Executive Licensing Panel - minutes

Centre 0098 (Lanarkshire Acute Hospital NHS Trust)

Renewal Inspection Report

Tuesday, 19 May 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Howard Ryan Dina Halai	Director of Strategy and Corporate Affairs Data Analyst Scientific Policy Manager
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 Lanarkshire Acute Hospital NHS Trust has held a treatment (insemination using partner/donor sperm) and storage licence with the HFEA since 2011 and provides basic fertility services. The centre has not used donated sperm in treatment since 2008. Other licensed activities at the centre include the storage of sperm for patients undergoing treatment which may affect their fertility.

1.3. The panel noted that, in 2019, the centre provided 109 cycles of treatment (partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.4. The panel noted that, as a result of the 109 cycles of partner inseminations, provided in 2019, the centre reported five pregnancies, and this is in line with the national average.

1.5. An inspection was carried out at the centre on the 12 March 2020.

1.6. The panel noted that at the time of the inspection, there were three major areas of non-compliance concerning the quality management system (QMS), staff and consent to treatment and storage. There was also one 'other' non-compliance regarding the safety and suitability of premises. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations concerning consent to treatment and staff, and where required, to audit the effectiveness of these actions within the prescribed timescales. The PR has given a commitment to fully implement the recommendations relating to the QMS and the safety and suitability of premises.

1.7. The panel noted that, in March 2020, the PR suspended fertility treatments at the centre 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 will liaise with the PR to consider an appropriate timescale for fully implementing the outstanding recommendations made in the report, taking into account the period of time for which treatments are suspended as a result of the pandemic.

1.8. 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.

1.9. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the agreed timescales.

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

1.11. The panel noted that the centre has not provided treatment with donor sperm since 2008 and does not intend to do so in the future. The Executive Licensing Panel (ELP) that considered the centre's last interim inspection report, in March 2018, felt that as the centre had not undertaken donor treatment for a long period, and in light of this, the licence type should be reviewed at the next renewal inspection. The inspection team discussed this with the PR, who agreed that the centre's licence should be amended to remove insemination using donor sperm; the PR had provided email confirmation of this agreed change.

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

2. Decision

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

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

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

2.4. The panel noted that the centre's own recent patient survey responses were reviewed, and these were generally positive, particularly about the friendliness of staff. 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. Noting the change to the centres licence type, therefore removing insemination using donor sperrm, the panel endorsed the inspectorate's recommendation to renew the centre's licence to a treatment (insemination using partner sperm) and storage licence, for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

26 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. 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: 12 March 2020

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: Mhairi West and Sandrine Oakes

Date of Executive Licensing Panel: 21 April 2020

Centre name	Lanarkshire Acute Hospital NHS Trust
Centre number	0098
Licence number	L/0098/16/c
Centre address	Infertility Department, Monklands Hospital, Monkscourt Avenue, Airdrie, Lanarkshire, ML6 0JS, United Kingdom
Person Responsible	Ms Seema Jain
Licence Holder	Iain Wallace
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 Lanarkshire Acute Hospital NHS Trust has held a Treatment (insemination using partner/donor sperm) and Storage licence with the HFEA since 2011 and provides basic fertility services. The centre has not used donated sperm in treatment since 2008.

The centre provided 109 cycles of treatment (partner intrauterine insemination (IUI)) in 2019. In relation to activity levels this is a small centre. Other licensed activities at the centre include the storage of sperm for patients undergoing treatment which may affect their fertility.

An application was submitted in February 2020 to request a change to the licence holder (LH). This application was approved.

An application was submitted in February 2020 to request a variation to the licensed premises to accommodate a new cryostore. This application was approved at ELP on 7 April 2020.

Pregnancy outcomes
In 2019, the centre reported 109 cycles of partner insemination with five pregnancies. This represents a clinical pregnancy rate of 5%, which is in line with the national average.

Summary for licensing decision

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

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

The 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 and one 'other' area of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that effective consent to treatment is obtained.
- The PR should ensure that all staff are qualified and competent for the tasks they perform.

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

Major areas of non compliance:

- The PR should ensure that the Quality Management System (QMS) is robust and fit for purpose and ensure that auditing processes are effective.

'Other' areas that require improvement:

- The PR should ensure that the centre's premises are safe and suitable for purpose.

Recommendation to the Executive Licensing Panel

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

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 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 centre has not provided treatment with donor sperm since 2008 and does not intend to do so in the future. The ELP that considered the centre's last interim inspection report felt that because the centre had not undertaken donor treatment for a long period, the licence type should be reviewed at the next renewal inspection. The inspection team discussed this with the PR, who agrees that the centre's licence should be amended to remove insemination using donor sperm. The PR has provided email confirmation of this.

Therefore, the executive recommends the renewal of the centre's Treatment (insemination using partner 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 0098 does not import gametes and does not require an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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) 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 compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

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
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre does not recruit donors for the provision of treatment services therefore this area of practice does not apply.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not recruit donors for the provision of treatment services therefore this area of practice does not apply.

Donor assisted conception (Guidance note 20)
The centre does not recruit donors for the provision of treatment services therefore this area of practice does not apply.

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
Transport and distribution of gametes
Receipt of gametes
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 broadly 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 (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners, or their gametes, or any material removed from them, are compliant with HFEA requirements to be accreditation 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, with the exception of the area described in QMS and recommendation 1.

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
The centre does not perform treatments that fall within the scope of this inspection theme; therefore this area of practice does not apply.

Multiple births (Guidance note 7; General Direction 0003)
The centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination 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 (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note15)
The centre does not receive gametes or embryos therefore this area of practice does not apply.

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

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 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 partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

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

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 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

Safety and suitability of premises and facilities (Guidance note 25)
The emergency alarm call system in the male production room is not tested at regular intervals.

Whilst the staff could explain how the autodial alarm system would work in the event of a low level nitrogen alarm in the cryostore, after discussion with the laboratory staff and also the PR, the inspector was not assured that there was sufficient communication between those on the call list to ensure that there would always be someone available to respond.

SLC T17; see recommendation 4.

Quality management system (QMS) (Guidance note 23)
The centre's standard operating procedure (SOP) relating to the management of medicines is narrow in scope, as it is focusses on prescribing only, which does not fully demonstrate that medicines management practices at the clinic are compliant with best practice guidelines. The SOP did not cover;

- Ordering and receiving of medicines, or stock management;
- Issuing medicines to patients, including 'out of hours' distribution;
- Labelling of medicines;
- Storage of medication, including fridge temperature monitoring and actions if measurements are 'out of range'.

In addition, an audit of the process has not been conducted in the last two years.

Patient having IUI treatment are only screened for blood borne viruses (BBV) if they are deemed at increased risk of a positive result based on their medical and/or travel history. This is not reflected in the patient screening SOP.

The reports of audits of witnessing, consent to storage and storage location were not sufficiently detailed. Despite a description of how audit reports should be structured in the centre's quality manual, the scope, method and sample size audited was not always fully defined, and description of findings lacked detail. Corrective actions and assessment of the need for a root cause analysis were insufficiently documented. The inspection team discussed this with the laboratory team and was assured that the audits had been performed to an acceptable level, they just hadn't been documented very well.

SLC T33b, T36 &T50; see recommendation 1.

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

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

What the centre could do better

Staff (Guidance note 2)
The PR could not provide competency records for staff regarding the provision of information, obtaining consent to treatment and storage and welfare of the child assessments.

This was a non compliance at the last renewal inspection in 2016.

SLC T12; see recommendation 2.

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);
The centre does not undertake preimplantation genetic screening therefore this area of practice does not apply.

Embryo testing and sex selection (Guidance note 10)

The centre does not undertake embryo testing and sex selection therefore this area of practice does not apply.
What the centre could do better Not applicable to 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. 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 PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were also reviewed. These were generally positive, particularly about the friendliness of the staff.

No patients were available to speak to inspectors during this visit.

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
Sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non discriminatory way.

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 providing relevant consent.

Sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake any egg or sperm sharing arrangements so this area of practice does not apply.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy services therefore this area of practice does not apply.

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)
The centre's procedures for providing information to patients 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 partially compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre has not performed any donor treatments since 2008, therefore this section does not apply.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
'Consent to disclosure to researchers' requirements are not relevant to basic partner IUI services and storage, and, given the centre has not used donated sperm in treatment since 2008 and has no plans to do so, this area of practice was not reviewed at this inspection.

What the centre could do better
Consent (Guidance note 5;6)
It is the centre's process that, if a patient storing sperm before oncology treatment wishes to provide his consent to enable a partner to use his sperm to create and store embryos in the event of his death, he will be asked to complete a 'men's consent to treatment and storage' (MT) form.

However, the centre does not ask the patient to complete page four of the MT form where he should specify the number of years that he would consent to any embryos created from his sperm being stored for (section 4.4), even though he has consented to embryo storage on the previous page. This missing information means that he has not provided effective written consent and his partner would not be able to store any embryos posthumously created with his sperm.

The inspection team acknowledges that, by the end of the inspection, the laboratory staff responsible for obtaining this consent had created a list of all patients who had completed an MT form, and decided on a process regarding how to contact them to update their consent forms.

Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and SLC T57; see recommendation 3.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre does not create embryos, therefore this area of practice does not apply.

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

Screening of patients and Storage of gametes

What the centre does well

Screening of patients (Guidance note 15)
The centre's procedures for screening patients are compliant with HFEA requirements with the exception noted in the QMS section of this report and recommendation 1. 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 (Guidance note 17)
The centre's procedures for storing sperm are compliant with HFEA requirements. These measures ensure that the sperm samples are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores sperm in accordance with the consent of the gamete providers. The storage of gametes 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.

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 use embryos for training staff, therefore this area of practice does not apply.

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 centre provided an annual return for treatments undertaken in 2019 within the required timeframe.

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 one area of critical non compliance, three 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

As this centre only provides partner IUI treatment, their success rates are not subject to ongoing monitoring via the HFEA risk tool and therefore the centre has not been issued with any performance alerts since the last inspection.

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, 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 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, 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 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 centre's standard operating procedure (SOP) relating to the management of medicines is narrow in scope, as described in the main body of the report. Patients having IUI treatment are only screened for blood borne viruses (BBV) if they are deemed at increased risk of a positive result based on their medical and/or travel history. This is not reflected in the patient screening SOP. The reports of audits of witnessing, consent to storage	The PR should ensure that the QMS is robust and fit for purpose. The PR should review and update the SOPs identified in this report, address the issues described, and provide a copy of the updated SOPs to the centre's inspector by 12 June 2020. The PR should conduct an audit of the updated medicines management process and provide the report to the centre's inspector by 12 September 2020.	New patient screening SOP to be completed. Audit structure to be reviewed with introduction of new audit template which will be discussed at next unit meeting once services resume after current covid crisis.	The executive acknowledges the PR's response to implementing this recommendation. The PR has suspended fertility treatments in the 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 will liaise with the PR to consider an appropriate timescale for fully implementing the recommendations. Further action required

and storage location were not sufficiently detailed. Despite a description of how audit reports should be structured in the centre's quality manual, the scope, method and sample size audited was not always fully defined, and description of findings lacked detail. Corrective actions and assessment of the need for a root cause analysis were insufficiently documented. SLC T33b, T36 &T50.	The PR should ensure that auditing processes are effective. The PR should review the structure of audit reports, referring the centre's own quality manual, and provide an updated template for an audit report, taking into account the findings described in this report, to the centre's inspector by 12 June 2020. Any changes should be communicated to all staff.		
2. Staff There has been no competency assessment completed for the practitioners who provide information to patients, obtain consent to treatment and storage, and complete the welfare of the child assessments. This was a non compliance at the last renewal inspection in 2016. SLC T12.	The PR should ensure that all staff are qualified and competent for the tasks they perform. The PR should ensure that competency assessments are completed for all practitioners who provide information to patients, obtain consent to treatment and storage, and complete welfare of the child assessments.	New competency assessments for staff to be introduced in patient information, obtaining consent for treatment and storage and completing welfare of child assessments.(Documents attached)	The executive acknowledges the PR's response to implementing this recommendation. The PR has acknowledged by email that there was an oversight after the last renewal inspection and development of staff competencies was not actioned. No further action required beyond confirmation of completed competency

	The PR should provide confirmation of completed assessments to the centre's inspector by 12 June 2020. The PR should investigate why this non-compliance has not been actioned since the renewal inspection in 2016 and provide a summary report to the centre's inspector when responding to this report.		assessments, which is due by 12 June 2020.
3. Consent to treatment and storage It is the centre's process that, if a patient storing sperm before oncology treatment wishes to name a partner who could use his sperm to create and store embryos in the event of his death, he is asked to complete a 'men's consent to treatment and storage' (MT) form. However, the centre does not ask the patient to complete page four of the MT form where he should specify the number of years that he would consent to any embryos created from his sperm being	The PR should ensure that effective consent to treatment is obtained. The PR should provide the centre's inspector with a plan of how to resolve this issue, on the return of this report. This plan should include an audit of patient records to identify patients who have completed an MT form and not specified the number of years they wish embryos to be stored. These patients should be contacted to clarify their wishes, and actions taken to resolve the issue.	Case notes have been reviewed and we have identified 12 patients that need the MT form to be amended and so far have contacted 5 of them. We have written this up and will submit it when complete. The scientific staff carry out competency assessments for completion of consent forms (example attached).	The executive acknowledges the PR's response to implementing this recommendation. The PR should ensure that the competency assessment for obtaining consent to storage includes consideration of the section found to be incomplete during inspection. No further action beyond submission of report of actions taken regarding the identified patients, which is due by 12 June 2020.

stored for (section 4.4), even though he has consented to embryo storage on the previous page. This missing information means that he has not provided effective written consent and his partner would not be able to store any embryos posthumously created with his sperm. The inspection team acknowledges that the laboratory staff responsible for obtaining this consent had created a list of all patient who had completed an MT form, and decided on a process regarding how to contact them to update their consent forms. Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended), SLC T57.	The PR should provide the centre's inspector with a report summarising the actions taken, which should include a review of any relevant SOPs and competency assessments of staff by 12 June 2020.		

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
4. Safety & suitability of premises The emergency alarm call system in the male production room is not tested at regular intervals. Whilst the staff could explain how the autodial alarm system would work in the event of a low level nitrogen alarm in the cryostore, the inspector was not assured that there was sufficient communication between those on the call list to ensure that there would always be someone available to respond. SLC T17.	The PR should ensure that the centre's premises are safe and suitable for purpose. The PR should provide a documented process for the regular testing of the centre's emergency alarm calls. They should submit this on return of this report and provide the centre's inspector with an audit of that process by 12 June 2020. The PR should ensure that there is documented policy to ensure that at least one of the people on the call list is available to respond to an alarm from the cryostore.	Documented process for auto-dialler and list of contact detaiils is attached. SOP for testing of all alarm systems including one in the male production room being written. Policy documenting on- call list and system for alarm monitoring to be submitted by June.	The executive acknowledges the PR's response to implementing this recommendation. The executive note that the PR has supplied the process, including contact details, for responding to the autodialler alarm. However she should ensure that she provides further details of how she is assured that at least one person on the contact list will be available to respond to the alarm at any particular time. Further action required.

	This policy should be submitted to the centre's inspector by 12 June 2020.		

Reponses from the Person Responsible to this inspection report