using donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable	I have had correspondence with the authority during the past month regarding this issue and completely accept that the waiting time is excessive and this will be addressed by the corrective	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action is required.

towards BICA accreditation was not seen. This could call into question the validity of the consents that patients have provided when receiving donated gametes. The inspection team considers that the patients have to wait an excessive length of time to access counselling. At the time of the inspection patients have to wait until March 2020 for an appointment. This impacts on their treatment as clinic protocols require counselling before having treatment using donated gametes. The centre's counselling audit was not robust in that it did not address findings of the audit relating to long waiting lists and did not implement any corrective actions to rectify this issue. During the inspection, the PR confirmed that interviews were being held for two additional 'bank' counsellors who would	opportunity to receive proper counselling. The PR must ensure that patients have the opportunity to receive proper counselling from a suitably qualified counsellor. The PR should review the centre's counselling service and ensure it is fit for purpose. This should include, but not exclusively, measures taken to ensure a suitably qualified counsellor is available and actions taken to address the lengthy waiting list. A summary report of this review together with actions taken/proposed and the timescales for implementation, should be provided to the centre's inspector when responding to this report. The PR should closely monitor the counselling waiting list to ensure that any corrective actions implemented have	actions described below. As for the training/competence element, a number of actions have already been implemented. ▪ An informal meeting with the counsellor to discuss progress of training ▪ Formal appraisal – scheduled for 22nd January ▪ Two counsellors have been appointed to effectively a 'bank or zero hours post' and will be utilised both to extend the scope and availability of counselling in general but also to reduce waiting time to no more than 2 weeks. ▪ Moreover, as one of these is BICA accredited, they will be part-utilised in a supervisory role to help and support the existing counsellor in the completion of her BICA portfolio. The intention over the coming weeks is to develop our patient	

work at the centre when required. Following the interviews, and prior to the report being sent to the PR, the PR confirmed that two counsellors with appropriate accreditation had accepted offers of employment. HF&E Act 1990 (as amended) schedule 3ZA. SLC T12; T14, T60 and T61; CoP Guidance note 2.14; 2.15; 3.8.	been effective in reducing patient and donor waiting times. In the interim period, the PR should ensure that the patients wishing to undergo treatment with donated gametes are not referred to the current counsellor, until the PR has confirmation of appropriate qualification. The PR should seek to find alternative provision for these patients. If this involves additional costs, these should be borne by the clinic not the patients.	support policy and ensure counselling takes a higher priority.	

Other areas of practice that requires improvement

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

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
None			

Responses from the Person Responsible to this inspection report
Overall the inspection report is fair and balanced. With the support of the trust, the non-conformities identified will be rectified in a timely manner and indeed corrective action was implemented almost immediately after inspection.