Executive Licensing Panel - minutes

Centre 0033 (Manchester Fertility)

Renewal Inspection Report

Friday, 16 February 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Anna Coundley Helen Crutcher	Head of Intelligence Information Access and Policy Manager Risk and Business Planning Manager
Members of the Executive	Nana Gyamfi Dan Howard Bernice Ash	Secretary Chief Information Officer (Observing) Committee Officer (Observing)
External adviser		
Observers		

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 Manchester Fertility has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

1.3. The panel noted that, in the 12 months to 30 September 2017, the centre provided 1,916 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre. The centre also stores gametes and embryos.

1.4. The panel noted that for HFEA held register data, between July 2016 and June 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. The panel noted that in 2016, the centre reported 31 cycles of partner insemination with 1 pregnancy.

1.6. The panel noted that an inspection was carried out at the centre on 21 and 22 November 2017.

1.7. The panel noted that at the time of the inspection on 21 and 22 November 2017, there were two major areas of non-compliance regarding witnessing and the Quality Management System (QMS) alongside one 'other' area of non-compliance concerning equipment and materials. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the major non-compliance recommendations concerning witnessing and the QMS and the 'other' area of non-compliance regarding equipment and materials. The PR has also committed, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that the success rates for IVF treatment in women under 38 years old are below the national average, and their multiple clinical pregnancy/live birth rates meet the target. The PR has been encouraged to ensure that the QMS is used to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

1.9. The panel noted that some improvement is required for the centre to demonstrate the suitability of their practices. The PR had been encouraged to use the QMS to its best effect to monitor and improve the service provided to patients.

1.10. The panel noted the low rate of patient feedback. There were only 17 responses in the most recent survey. This constitutes less than 2% of patients.

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

1.12. The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) 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 noted that although an application was submitted for treatment and storage only, the PR confirmed by email that she would like the renewed licence to be for treatment (including embryo testing) and storage in line with the activities on the centre's current licence. Therefore, the panel 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 encouraged the PR to continue working with the inspectorate to ensure that the QMS is utilised to the best possible effect to improve birth rates.

2.5. The panel encouraged the clinic to continue to seek comments from patients in order to improve the rate of patient feedback.

2.6. The panel encouraged the PR to provide the outstanding audits, concerning witnessing and the QMS, by the specified timeframes.

2.7. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) 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

Caylin Joski-Jethi

Date

21 February 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: 21 and 22 November 2017

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) 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: Vicki Lamb, Susan Jolliffe, Andy Glew, Mhairi West (observer)

Date of Executive Licensing Panel: 16 February 2018

Centre name	Manchester Fertility
Centre number	0033
Licence number	L/0033/14/b
Centre address	3 Oakwood Square, Cheadle Royal Business Park, Cheadle, Cheshire, SK8 3FS
Person Responsible	Dr Deborah Falconer
Licence Holder	Dr Ilan Lieberman
Date licence issued	1 May 2014
Licence expiry date	30 April 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Manchester Fertility has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

It provided 1916 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2017. In relation to activity levels this is a large centre. The centre also stores gametes and embryos.

The current licence was granted on 1 May 2014, for a four-year period and expires on 30 April 2018.

In April 2017, the centre was granted a variation of licence to add embryo testing.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period July 2016 – June 2017 show the centre's success rates are in line with national averages with the following exception:

- success rates following IVF treatment in women under 38 years old are lower than average at a statistically significant level.

The Executive will continue to monitor these success rates.

In 2016, the centre reported 31 cycles of partner insemination with one pregnancy which is likely to be in line with the national average.

Multiple births[2]

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

Between July 2016 and June 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. 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;
- 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 two major and one 'other' area of non-compliance:

Major areas of non-compliance:

- The PR should take immediate action to ensure that all relevant procedures involve double checking of the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.
- The PR should ensure that when audits show that quality indicators are not met, appropriate corrective actions are taken and documented, and activities are carried out in line with the relevant SOP.

'Other' area of non-compliance:

- The PR should ensure that the acceptable limits within which equipment must operate are documented, and that procedures for the operation of all critical equipment outline what to do if the equipment malfunctions or fails.

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

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 the success rates for IVF treatment in women under 38 years old are below the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR should ensure that the quality management system (QMS) is used to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

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 inspection team recommends the renewal of the centre's treatment (including embryo testing) 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 partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Centre staff do not witness the discarding of sperm and when embryos are transferred to research there is a cross-check of the information on the storage container against the research consent form but not against the information in the patient records (standard licence condition (SLC) T71). See recommendation 1.

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

What the centre does well

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

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

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

The centre is compliant with HFEA requirements to process gametes and 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 broadly compliant with guidance.

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

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

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

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

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and

that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
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 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 has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements. The centre does not require any transport agreements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly 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, but not documented

procedures to follow if equipment malfunctions.

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

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

What the centre could do better

Medicines management (Guidance Note 25)
In an audit, four out of four patient records cross-checked with the controlled drug (CD) register had no time of administration in the CD register. This practice differs from the centre's controlled drug SOP (SLC T33b). See recommendation 2.

QMS (Guidance note 23)
Although quality indicators have been established for ICSI and audits are performed regularly, corrective actions have not always been taken when quality indicators for egg damage rates have been breached (SLC T36). See recommendation 2.

Equipment and materials (Guidance note 26)
The centre has not documented the acceptable limits within which equipment must operate, although it is acknowledged that staff are aware of what those limits are (SLC T24). The centre has not established a documented procedure in the event of malfunction or failure of equipment (SLC T27). 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 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.

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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to three patients who provided feedback on their experiences. The centre's most recent patient survey responses were also reviewed for the period 1 January 2017 to 30 June 2017. A total of 17 responses were reviewed, all of which provided feedback that was positive.

On the basis of 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(s) (where

relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are 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 with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well

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

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

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

What the centre does well

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

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

cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in November 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. Six 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 with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. 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 2015, recommendations for improvement were made in relation to two areas of critical non-compliance, three areas of major non-compliance and one 'other' area of non-compliance. An additional inspection was conducted in 2016 which found 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

In December 2016, the centre was asked to review procedures for the provision of IVF involving fresh embryos in women under 38 years old because of a low clinical pregnancy rate, and in January 2017, the centre was similarly asked to review procedures for the provision of ICSI involving fresh embryos in women under 38 years old.

No further success rate alerts were issued until October 2017 when the centre was asked to review procedures for the provision of IVF involving fresh embryos in women aged 38 and over and ICSI involving fresh embryos in women under 38 years old because of a low clinical pregnancy rate.

In all four cases the PR responded promptly to the request and provided a commitment to keep success rates in this group of patients under review.

The Executive will continue to monitor these success rates, and a recommendation is not considered to be necessary at this time.

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 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 Centre staff do not witness the discarding of sperm and when embryos are transferred to research there is a cross-check of the information on the storage container against the research consent form but not against the information in the patient records (SLC T71).	The PR should take immediate action to ensure that all relevant procedures involve double checking of the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. The HFEA should be advised of the measures taken to ensure that this happens by the time the PR responds to this report Three months after the implementation of revised witnessing procedures, the PR should conduct an audit of	OP-EM-2 Labelling and Witnessing of Materials in the Laboratory has been amended to include instructions for manually double witnessing discarding gametes and embryos. FM-EM-47 Laboratory details form now has a section for contemporaneous double manual witnessing of discarding of semen sample pots and semen preparation tubes after either ICSI or IVF fertilisation check. In addition, the RI witness point diagram has been modified to add a reminder, at the point of	The PR has taken action to ensure that all relevant procedures involve double checking of the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process, and provided a summary of the changes to the inspector. A summary report of the audit is due to be submitted by 22 April 2018. Further action required.

	witnessing and a summary report of the findings of the audit should be provided to the HFEA by 22 April 2018.	placing fertilised eggs into the embryo culture dish, to discard the sperm with a witness. FM-EM-35 Transfer of Frozen Research Embryos form has been modified to record that a cross check is performed of completed research consent forms against patient records and that the correct patient embryos removed from storage for transfer to research centre. Double witnessed manually at point of removal from storage and signatures/date/time recorded on form which is then stored in patient records. Audit of revised witnessing procedure scheduled for 01.04.2018.	
2. QMS Although quality indicators have been established for ICSI and audits are performed regularly, corrective actions have not always been taken when quality indicators for egg damage rates have been	The PR should ensure that when audits show that quality indicators are not met, appropriate corrective actions are taken and documented. The PR should inform the centre's inspector of the actions taken to implement this	Corrective action to be formally implemented where quality indicators are breached for laboratory KPIs. CA/PA to be raised on quality management system (Q-Pulse) to document where KPI acceptable levels have been breached and followed up with corrective	The PR has updated the inspector as required, within the timescale specified. A summary report of the audit is due to be submitted by 22 July 2018. Further action required.

breached (SLC T36).	recommendation when responding to this report. The PR should conduct an audit in six months, to ensure that where quality indicators have not been met, the appropriate corrective actions have been implemented and documented. A summary report of this audit should be provided to the centre's inspector by 22 July 2018.	action and/or root cause analysis where appropriate. Audit after 6 months scheduled 01.06.18.	
In an audit, four out of four patient records cross-checked with the CD register had no time of administration in the CD register. This practice differs from the centre's controlled drug SOP (SLC T33b).	The PR should ensure that the CD register is completed in line with the management of controlled drugs SOP. Three months after the implementation of corrective action the PR should conduct an audit of the CD register and a summary report of the findings of the audit should be provided to the HFEA by 22 April 2018.	Time of administration of CDs is being recorded in the CD Register. Audit results to follow by 22.4.18.	The PR has updated the inspector as required, within the timescale specified. A summary report of the audit is due to be submitted by 22 April 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. Equipment and materials The centre has not documented the acceptable limits within which equipment must operate, although it is acknowledged that staff are aware of what those limits are (SLC T24).	The PR should ensure that the acceptable limits within which equipment must operate are documented. The PR should inform the centre's inspector of the actions taken to implement this recommendation when responding to this report.	Reference values and ranges added to appropriate SOPs and forms: FM-EM-29 Monthly Temperature Checks Form WI-EM-6 Monthy Temperature Checks WI-EM-5 Incubator Temperature Mapping FM-EM-44 Embryoscope Temperature CO2 and O2 FM-EM-34 G185 Temperature CO2 and O2 Measurements FM-EM-28 Incubator Temperature Mapping Form FM-EM-32 G185 Incubator Temperature Mapping form	The PR has updated the inspector as required, and has confirmed that the corrective action has been taken. No further action required.
The centre has not established a documented procedure in the event of malfunction or failure of	The PR should ensure that procedures for the operation of all critical equipment outline what to do if the equipment	Procedure being written for lab equipment - what to do in the event of an equipment failure. Critical equipment forms being	The PR has confirmed that she will tell the inspector when the relevant procedures have been updated.

equipment (SLC T27).	malfunctions or fails by 22 February 2018. When the required operating procedures are revised, the PR should provide the centre's inspector with a list of all critical equipment: a sample of the associated operating documents will then be requested for review.	created for other areas with equipment/maintenance details, acceptable parameters, contact details in the event of malfunction, competent staff. To be stored in departments and accessible to all.	Further action required.

Reponses from the Person Responsible to this inspection report