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
24 July 2015

Minutes – item no. 2

Centre 0307 (Complete Fertility Centre Southampton) – Renewal Inspection Report

Members of the Panel:	Paula Robinson Head of Business Planning (Chair) Nick Jones Director of Compliance & Information David Moysen Head of IT
Members of the Executive in attendance:	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 an 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 medium-sized centre.

3. The panel noted that the centre has been licensed by the HFEA since November 2008.

4. The panel noted that in the 12 months to 31 March 2015, the centre provided 623 cycles of treatment (excluding partner intrauterine insemination).

5. For IVF and ICSI, HFEA-held register data for the period 1 January 2014 to 31 December 2014 showed the centre's success rates were in line with national averages with the following exceptions:

    - success rates for IVF and ICSI in women under 38 years old are significantly lower than the national averages.

6. The panel noted that in 2014, the centre reported 58 cycles of partner insemination with four pregnancies. This equated to a 7% clinical pregnancy rate, which was consistent with the national average.

7. Between 1 January 2014 and 31 December 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 9%. This means that the centre's multiple live birth rate is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the inspection on 20 and 21 May 2015, the inspectorate identified one critical, one major and five other areas of non-compliance.

9. The panel was concerned to note in particular the critical non-compliance relating to the use of embryos solely for validation purposes, in the absence of training activity. However the panel also noted the inspectorate's considered view that this critical non-compliance was an isolated incident, addressed immediately, and that the inspectorate did not perceive a pattern of practice indicative of a lack of respect for the special status of the embryo.

10. The panel noted that the PR has also addressed the major area of non-compliance and completed actions for most of the other areas of non-compliance. The panel noted that the PR has committed to fully implementing the outstanding recommendation.

11. The panel noted that the PR has engaged with the inspectorate on success rates and has committed to keeping success rates for IVF and ICSI treatment in woman under 38 years under review. The panel noted the explanation given, during the inspection, of how the centre's risk averse approach to OHSS leads to the conversion of cycles to 'freeze-all' in a higher proportion of cases than occurs at other centres. This effectively reduces the success rates because they are calculated as clinical pregnancies per cycle started. Therefore it was not considered proportionate to make a recommendation about the centre's success rates in this patient cohort at this time.

12. The panel noted that the inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions.

Decision

13. 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.

14. 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 has discharged their duty under section 17 of the HFE Act 1990 (as amended).

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

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

Signed: Date: 4 August 2015
Paula Robinson (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: 20/21 May 2015

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

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

Inspectors: Andrew Leonard (Lead), Janet Kirkland, Louise Winstone, Grace Lyndon (observer), Lesley Brown (observer), Neil McComb, Johanni Davies.

Date of Executive Licensing Panel: 24 July 2015

Centre name	Complete Fertility Centre Southampton
Centre number	0307
Licence number	L/0307/2/a
Centre address	G Level, Princess Anne Hospital, Coxford Road, Southampton, SO16 5YA.
Person Responsible	Professor Nick Macklon
Licence Holder	Dr Michael Marsh
Date licence issued	1 November 2011
Licence expiry date	31 October 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Complete Fertility Centre is located in the Princess Anne Hospital, Southampton. The centre has held a licence with the HFEA since 1 November 2008. The centre provides a full range of fertility services and provided 623 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2015. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 January 2014 – 31 December 2014 show the centre's success rates are in line with national averages with the following exceptions:

- success rates for IVF and ICSI in women under 38 years old are significantly lower than the national averages.

In 2014, the centre reported 58 cycles of partner insemination with four pregnancies. This equates to a 7% 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 1 January 2014 – 31 December 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 9%: this means that the centre's multiple live birth rate is not likely to be statistically different from the 10% 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 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, one major and five 'other' areas of non compliance, which resulted in recommendations for improvement.

Since the inspection, the PR has provided evidence that the following recommendations have been implemented:

Critical areas of non compliance:

- **The PR must take immediate actions to stop the use of embryos solely for validation purposes.**

Major areas of non compliance:

- The PR should ensure that all staff are, where necessary, provided with regular update training and assessment of their competence to manage medicines and regarding fire safety.

'Other' areas that require improvement:

- The PR should ensure the documentation of information regarding the traceability of all critical equipment, notably the centrifuges, used during gamete and embryo processing.
- The PR should consider the practice used to record the sperm provider's signature in the records to confirm their identity and take action to ensure that the signature is recorded in all cases.
- The PR should ensure the standard operating procedure (SOP) describing egg donor screening is compliant with HFEA requirements regarding the timing of screening tests prior to egg donation.
- The PR should review procedures for the monitoring of critical parameters in the transport dewar.

The PR has also committed to implement the following recommendation and actions to do so are on-going:

'Other' areas that require improvement:

- The PR should take immediate action to ensure a fully functional oxygen monitoring system within the cryostore.

Recommendation to the Executive Licensing Panel

The centre had one critical and one major areas of concern at the time of the inspection.

The inspection team notes the centre's success rates for ICSI and IVF in women under 38 years old are below the national average. The multiple clinical pregnancy/live birth rates meet the target.

Some improvement is required in order for the centre to reflect suitable practices. The PR should ensure that the Quality Management System (QMS) is used to best effect to monitor and improve the success rates and the quality of the service offered to patients.

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better
In one set of records, witnessing of the sperm provider's identity at the point of sperm production was not properly documented, since the signature of the sperm provider was absent (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 broadly 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 for giving and receiving money or other benefits in respect to any supply of gametes or embryos are compliant with HFEA requirements. 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 all required information.

What the centre could do better
The SOP describing the process by which egg donors are screened included that screening should be performed in the three months prior to egg donation. This is non-compliant with SLC T53b since the Authority requires screening at the time of donation. A review of egg donor records indicated that the donors had been screened in a manner compliant with HFEA guidance – i.e. blood samples had been taken during the cycle leading to egg donation. Thus screening practices at the centre appear compliant but the SOP documents non-compliant practice (SLC T33b, see recommendation 6).

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 partially compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre has no satellite/transport facilities.

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

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

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

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

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

as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if 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; 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 broadly 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 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 no satellite/transport facilities.

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

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The oxygen monitor in the cryostore was located more than five metres from the storage dewars and was behind a freezer. This could undermine the function of the monitor, increasing the risk to staff within the cryostore (SLC T17, see recommendation 3).

Traceability (Guidance note 19)
The centre does not document, for traceability purposes, which centrifuge has been used to prepare sperm for use in treatment (SLC T22, see recommendation 4).

Equipment and materials (Guidance note 26)
The following equipment that may affect critical processing or storage parameters is not subject to appropriate monitoring: temperature monitoring of the transport dewar during the transfer of gametes and embryos between centres (SLC T24, see recommendation 7). Such monitoring is necessary because regular checks of the transport dewar performance are not carried out.

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 medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1174/8).

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements. The centre has suitably qualified and broadly 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
Fire safety training is provided annually through a trust-wide computer-based system but no assessment is subsequently made of staff understanding and competence in fire safety (SLC T12; see recommendation 2). This was of concern because some staff, when

questioned, were unsure regarding their response in case of fire.

Nursing staff do not have regular update training and assessment of their competence to manage medicines (SLC T12, see recommendation 2). This was of concern because the previous three audits of medicines management performed by the centre had found non compliances.

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
The centre does not undertake embryo testing.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, no patients were available to discuss their experiences at the centre. Thirteen patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly positive, with eight 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.
- provides a caring and supportive environment for patient treatment

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 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 does not provide treatment involving surrogacy.

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
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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.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The HFEA Register is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA

is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements and therefore ensure that the HFEA holds an accurate record of patient consent to disclosure to researchers, so that it only releases the patient's identifying information with their consent.
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 partially 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

Discussion with centre staff indicated that embryos have been used for validation purposes in the absence of training activity. The information provided to patients about the use of their embryos in training, prior to them signing the training consent form, includes the possible use of embryos in validation. However, the use of embryos solely for validation is not a use of embryos specified as licensable in Schedule 2 of the HF&E Act 1990 (as amended) (see recommendation 1).

The inspection team considers that this non-compliance was an isolated incident and did not perceive a pattern of practice indicative of a lack of respect for the special status of the embryo.

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 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
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 HFEA has a legal responsibility to maintain a register containing information about all licensed activities, including information on donors and on any children conceived as a result of their donation. In order to maintain this register, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's submission of information about licensed activities is compliant with HFEA requirements and ensures the HFEA can supply accurate information to a donor-conceived person and their parents.

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

Section 3: Monitoring of the centre's performance

Following the last inspection of the centre in 2013, recommendations for improvement were made in relation to two major and eight 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last inspection, the centre has been sent two emails due to low success rates for IVF and ICSI treatment in woman under 38 years, which asked for a review of the relevant treatment processes. The centre responded appropriately on both occasions and provided thorough reviews. During discussions on this inspection, the PR discussed how the centre's risk averse approach to OHSS leads to the conversion of cycles to 'freeze-all' in a higher proportion of cases than occurs at other centres. This reduces the success rates because they are calculated as clinical pregnancies per cycle started. The PR provided a commitment to keep success rates for IVF and ICSI treatment in woman under 38 years under review. As a result of these discussions, it was not consider proportionate to make a recommendation with respect to the centre's success rates in this patient cohort 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre has used embryos which are consented for use in training, solely for validation purposes. The information provided to patients about the use of embryos in training, also discusses the use of embryos for validation purposes alone. The use of embryos solely for validation is unlawful and is not a use of embryos specified as licensable in	The PR must take immediate actions to stop the use of embryos solely for validation purposes and to ensure that embryos are only used in training activities which are approved by the Authority, or in other 'licensable' activities. The patient information concerning the use of embryos in training should be revised to delete any reference to the use of embryos in validation. These recommendations	This area has been immediately addressed by changing the working of the patient information sheet to remove the option of consenting for embryos to be used for validation purposes only. With immediate effect embryos will only be used for validation purposes in the context of training, when consent has been given for the embryos to be used in training. It appears that a misunderstanding accounted for the previous interpretation,	The inspection team acknowledges the PR's response and the actions taken. It is noted that the PR has been advised that the Act does not permit the use of embryos for validation purposes. The PR has also been advised that information gained when providing staff members with training in embryological techniques using embryos, can be used for validation purposes but that validation

Schedule 2 of the HF&E Act 1990 (as amended).	should be actioned with immediate effect. The Executive should be advised of the actions taken by the time the report is considered by a licensing committee. The PR should also investigate how the centre allowed embryos to be used solely for validation purposes and why audits of the use of embryos in training against CoP requirements failed to identify this non-compliance. A report of this review should be provided to the Executive by 21 August 2015.	since it is a licence requriement that critical equipment such as incubators are validated, and this would normally be interpreted to require embryos. It is now our understanding that the HFEA requires that a consented training element must always be made to apply when such validation occurs, and this has been implemented.	cannot be the primary purpose of the activity. No further action is required.

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. Nursing staff do not have regular update training and assessment of their competence to manage medicines. Competence assessment regarding fire safety is also not performed (SLC T12).	The PR should ensure that all staff are, where necessary, provided with update training and assessment of their competence to manage medicines and regarding fire safety. This recommendation should be implemented by 21 August 2015 and the HFEA informed of the actions taken. Three months after the implementation of the recommendation, the PR should arrange audits of medicines management and fire safety, to ensure that suitable practices are being	Training and assessment of competency to manage medicines has been added to the nursing competency requirements and the respective SOP updated. Fire safety competency, including patient evacuation, has been added to staff compentency requirements. Additional training has been arranged and will be subject to regular testing by fire drills, carried out as part of the Trust Fire drill programme. The requested audits will also be performed within the required time period.	The inspection team acknowledges the PR's response, the actions taken and the PR's commitment to complete the required audits. No further action is required beyond the completion of the audits.

	used. Summary reports of these audits should be provided to the HFEA by 21 November 2015.		

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
3. The oxygen monitor in the cryostore was located more than five metres from the storage dewars and was located behind a freezer. This is likely to undermine the monitor's function and lead to an increase in risk to staff using the cryostore (SLC T17).	The PR should take immediate action to ensure a fully functional oxygen monitoring system is provided within the cryostore. The HFEA should be advised of the actions taken by the time a licensing committee considers this report.	The Trust Estates department have been asked to address this issue as soon as possible. Quotes for moving the oxygen monitor and for installing a replacement have been sought, and the Fertility Centre management is liaising regularly with the relevant Trust department to encourage rapid action on this point.	The inspection team acknowledges the PR's response, the actions taken and the PR's commitment to implement the recommendation. The PR should keep the centre's inspector updated regarding progress to ensure a fully functional oxygen monitoring system is provided within the cryostore.
4. The centre does not document, for traceability purposes, which centrifuge has been used to prepare sperm for use in treatment (SLC T22).	The PR should ensure the documentation of information regarding the traceability of all critical equipment, notably the centrifuges, used during gamete and embryo processing. The HFEA should be advised of the actions taken to implement this recommendation by 21 August 2015.	The necessary changes have been made to the Sperm preparation SOP and Sperm preparation worksheet. The respective change in practice has already been implemented.	The inspection team acknowledges the PR's response and the actions taken. No further action is required.

5. In one set of records, witnessing of the sperm provider's identity at the point of sperm production was not properly documented, since the signature of the sperm provider was absent (SLC T71).	The PR should consider the practice used to collect the sperm provider's signature when their identity is witnessed. Action should be taken to ensure that the signature is recorded in all cases. The HFEA should be advised of the actions taken by 21 August 2015. Three months after the implementation of the recommendation, the PR should arrange an audit of the records of witnessing of the sperm provider's identity, to ensure the signature of the provider is consistently documented. A report of this audit, including any further corrective actions necessary, should be provided to the HFEA by 21 November 2015.	The cause of this ommission was identified to reside with the policy of asking for the witnessed signature of the sperm provider after sperm was collected. This practice has now been altered . The signature is requested prior to sperm production at the time of checking identity. The SOP has been duly altered and this will be audited in due course.	The inspection team acknowledges the PR's response and the actions taken. No further action is required beyond the completion of the audit.
6. The SOP describing the process by which egg donors are screened included that screening should be performed in the three months prior to egg procurement and	The PR should ensure the SOP describing egg donor screening is compliant with HFEA requirements regarding the timing of screening tests prior to egg donations. The PR is directed to CoP Guidance 11.23, Clinic	We have indeed identified the SOP describing the screening process needs to be adjusted to include a second screening. After discussion we have elected to make this a full rather than selective	The inspection team acknowledges the PR's response and the actions taken. No further action is required beyond the completion of the

donation. The centre's normal practice is to screen egg donors in the cycle leading up to egg donation. Thus the SOP does not accurately reflect the centre's practice (SLC T33b).	Focus March 2013 and the EU Directive 2006/17/EC for those requirements. The revised SOP should be provided to the HFEA by 21 August 2015.	screening. We have updated the respective SOP accordingly, and implemented this change into practice	audit.
7. The following equipment that may affect critical processing or storage parameters is not subject to appropriate monitoring: temperature monitoring in the transport dewar during use (SLC T24, T108).	The PR should review procedures for the monitoring of critical parameters in the transport dewar. A summary report of the findings of the review including corrective actions and the anticipated timescales for the implementation of the actions should be submitted to the HFEA by 21 August 2015.	Fit for purpose data loggers are being sought to addresss this issue. Until these have been identified and procured, appropriate temperature monitoring will be confirmed by validation with gametes.	The inspection team acknowledges the PR's response and the actions taken. No further action is required.

Reponses from the Person Responsible to this inspection report
I would like to thank the inspectors for their rigorous and fair inspection, and for the constructive spirit in which it was performed. The areas of practice identified have received our immediate attention, and we will be forwarding written evidence of the actions taken and planned before the deadline of 21 August.