Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
15 April 2015

Minutes – item no. 1

Centre 0067 (St Mary's Hospital) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Hannah Verdin Head of Regulatory Policy David Moysen Head of IT
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of application

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

2. The panel noted that this is a treatment and storage centre which provides a full range of fertility services. The Panel noted that in relation to activity levels this is a large centre.

3. The panel noted that the centre has been licensed by the HFEA since 1992 and is on a three-year licence due to expire on 31 July 2015.

4. The panel noted that in the 12 months to 31 December 2014, the centre provided 1369 cycles of treatment (excluding partner intrauterine insemination).

5. The panel noted that for IVF and ICSI, HFEA-held register data for the period October 2013 to September 2014 showed the centre's success rates were in line with national averages.

6. The panel noted that in 2013, the centre reported 51 cycles of partner insemination with six pregnancies. This was consistent with the national average.

7. Between October 2013 and September 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 23%. This represented performance that was likely to be greater than the 10% maximum multiple live birth rate target for this period.

8. The panel noted that the Person Responsible (PR) is encouraged to continue to use the Quality Management System (QMS) to improve the quality of the service offered to patients by monitoring and improving the centre's clinical pregnancy/live birth rates, and implementing an effective strategy to reduce the multiple birth rate to meet the target set by the HFEA.

9. The panel noted that at the time of the inspection on 3 and 4 February 2015, the Inspectorate identified one critical, three major and eight other areas of non-compliance. The panel noted that since the inspection the PR had fully implemented some of the recommendations. The PR has committed to fully implement all of the outstanding recommendations within the prescribed timescales.

10. The panel noted that significant improvement is required in order for the centre to reflect suitable practices, and that the Inspectorate will continue to monitor the centre's performance.

11. The panel noted that the Inspectorate recommend 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.

Decision

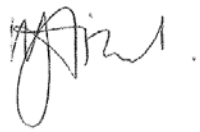
12. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

13. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

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

15. The panel noted that the centre's multiple clinical pregnancy rates are unlikely to meet the multiple birth rate target and urged the centre to continue to be proactive and reduce the multiple birth rate to meet the target set by the HFEA.

16. The panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance and agreed to renew the centre's treatment and storage licence for a period of four years without additional conditions.



Signed: Date: 28 April 2015
Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 3 and 4 February 2015

Purpose of inspection: Renewal of a licence to carry out treatment and storage

The centre has applied to add the following activities: None

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 (lead), Andrew Leonard, Kathryn Mangold and Lesley Brown (observer)

Date of Executive Licensing Panel: 15 April 2015

Centre name	St Mary's Hospital
Centre number	0067
Licence number	L/0067/17/c
Centre address	The Department of Reproductive Medicine, Regional IVF and DI Unit, Whitworth Park, Manchester, M13 0JH, UK
Person Responsible	Mr Gregory Horne
Licence Holder	Mr M Deegan
Date licence issued	01/08/2012
Licence expiry date	31/07/2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
St Mary's Hospital has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 1369 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/12/2014. In relation to activity levels this is a large centre.

The current licence has been varied to reflect the following changes:
07/11/2013 – change of Person Responsible (PR) to Yasmin Sajjad
15/10/2014 – change of PR to Gregory Horne

The centre is applying to renew the treatment and storage licence.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2013 – September 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported 51 cycles of partner insemination with 6 pregnancies. This equates to a 12% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between October 2013 and September 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%: this represents performance that is likely to be greater than the 10% multiple live birth rate target for this period.

[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 PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their 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 one critical, three major and eight 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should ensure that no embryos are kept in storage for longer than the consented storage period.

'Other' areas that requires improvement:

- The PR should ensure that taps can be operated as intended.
- The PR should ensure that equipment is suitably maintained and that this is recorded.

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

Critical area of non compliance:

- **The PR should ensure that consent to treatment is always obtained whenever required.**

Major areas of non compliance:

- The PR should ensure that audits are performed in a rigorous manner.
- The PR should ensure that incidents are reported to the HFEA where appropriate.

'Other' areas that requires improvement:

- The PR should ensure that witnessing is undertaken correctly.
- The PR should ensure that wherever possible only CE marked medical devices are used.
- The PR should ensure that floor coverings do not increase the risk of slips, trips and falls.

- The PR should ensure that standard operating procedures (SOPs) are established for all relevant activities.
- The PR should correct the consent to disclosure submissions and ensure that disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure that the systems and processes employed by the centre ensure that accurate data is submitted to the HFEA.

Recommendation to the Executive Licensing Panel

The centre has one critical area of concern and three major areas of concern.

The inspection team notes that the success rates are consistent with the national average but the centre's multiple clinical pregnancy rates are unlikely to meet the multiple birth rate target. The PR is encouraged to continue to use the Quality Management System (QMS) to improve the quality of the service offered to patients by monitoring and improving the centre's clinical pregnancy/live birth rates, and implementing an effective strategy to reduce the multiple birth rate to meet the target set by the HFEA.

Significant improvement is required in order for the centre to reflect suitable practices, and the inspector will continue to monitor the centre's performance.

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 broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

During observations in the procedure room, a patient who was due to have an egg collection had her name read to her and was asked to state whether that name was correct. Code of Practice guidance at 18.18 recommends that when collecting eggs or sperm, transferring embryos and carrying out insemination, staff should ask patients and donors to give their own identifying information (full name and date of birth), rather than asking the donor or patient to confirm or reject information read out to them. This aims to mitigate the risk of a patient responding automatically to a question. During discussions after the egg collection the inspector was informed that this is not the normal way of identifying patients and patients would usually be asked to state their name themselves. It was not clear why the identification of the patient had been performed in this way in this particular case (SLC T71). See recommendation 5.

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; Directions 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)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this 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 broadly 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 to ensure 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 for accreditation 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
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

Pre-operative assessment and the surgical pathway
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; Directions 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 PR is aware that currently the multiple pregnancy rate at this clinic is likely to result in a multiple live birth rate that is greater than the 10% multiple live birth rate target, and he has been proactive in attempts to reduce the multiple pregnancy rate at this clinic and due to this no further recommendation is considered proportionate at this time.

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; Directions

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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for import and export of gametes and embryos are compliant 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 in place 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; Directions 0010)
The centre does not have any transport or satellite centres, therefore this guidance note is not applicable.

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are broadly compliant with HFEA requirements.

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 partially compliant with HFEA requirements. The centre reports some adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. There is a clear culture of openness in reporting incidents internally within the centre, and this was evidenced during discussions with staff and through review of documented incidents. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services they offer.

What the centre could do better

Safety and suitability of premises and facilities
The floor covering in the oncology storage area was damaged and uneven which is likely to increase the risk of slips, trips and falls (SLC T17). See recommendation 7.

Infection control
Although the taps in the procedure room are intended to be elbow operated, due to the way they have been fitted elbow operation is not possible and staff must use their hands to operate them. This creates an infection risk (SLC T17). See recommendation 8.

Medicines management
Audits of drugs used in theatre have not identified the poor practice in recording drug usage and disposal that was observed during the inspection; figures for drugs used and disposed of did not match drugs removed from the drugs cupboard and changes to figures were not documented clearly (SLC T36). See recommendation 2.

Quality management system (QMS)
Errors identified by the centre's electronic witnessing system are not robustly audited to ensure any mismatches are not due to systems or process errors (SLC T36). See recommendation 2.

There is no SOP documenting the processes by which equipment is maintained and repaired (SLC T33(b)). See recommendation 9.

Equipment and materials
Some of the test-tubes used for gametes are not CE marked (SLC T30). See recommendation 6.

One of the dewar alarms is faulty and is activated each time liquid nitrogen is added to the dewar (SLC T23). See recommendation 10.

Although centre staff assured the inspector that all equipment was regularly maintained and inspected, they were not able to provide documented evidence of the maintenance and regular inspection of all equipment (SLC T26). See recommendation 10.

Adverse incidents
On reviewing the incidents reported by the centre to the HFEA and comparing them to the incidents listed in the centre's incidents log, it was apparent that not all minor incidents were being reported to the HFEA, although it was clear that non-minor incidents were appropriately reported (SLC T118). See recommendation 4.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
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 (PREP number T/1272/82).

Staff (Guidance note 2)
The centre has 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 the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
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 perform these activities, therefore these guidance notes are not applicable.

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 two patients who provided feedback on their experiences. A further 44 patients also provided feedback directly to the HFEA in the time since the last inspection, with 19 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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 and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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 and sperm sharing arrangements (Guidance note 12; Direction 0001)
The centre does not provide this service, therefore this guidance note is not applicable.

Surrogacy (Guidance note 14)
The centre does not provide this service, therefore this guidance note is not applicable.

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; 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 partially compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information held on the HFEA Register for use in research (General Directions 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.

The centre's procedures for reporting consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Consent
In the course of the review of five sets of patient records, it was observed that in one case the written consent to treatment from the male partner of an egg recipient was not present in the patient's notes (Schedule 3, HF&E Act 1990 (as amended) and General Directions 0007). See recommendation 1.

Disclosure of information held on the HFEA Register for use in research
Five discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register (General Directions 0005 and SLC T9e). See recommendation 11.

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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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
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 partially 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

Storage of gametes and embryos

On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved embryos for one patient couple (Schedule 3, 8(1) HF&E Act 1990 (as amended) and T79). The inspection team discussed this case with the PR who said that the centre had contacted the patient couple as the centre's bring-forward process required. The patient couple had delayed responding and then had had problems attending the centre to document their consent to store their embryos for an extended period. The storage period had then expired just prior to the inspection. The inspection team considered that this one case did not reflect failings in the centre's bring forward system. See recommendation 3.

Use of embryos for training staff (Guidance note 22)

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
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 ; Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly 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 partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

What the centre could do better

Obligations and reporting requirements
The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

2% (2/129) of the IVF and 18% (6/34) of the DI treatments reviewed at inspection had not been reported to the HFEA as required by Direction 0005, and there were a number of data quality issues with the submitted data (SLC T9(e)).

When transferring gametes or embryos into or out of the centre, the relevant data has not been provided to the HFEA (SLC T9(e)). See recommendation 12.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to two areas of critical non-compliance, one area of major non-compliance and two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

In 2014, the PR was not asked to review procedures for the provision of any treatments, but was asked to review procedures for maintaining the multiple birth rate below the current target. The PR responded to the request and during discussions at the time of the inspection provided a commitment to keep the multiple birth and pregnancy rates under review.

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, 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Consent In the course of the review of five sets of patient records, it was observed that in one case the written consent to treatment from the male partner of an egg recipient was not present in the patient's notes (Schedule 3, HF&E Act 1990 (as amended) and General Directions 0007).	The PR should undertake an audit of patient records to identify whether the inspection observations represent a systemic failure or a rare occurrence. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 4 May 2015. The PR should provide monthly updates to the HFEA	A new procedure and documentation has been introduced. In future the nurses check for each new treatment cycle that the appropriate consents are in place. This is documented in the Fresh, Frozen and IUI integrated care pathway booklets. An immediate audit of 25 new patient cycles is being conducted following the inspection. The findings of this	This is a satisfactory response and the inspector awaits the audit report. Further action required.

	on progress in implementing corrective actions. Three months after the completion of the corrective actions, the PR should conduct an audit of consent to treatment to ensure the corrective actions have been effective. A summary report of the findings of the audit should be provided to the HFEA.	audit will be submitted to the HFEA by the 4th of May 2015, with monthly reports in the meantime. This audit will be repeated in 3 months and the findings submitted to the HFEA.	

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Quality management system (QMS) The centre's audits of certain areas of practice were not robust eg, the management of drugs used in the procedure room and errors identified by the centre's electronic witnessing system (SLC T36).	The PR should review the audit processes and ensure that audits are performed in a suitably rigorous manner. A summary report of the review findings including detail of any corrective actions and/or changes to audit methodology and the timescale for their implementation should be submitted to the HFEA by 4 May 2015. A copy of the audit schedule for the next 12 months should be submitted to the HFEA by 4 May 2015.	We were pleased to note the comments from the inspectors on the day of our inspection congratulating us on our quality management system and outstanding audit system. We are keen to rectify the 2 areas identified and will review our procedures in other areas. The 2 audits identified here have been immediately reviewed and will be dealt with as described below: The drug management audit schedule in the procedure room will be drawn up by pharmacy.	The inspector will await the centre's submissions due by 4 May 2015, and subsequently liaise with the PR to ensure that suitable improvements are made in these areas. Further action required.

		The electronic witnessing audit schedule will be drawn up by embryology laboratory staff. Both of these will be submitted to HFEA by May 4th with our revised schedule.	
3. Storage of gametes and embryos On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved embryos for one patient couple (Schedule 3, 8(1) HF&E Act 1990 (as amended) and T79).	The inspection team recognise that action is being taken to resolve this issue by the PR, but this has unfortunately not been achieved by the time the current consented storage period expired. By the time this report is considered by a Licensing Committee, where gametes or embryos remain in store without effective consent a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions.	The couple were adamant that they wanted to extend storage of their embryos and the two appointments they missed were for reasons beyond their control. An incident was reported to the HFEA on the 2nd of Feb 2015 Prior to the inspection the couple were sent a third appointment. Incident closed by the HFEA on the 3rd of Mar 2015.	Since commenting on this report, the PR has reported that this issue has been resolved. No further action.

4. Adverse incidents Not all relevant incidents are reported to the HFEA (SLC T118).	Whilst it is recognised that the under-reporting of incidents is not intentional, the PR should take immediate action to review the current criteria for submitting incidents to the HFEA. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 4 May 2015. Six months after the completion of the corrective actions, the PR should conduct an audit of submission of incidents to the HFEA and a summary report of the findings of the audit should be provided to the HFEA.	The PR will review the current criteria for submitting incidents to the HFEA. A summary report of any findings and corrective action will be sent to the HFEA by the 4th of May 2015. Paula Nolan (Clinical Governance Lead/Inspector) will visit the Department to give an incident reporting presentation at the Reproductive Medicine Multidisciplinary Meeting (TBA). Following on from this meeting a 6 month audit will be carried out by the PR and a summary will be sent to the HFEA.	This is a satisfactory response and the inspector awaits submission of the review findings. The inspector notes the positive approach the PR has taken to addressing this issue by welcoming the HFEA incidents inspector to a multidisciplinary meeting. 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
5. Witnessing A patient who was due to have an egg collection had her name read to her and was asked to state whether that name was correct, rather than being asked to state her name herself (SLC T71).	The PR should undertake a review to establish the factors that contributed to the observation of this non-compliance. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 4 May 2015. Three months after the completion of any corrective actions, the PR should conduct an audit of witnessing of patient and/or partner identity to assess the effectiveness of the corrective actions. A summary report of the findings of the audit should be provided to the HFEA.	A review of the SOP and random observations will be conducted to establish the factors that contributed to this observation and the report including corrective measures sent to the HFEA by 4th of May 2015. There will be a three month theatre audit by the PR and report sent to the HFEA by 4th of May 2015.	This is a satisfactory response and the inspector awaits submission of the review findings. Further action required.

6. Equipment and materials The following medical devices used by the centre are not CE marked: test-tubes (SLC T30).	The PR should provide the HFEA with a list of all medical devices currently in use in the clinic that are not CE-marked. The list should document either the anticipated time by which a CE-mark is expected to be obtained or the action that will be taken to ensure compliance within the next year. The list should be submitted to the HFEA by 4 May 2015.	All non-CE marked plastics had a risk assessment completed prior to being used, in line with the CoP. The manufacturers have been contacted to request CE marked products. A list of any remaining non-CE marked products will be compiled and the risk assessment completed again. The list will be submitted to the HFEA by the 4th of May 2015.	The inspector will await the centre's submissions due by 4 May 2015, and subsequently liaise with the PR to ensure that suitable improvements are made in these areas. Further action required.
7. Safety and suitability of premises and facilities The floor covering in the oncology storage area was damaged and uneven (SLC T17).	The PR should investigate what measures can be taken to improve this situation. The PR should inform the centre's inspector of the findings of this investigation and provide an action plan to reduce the risk of slips, trips and falls in this area by 4 May 2015.	The cryo-store has been independently inspected and a quote requested. Funding has been identified to carry out required works. A timeline to completion of the repairs to be sent by 4th of May 2015.	The inspector is pleased that action has been taken so promptly to address this issue and awaits the information requested. Further action required.
8. Infection control Taps in the procedure room cannot be elbow operated, creating an infection risk (SLC T17).	The PR should investigate what measures can be taken to improve this situation. The PR should inform the centre's inspector of the findings of this	These have already been replaced.	The inspector is pleased that action has been taken so promptly to address this issue. No further action required.

	investigation and provide an action plan to ensure that appropriate infection control measures are in place by 4 May 2015.		
9. Quality management system (QMS) There is no SOP documenting the processes by which equipment is maintained and repaired (SLC T33(b)).	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the HFEA by 4 May 2015.	The Laboratory closure SOP, including documenting the processes by which equipment is maintained and replaced, has been completed. It is to be kept on Qpulse and distributed to all staff concerned. A copy will be submitted to the HFEA by May 4th.	This is a satisfactory response and the inspector awaits submission of this document. Further action required.
10. Equipment and materials One of the dewar alarms is faulty and is activated each time liquid nitrogen is added to the dewar (SLC T23). Centre staff were not able to provide documented evidence of the maintenance and regular inspection of all equipment (SLC T26).	The PR should ensure that the alarm is repaired to prevent repeated erroneous alarms. The PR should inform the centre's inspector when the alarm has been repaired. The PR should establish, and ensure all staff are aware of, a suitable system to record the maintenance and regular inspection of all equipment. The PR should inform the	The cryo dewar alarm has been repaired and checked. All 3rd party and service agreements will be logged on Qpulse. Any inspection or service reports will be kept with agreements on Qpulse. All Staff notified of this change	The inspector is pleased that action has been taken so promptly to address this issue. No further action required.

	inspector when this has been established. By 4 May 2015.	in procedure.	
11. Disclosure of information held on the HFEA register for use in research Five discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. (General Directions 0005 and SLC T9e). *(NB. The PR has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected.)*	The PR should correct the submissions that have been identified as being incorrect, and review systems and processes to ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 4 May 2015. Within six months of the implementation of the corrective actions, the centre should conduct an audit of consent to disclosure and a summary report of the findings of the audit should be provided to the HFEA.	A series of corrective measures will be followed to ensure that the patient and partner disclosure consent information supplied to the Authority is accurate Correct incorrect submissions Check staff competencies in this area. Review use of SOP and acknowledged on Qpulse. A staff training session is to be implemented, including examples of research projects using consent for disclosure. Rolling monthly audit of 10 sets of notes to ensure accuracy of CD recording. Results of this audit to be submitted by timelines indicated.	This is a satisfactory response and the inspector awaits submission of the review findings. Further action required.

12. Obligations and reporting requirements 2% (2/129) of the IVF and 18% (6/34) of the DI treatments reviewed at inspection had not been reported to the HFEA as required by General Directions 0005. There were also a number of data quality issues with the submitted data. When transferring gametes or embryos into or out of the centre, the relevant data has not been provided to the HFEA (SLC T9(e)). *(NB The PR has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).*	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Directions 0005, and that the reporting of treatments and movements identified as unreported at the time of inspection is completed. The PR should review systems and processes for accurate and timely data submission. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 4 May 2015. Within six months of the implementation of the corrective actions, the centre should conduct an audit of data submission and a summary report of the findings of the audit should be provided to the HFEA.	The competences of all staff involved with reporting licenced treatment activity will be checked We will be introducing an early warning system on our new database to notify the department if a licenced procedure report is timing out. The Andrology staff will back date the GI forms for the donor sperm purchased elsewhere and transferred into the Department. Audits of data submission processes will be carried out and submitted to the HFEA as indicated.	This is a satisfactory response and the inspector awaits submission of the review findings. Further action required.

Reponses from the Person Responsible to this inspection report
I would like to thank the inspectors for a thorough inspection and welcome the findings submitted in this report. I appreciate and welcome the many positive remarks on the quality of our service and also regarding the improvement observed in practices and procedures since the last inspection. I would like to reassure the Authority that we are still not where we want to be and intend to improve continuously and go from strength to strength.