Executive Licensing Panel - minutes

Centre 0068 (Leicester Fertility Centre)

Renewal Inspection Report

Wednesday, 26 September 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Erin Barton	Director of Strategy & Corporate Affairs Chief Information Officer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance 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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that the Leicester Fertility Centre has held a licence with the HFEA since 1992 and provides a full range of licensed fertility treatments.

1.3. The panel noted that the centre currently has an application in progress to add embryo testing to the licence. This application will be considered at a later date and separate to the renewal licence application.

1.4. The panel noted that, in the 12 months to 30 April 2018, the centre provided 484 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a medium sized centre.

1.5. The panel noted that, between March 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that, for IVF and ICSI, HFEA held register data for the period of 1 March 2017 to 28 February 2018, show the centre's success rates are in line with national averages.

1.7. The panel noted that, in 2017, the centre reported 290 cycles of partner insemination with 26 pregnancies. This represents a clinical pregnancy rate of 9%, which is in line with the national average.

1.8. An inspection was carried out at the centre on the 26th and 27th June 2018.

1.9. The panel noted that at the time of the inspection, there were two major areas of non-compliance concerning the safety and suitability of premises and facilities and medicines management. There was also one 'other' area of non-compliance regarding the Quality Management System (QMS). Since the inspection, the Person Responsible (PR) has fully implemented the recommendation concerning the suitability of premises and facilities, and where required, and by the dates specified, will provide an update or summary of audits conducted to ensure that the corrective actions taken, have been effective. The PR has provided a commitment to fully implementing the recommendations made in the report concerning medicines management and the QMS.

1.10. The panel noted that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates so as to improve the quality of service offered to patients.

1.11. The panel noted the inspectorate recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions, subject to the recommendations in the 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).

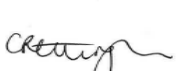
2.4. The panel voiced particularly concern about the non-compliance relating to the safety and suitability of premises and facilities, noting this affected the treatment and phlebotomy rooms. The panel requested that, one or more unannounced inspections are conducted, between now and the interim inspection, to ensure the centre is addressing this non-compliance. The panel requested to receive an update report on the centre's progress in relation to this non-compliance.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

5 October 2018

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: 26 and 27 June 2018

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

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

Inspectors: Janet Anderson-Pearce (lead), Susan Jolliffe, Polly Todd, Louise Winstone and Julie Katsaros (observing)

Date of Executive Licensing Panel: 26 September 2018.

Centre name	Leicester Fertility Centre
Centre number	0068
Licence number	L/0068/16/a
Centre address	Assisted Conception Unit, Women's Hospital, Leicester Royal Infirmary, Leicester, LE1 5WW, United Kingdom
Person Responsible	Mrs Jane Blower
Licence Holder	Mr Tarek Gelbaya
Date licence issued	1 October 2014
Licence expiry date	30 September 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Leicester Fertility Centre has held a licence with the HFEA since 1992 and provides a full range of licensed fertility treatments.

The centre provided 484 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2018. In relation to activity levels this is a medium-sized centre.

The centre currently has an application in progress to add embryo testing to the licence. This application will be considered at a later date and separate to this renewal licence application.

Other licensed activities at the centre include the storage of gametes and embryos.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 March 2017 and 28 February 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported 290 cycles of partner insemination with 26 pregnancies. This represents a clinical pregnancy rate of 9% which is also in line with the national average.

Multiple births[2]

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

Between 1 March 2017 and 28 February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles, for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), 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 notwithstanding the non-compliance related to premises in this report;
- 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 require improvement including two major and one 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that the corrective actions taken, have been effective.

Major area of non-compliance:

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

The PR has committed to implementing the following recommendations:

Major area of non-compliance:

- The PR should ensure medicines management practice is compliant with regulatory and best practice guidance.

'Other' areas that require improvement:

- The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates so as to improve the quality of service offered to patients.

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

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

donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not undertake transport and satellite activities 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 or embryos clinically ineffective or harmful to the recipient.

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)

On inspection the following issues were noted:

- The centre facilities are cramped, and inadequate storage provision has resulted in large cardboard boxes of consumables being stored under work tables and in the corridors.
- The inspection team was also concerned that staff did not appear to have a designated area to have a scheduled break from their work activities away from their desks or work stations. The inspection team considered this to be a health and safety risk and not conducive to good ways of working and likely to impact on staff morale.
- A room housing the liquid nitrogen dewars was full to capacity and the dewars were obstructing access to clinical equipment. As a consequence, empty cylinders were kept in the main corridor.
- In the theatre there were areas of bare plaster and paint peeling off the wall in some places.
- Two treatment rooms and the phlebotomy room were visibly dusty.

SLC T17; Health and Safety at Work Act 1974, see recommendation 1.

Medicines management (Guidance Note 25)

The carry-over of stock is not recorded in the controlled drugs register and the centre only record a single patient identifier (patient name) in the controlled drugs register.

SLC T2, DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)', see recommendation 2.

Quality management system (QMS) (Guidance note 23)

Corrective actions in the consent audit were not progressive in that they would not achieve improvement in practice. For example, corrective actions were listed as 'continue to monitor at management meetings' and 'significantly higher number of consent issues'.

SLC T36, CoP 23.27 and 23.28, see recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)

The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological science and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing
Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake preimplantation genetic screening or embryo testing and sex selection, therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable.

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. Whilst only 10 patients provided feedback directly to the HFEA, it was positive. In addition, during the inspection visit the inspectors spoke to two patients who provided feedback on their experiences, and the centre's most recent patient survey responses collected between April 2018 and June 2018 were reviewed. The feedback from 98 patients was generally very positive.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

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

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;

- egg providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg provider and recipient.

Surrogacy (Guidance note 14)
The centre has not done any surrogacy treatments since 2013 and it is based on the review of those records that the centre's procedures for treatment involving surrogacy are considered compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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 HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the

partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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. At the inspection in March 2016, legal parenthood consenting processes were found to be robust.

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

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

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

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

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

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

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

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)

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

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register 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 2016, recommendations for improvement were made in relation to two areas of major non-compliance.

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

On-going monitoring of centre success rates

The centre has not received any risk tool alerts relating to success rates since the interim inspection in 2016.

Areas of practice requiring action

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

Critical area of non-compliance

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

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

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

Major area of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Safety and suitability of premises and facilities: On inspection the following issues were noted: • The centre facilities are cramped, and inadequate storage provision has resulted in large cardboard boxes of consumables being stored under work tables and in the corridors. • The inspection team was also concerned that staff did not appear to have a designated area to have a scheduled break from their work activities away from their desks or work stations. This is a health and safety risk and not conducive to good ways of working and likely to impact on staff morale. • A room housing the liquid nitrogen dewars	The PR should ensure that the centre's premises are safe and suitable for purpose and the level of activities undertaken. The PR should commission an independent review of the premises for their suitability to provide ongoing treatment services including, (but not exclusively), the issues identified in this report. The PR should review current activity levels in line with the capacity to provide treatment services in a safe environment and with the staff available. This should include, (but not exclusively), capacity and suitability of the premises for current treatment activity levels, capacity and suitability for treatment activity should the PR proceed with an application to include embryo testing to the licence at a later date, and arrangements for the	This review will be undertaken with the support of the Trust. The Trust is planning to relocate the department as part of the plans to build a new purpose designed Womens Hospital The card board boxes stored under the worktables have been removed. There are no boxes stored in the corridors. The Trust provides a 24/7 staff restaurant which staff are able to use	The Executive acknowledges the PR response and commitment to implementing this recommendation. No further action beyond submission of commissioned reports of suitability of premises for current and proposed activity due by 26 January 2019.

was full to capacity and the dewars were obstructing access to clinical equipment. As a consequence, empty cylinders were kept in the main corridor. • In the theatre there were areas of bare plaster and paint peeling off the wall in some places. • Two treatment rooms and the phlebotomy room were visibly dusty. SLC T17. Health and Safety at Work Act 1974.	removal of surplus and de-commissioned items. A copy of the summary reports of these reviews should be provided to the centre's inspector by 26 January 2019.	The clinical equipment referred to is obselete and has been de-commissioned and was awaiting disposal, it has now been decommissioned and disposed of in accordance with Trust policy. Empty cylinders were awaiting collection by the porters for re-filling. These were fully labelled Reports will be provided within the timescale requested by the HFEA. The bare plaster has been repaired We are working with domestic services to ensure cleaning and audits are more robust	
2. Medicines management: The carry-over of stock is not recorded in the controlled drugs register and the centre only record a single patient	The PR should ensure medicines management practice is compliant with regulatory and best practice guidance.	The issues identified and the audits will be carried out with the support of the Trust chief pharmacist	The Executive notes the PR's response and looks forward to receipt of the summary report of the review of medicines management practice due by

identifier (patient name) in the controlled drugs register. SLC T2. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.	The PR should review medicines management practice and address the issues identified in this report. A summary report of this review including corrective actions taken, should be provided to the centre's inspector by 26 September 2018. Three months after the review, the PR should audit medicines management practices to ensure that corrective actions implemented, have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 26 January 2019.		26 September 2018. Further action required.

Other areas of practice that requires improvement

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

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
3. QMS: Corrective actions in the consent audit were not progressive in that they would not achieve improvement in practice. For example, corrective actions were listed as 'continue to monitor at management meetings' and 'significantly higher number of consent issues'. SLC T36. CoP 23.27 and 23.28.	The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice. The PR should conduct a review of all audits undertaken in the last two years to ensure that corrective actions are appropriate and have been effective in achieving compliance and improvements. A summary report of this review, including any further actions implemented, should be provided to the centre's inspector by 26 January 2019.	A review of audits will be undertaken and reccomendations for actions implemented.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

Responses from the Person Responsible to this inspection report