Executive Licensing Panel - minutes

Centre 0301 (London Women's Clinic, Wales) – Renewal Inspection Report

Friday 11 December 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Nick Jones Ian Peacock	Director of Strategy & Corporate Affairs Director of Compliance & Information Analyst Programmer
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
Observers	Anna Rajakumar	Scientific Policy Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that this is a treatment (including embryo testing) 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.

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

1.4. The panel noted that in the 12 months to 31 July 2015, the centre provided 572 cycles of treatment (excluding partner intrauterine insemination).

1.5. For IVF and ICSI, HFEA-held register data for the period May 2014 to April 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014 to 2015 the centre reported 21 cycles of partner insemination with four pregnancies. This was consistent with the national average.

1.7. Between May 2014 and April 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 22%. This represents performance that is likely to be greater than the 10% maximum multiple live birth rate target for this period. The Person Responsible (PR) is encouraged to continue to use the quality management system to best effect, to implement and monitor an effective strategy to reduce multiple birth rates to meet the target, so as to improve the quality of the service offered to patients.

1.8. The panel noted that at the time of the inspection on 15 and 16 September 2015, one critical, six major and two other areas of non-compliance were identified. The panel noted that the critical area of non-compliance was corrected on the day of inspection. Since the inspection, the PR has implemented all of the recommendations and has committed to providing the required audits.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate suitability of its practices.

1.10. The panel noted that the inspectorate recommended the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being fully implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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

2.5. The panel noted the centre's multiple clinical pregnancy rate and that the centre is unlikely to meet the current 10% maximum live birth rate target. The panel noted the PR's response to this non-compliance and looks forward to seeing a reduction in the centre's multiple birth rate.

2.6. The panel encouraged the centre to complete the audits within the prescribed timescales.

2.7. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

23 December 2015

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: 15 & 16 September 2015.

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage.

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

Inspectors: Janet Kirkland MacHattie, Gill Walsh, Louise Winstone, Shanaz Pasha.

Date of Executive Licensing Panel: 11 December 2015.

Centre name	London Women's Clinic, Wales
Centre number	0301
Licence number	L/0301/3/c
Centre address	15 Windsor Place , Cardiff, CF10 3BY, UK
Person Responsible	Dr Hemlata Thackare
Licence Holder	Dr.Kamal Ahuja
Date licence issued	01/03/2012
Licence expiry date	29/02/2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Women's Clinic, Wales has held a licence with the HFEA since 2008. Their initial licence was for treatment (insemination using partner/donor sperm) with storage. In 2012, the Executive Licensing Panel (ELP) approved a licence variation application to change the premises, name and licensed activities, to include treatment and storage. In April 2013 the ELP approved a licence variation to include embryo testing.

The centre provides a full range of fertility services.

The centre provided 572 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2015. In relation to activity levels this is a medium sized centre.

This licence renewal inspection was conducted in conjunction with Health Inspectorate Wales. The report of their inspection will be published separately.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period May 2014-April 2015 show the centre's success rates are in line with national averages.

In 2014-2015 the centre reported 21 cycles of partner insemination with four pregnancies: this is consistent with the national average.

Multiple births[2]

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

Between May 2014 and April 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 22%: 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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of 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, six major and two 'other' areas of non compliance.

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

Critical area of non-compliance:

- **the PR should ensure that all equipment is regularly inspected and maintained and is fit for purpose;**

Major areas of non compliance:

- the PR should ensure that the disposal of sperm is witnessed;

'Other' areas that require improvement:

- the PR should ensure that the centrifuge used in the processing of each semen sample is traceable.

The PR has implemented the following recommendations and has committed to provide the required audits in due course:

Major areas of non compliance:

- the PR should ensure that the centre's multiple live birth rate does not exceed the 10% target;
- the PR should perform a comprehensive review of the effectiveness of the quality management system;
- the PR should audit their process for information provision to ensure that patients are fully informed about their treatment options and pathway;
- the PR should ensure that there is valid consent for all gametes and embryos in storage;
- the PR should ensure that patient records are traceable to the patient to whom they refer.

‘Other’ areas that require improvement:

- the PR should ensure that patients and their partners are screened in accordance with the timeframes specified by the Authority.

Recommendation to the Executive Licensing Panel:

The centre had one critical area of concern (corrected on the day of inspection) and six major areas of concern.

Some improvement is required in order for the centre to demonstrate the suitability of their practices.

The inspection team notes that the centre's success rates are consistent with the national average.

It is also noted that the centre’s multiple clinical pregnancy rate according to HFEA data is 22%. If it continues on this trajectory, the centre is unlikely to meet the current 10% live birth rate target. The PR is encouraged to continue to use the quality management system to best effect, to implement and monitor an effective strategy to reduce multiple birth rates to meet the target, so as to improve the quality of the service offered to patients.

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better
It was observed on inspection that the disposal of sperm not required for use in treatment is not witnessed. The centre's standard operating procedure (SOP) was amended on the day of inspection to include this witness step (SLC T71).
See recommendation 2.

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

Donor assisted conception (Guidance note 20)
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 suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and 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 single biggest risk of fertility treatment is a multiple pregnancy. 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.

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

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

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

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

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and there is enough information to permit the gametes and embryos to be stored or used in

treatment in a way that does not compromise their quality and safety.

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

Traceability (Guidance note 19)
The centre's procedures are 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;
- 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; General Direction 0010)
The centre does not conduct transport IVF. The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by transport or satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and most 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 is compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

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

centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Multiple births (Guidance note 7; General Direction 0003)
The PR was asked to review the centre's multiple birth minimisation strategy following the issue of alerts from the HFEA risk tool relating to high multiple clinical pregnancy rates.

The PR responded to the alerts, has revised the centre's strategy and has committed to monitor its effectiveness. The centre's own data seen on inspection indicates that the revised strategy is having a positive effect. However, HFEA data (three month lag) show the centre's multiple clinical pregnancy rate for treatments between 1 May 2014 and 30 April 2015 was 22% (SLC T2).
See recommendation 3.

Traceability (Guidance note 19)
The centrifuge used in the preparation of each individual semen sample is not recorded (SLC T99).
See recommendation 8.

QMS (Guidance note 23)
The QMS was considered by the inspection team to be non-compliant in several areas:

- There was no formal process in place for reviewing the performance of the quality management system to ensure continuous and systematic improvement (SLC T32).
- There was no formal system for the review of documents including SOPs and review dates were in some instances unclear to the centre team (SLC T34).
- Corrective actions following audits of activities were in some instances unclear and did not appear to address the actual non-conformance. In addition the implementation of corrective actions was not reviewed. For example corrective actions following an audit of consent were documented as 'nurse off sick' (SLC T36).
- The centre's methodology for audit did not appear to be comprehensive or robust. For example, the audit of provision of information to patients only questioned whether a letter sent to patients following consultation included a link to an online information booklet (SLC T36).

See recommendation 4.

Equipment and materials (Guidance note 26
The laryngoscope on the centre's emergency trolley did not have a battery and was therefore not fit for purpose in the event of an emergency (SLC T23).
See recommendation 1.

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 T/1145/7.

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

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection no patients elected to speak with members of the inspection team about their experiences. Five patients had however provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with three of the individuals providing written feedback to the HFEA commenting that they had compliments about the care that they received but two patients provided feedback commenting that not all treatment options were discussed and that there was not enough information provided before or during treatment.

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;
- provides patients with satisfactory facilities for their care

What the centre could do better

The inspection team acknowledges that patient comments received at the HFEA may not be representative of the majority of patients. However the patient information audit seen on inspection was not robust, the audit process only appearing to check that patients are provided with a link to a generic on-line leaflet. This on-line information described a number of treatment options and so was not patient specific. The inspection team was not assured that patients were being provided with sufficient information regarding their specific treatment (SLC T58 & T59).
See recommendation 5.

Treating patients fairly
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

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

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and/or donors are partially 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
See reference in patient feedback and recommendation 5.

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 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 patient identifying information, to researchers, with patient consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). 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 15;17)

The centre's procedures for screening patients are broadly 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, and 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

Screening of patients (Guidance note 17)

Patients are not being screening in accordance with the timeframes specified by the Authority. Male partners are being screened within three months of the first treatment cycle however female partners are not (SLC T51b).

See recommendation 9.

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved sperm for one patient and embryos for two couples (HF&E Act 1990 (as amended), Schedule 3, 8(1)).

The PR explained that all gametes and embryos are being stored within the statutory storage period but that extension to storage is being sought from one patient with sperm samples and one couple with embryos stored for the preservation of fertility.

The PR also explained that the second set of embryos stored is subject to a legal dispute where one gamete provider has withdrawn consent to store.

Having gametes/embryos in storage without consent would normally be classified as a critical non-compliance, however, the inspection team take into account the circumstances described by the PR and consider it proportionate to grade this non-compliance as a major. See recommendation 6.

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 does not use embryos for training staff.

What the centre could do better
Not applicable.

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 partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

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

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre operates a 'paper light' system. Where paper copies of consent or other documents are required, these are then scanned into the centre's patient information data base.

During an audit of patient files, it was observed that scanned documents did not have patient identifiers on each page and, in one instance, the history documented did not appear to correlate with other records in the file. For example, an allergy was noted but this was not referred to in any other part of the record, including the pre-operative assessment. The inspection team could therefore not be assured that all of the documentation on the scanned record did in fact relate to that patient (SLC T47).
See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to one area of major non compliance and three '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

The centre has not received any HFEA performance related alerts relating to clinical pregnancy rates following treatment, however, between May 2014 and September 2015 the centre received three alerts relating to multiple clinical pregnancy rates. In response to this the centre reviewed the effectiveness of their multiple births minimisation strategy (General Direction 0003; see section on multiple births).

The PR has given a commitment to keep the multiple birth strategy 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, General Direction 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 noncompliance 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 noncompliance 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 laryngoscope on the emergency trolley did not have a battery and was therefore not fit for use in the event of an emergency. It should be noted that this was corrected immediately (SLC T23).	The PR should review the process for ensuring key equipment is regularly inspected and fit for purpose, to identify if there are any barriers to this being done effectively. The centre's inspector should be advised of the measures taken to ensure that this happens when responding to this report.	This was corrected immediately. The list of all key equipment has been reviewed to ensure that the equipment is inspected and fit for purpose. The theatre nurse has been assigned responsibility for checking and signing off the checklist for all critical equipment in theatre and on the emergency trolley . The daily theatre record has been amended for anaesthetist to sign that equipment was checked.	The inspector acknowledges the PR's response. 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. The disposal of sperm not required for treatment is not witnessed (SLC T71).	The PR took immediate action to ensure that the disposal of sperm was witnessed on the day of the inspection and the centre's SOP was updated to reflect this. The PR should, after three months, audit compliance with these witnessing requirements, to ensure the corrective action has been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 1 February 2016.	The SOP has been revised Witnessing requirements will be audited and summary of audit provided to the centre's inspector by 01.02.2016	The inspector acknowledges the PR's response. Audit summary to be provided by 1 February 2016. Further action is required.
3. Between 1 May 2014 and 30 April 2015, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: this represents performance	The PR assured the inspection team that she had reviewed and revised the multiple birth minimisation strategy in response to alert emails from the HFEA risk tool, sent to the PR in response to the centre's high multiple clinical	The centre has audited the multiple clinical pregancy rate after the multiple birth minimisation strategy was revised at the end of February 2015 and our recent	The inspector acknowledges the PR's response and her commitment to monitor the centre's multiple clinical pregnancy rate. The PR is encouraged to review the centre's multiple birth

that is likely to be greater than the 10% multiple live birth rate target for this period (SLC T2).	pregnancy rate. The centre's own data indicates that the revised strategy is having a positive effect. The PR should continue to monitor the effectiveness of their multiple births minimisation strategy.	audit shows that the rate has reduced significantly. The HFEA data does not reflect this as it includes data before the strategy was revised. We will be monitoring the centre's clinical multiple pregnancy rate.	minimisation strategy again if the recent changes to the strategy prove unsuccessful. The centre's inspector will also continue to monitor the centre's multiple clinical pregnancy rate using the HFEA risk tool. Further action is required.
4. The quality management system was considered by the inspection team to be non-compliant in several areas as described in the body of the report (SLC T32, T34, T36).	The PR should conduct a review of the quality management system This should include a review of centre's SOPs and audit process. The PR should review audits conducted in the time since the last inspection, to ensure that findings and corrective actions are clearly documented and have been implemented. By 1 February 2016 the PR should provide a summary of the review and an action plan with time scales for corrective actions to be completed. Thereafter, the PR should provide a monthly update on progress with the action plan to the centre's inspector.	I appreciate the HFEA inspection team observations as there is always room for improvement. However I feel that our QMS is quite robust such that the feedback received from patients is positive, our success rates are in line with the national average, we receive very few complaints and non-conformances/adverse incidents/adverse events are minimal when compared with the number of patients treated at the centre. The documentation of CAPA and follow up may not have reflected correctly the purpose and standards of the audit. However our KPIs are	The inspector acknowledges the PR's response and her commitment to review the bring forward system for document review, in addition to providing staff training in audit methodology and management of corrective actions. Audit summary to be provided by 1 February 2016 in addition to monthly updates regarding the action plan to address any outstanding corrective actions. Further action is required.

		audited annually and in some instances half yearly and are compared with previous year's performance. This immediately informs us whether there has been improvement or not. Our local quality lead will create a bring forward system to review documents in a timely manner. Our document control SOP is being reviewed by the Quality Assurance Coordinator. To improve the process further we are organising staff training on Audit process, methodolgy and CAPA management. Audits conducted post-inspection will be reviewed and summary with action plan will be provided to the centre's inspector by 01.02.2016.	
5. Patient feedback received at the HFEA indicated that patients did not, in some instances, receive enough information (SLC T58 and	The PR should audit processes for giving information to ensure that patients are fully informed about their treatment options and pathway.	The number of patients giving feedback to HFEA was extremely small (five patients = 1% of total number of patients treated).	The inspector acknowledges that the patient feedback received at the HFEA was from a small percentage of patients who have attended

T59)	When responding to this report the PR should provide the centre's inspector with a plan of how they intend to conduct this audit, to ensure that it is comprehensive and will identify any gaps in the information process. Following review of the audit methodology, the PR should perform an audit of the patient information process and provide a summary of the audit, including corrective actions and their timescales for implementation, by 1 February 2016.	It is difficult to draw any reliable conclusions based on these very small numbers. The centre independently asks patients to reply anonymously to Survey Monkey questionnaire - this was presented to the inspection team. 132 patients provided treatment feedback over the past two years. The feedback analysis reported that less than 10% were either dissatisfied or very dissatisfied with explanation of treatment plan, purpose of medication, consents, procedures, risks, costs, etc. 26 patients have provided feedback after initial consultation from January to August 2015. Of these 23 patients felt that all available treatment options were discussed in great detail, understood what to expect from treatment and were happy with treatment/diagnosis offered.	the centre. The inspector also acknowledges that the centre's own patient survey indicates a high level of satisfaction with the information received regarding treatment options. The inspector also acknowledges the PR's commitment to document the information that is given to patients and to continually monitor patient satisfaction. The required audit should be provided by 1 February 2016. Further action is required.

		I am hence disappointed that the inspection team did not take this into consideration. Patients will be provided paper copies of treatment information and the pathway. Consultants will complete a check list for each patient. We will check medical records for details of discussion about treatment options and treatment pathway and whether checklist completed or not. We will continue to montor anomymous feedback through Survey monkey questionnaires.	
6. On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved sperm for one patient and embryos for two couples. This would normally be classified as a critical non compliance however the inspection team, taking into account the circumstances described in the body of the report,	The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent when responding to this report. In addition, 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.	Consents for extension of storage for cryopreserved sperm for one patient and embryos for one couple have been received. I am unclear why the 3rd case has been included - Cryopreserved embryos for one couple remain in storage as the embryos are 'in dispute'. Please refer to my long standing correspondence with senior	The inspector thanks the PR for this comprehensive update. The inspector also acknowledges the clarification regarding the embryos which remain in storage and are in the 'cooling off period'. No further action is required.

considered that this could reasonably be categorised as a major non compliance. HF&E Act 1990 (as amended), Schedule 3, 8(1).	The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	inspector Sara Parlett regarding this case. I received a written reply on 15.10.2015 to the query I sent on 11.09.2015 after receiving withdrawal of consent to storage. As per advice received from HFEA and having taken our own legal advice, the ex-partner who is the non-gamete provider as the 'interested party' has been informed of the withdrawal of consent to storage by the gamete provider. As yet, we have not received response from the ex-partner. The embryos are currently in the 'cooling-off' period. At the time of this report there are no other embryos/gametes in storage without effective consent in place.	
7. The centre has adopted a ‘paper light’ system with patient records being scanned and saved on computer.	The PR should ensure that patient records are fully traceable to the patient to whom they refer. The PR should review the process	The team have been sent an email reminding that each page of patient document should have patient name, date of birth and/or unique	The inspector acknowledges the PR’s response. Audit summary to be provided by 1 February 2016.

During an audit of patient files, it was observed that the scanned documents did not have patient identifiers on each page and in some instances the history documented did not correlate with other records within a file. Thus the inspection team could not be assured that all the documentation within a file did in fact relate to that patient (SLC T47).	to ensure that each document is identified as it relates to that patient. The PR should provide the centre's inspector with a copy of the review and any corrective actions when responding to this report. Three months after the implementation of any changes the PR should perform an audit of patient records to ensure that all sections of the patient record are traceable to the patient to whom they relate. The PR should provide a summary of the audit finding to the centre's inspector by 1 February 2016.	MRN number. This was also reiterated and minuted at the monthly team meeting chaired by our Medical Director. An audit will be carried out in January 2016 and findings submitted by 01.02.2016	Further action is 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
8. The centre does not record which centrifuge is used in the preparation of each individual semen sample (SLC T99).	The PR should take immediate action to ensure that the centrifuge which is used in the preparation of semen samples is documented. The PR should advise the centre's inspector of measures taken to ensure this happens when responding to this report.	The lab record and lab SOP have been amended and the lab sheet now records the centrifuge which is used in the preparation of individual semen sample.	No further action is required
9. Patients are not screened in accordance with the timeframes specified by the Authority. (SLC T51b).	The PR should review the patent/partner screening SOP to ensure that that it is compliant with current regulations. On completion of the review the PR should ensure that all staff are aware of current screening requirements. The PR should perform an audit of patient and partner screening three month after the review and implementation of any corrective actions.	The SOP has been reviewed and all staff are aware of current screening requirements for patient and partner. An audit will be conducted and findings submitted to the centre inspector by 01.02.2016	The inspector acknowledges the PR's response. Audit summary to be provided by 1 February 2016. Further action is required.

	The PR should provide a summary of the review and audit results to the centres inspector by 1 February 2016.		

Reponses from the Person Responsible to this inspection report

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: 15 & 16 September 2015.

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage.

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

Inspectors: Janet Kirkland MacHattie, Gill Walsh, Louise Winstone, Shanaz Pasha.

Date of Executive Licensing Panel: 11 December 2015.

Centre name	London Women's Clinic, Wales
Centre number	0301
Licence number	L/0301/3/c
Centre address	15 Windsor Place , Cardiff, CF10 3BY, UK
Person Responsible	Dr Hemlata Thackare
Licence Holder	Dr.Kamal Ahuja
Date licence issued	01/03/2012
Licence expiry date	29/02/2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Women's Clinic, Wales has held a licence with the HFEA since 2008. Their initial licence was for treatment (insemination using partner/donor sperm) with storage. In 2012, the Executive Licensing Panel (ELP) approved a licence variation application to change the premises, name and licensed activities, to include treatment and storage. In April 2013 the ELP approved a licence variation to include embryo testing.

The centre provides a full range of fertility services.

The centre provided 572 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2015. In relation to activity levels this is a medium sized centre.

This licence renewal inspection was conducted in conjunction with Health Inspectorate Wales. The report of their inspection will be published separately.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period May 2014-April 2015 show the centre's success rates are in line with national averages.

In 2014-2015 the centre reported 21 cycles of partner insemination with four pregnancies: this is consistent with the national average.

Multiple births[2]

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

Between May 2014 and April 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 22%: 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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of 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, six major and two 'other' areas of non compliance.

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

Critical area of non-compliance:

- **the PR should ensure that all equipment is regularly inspected and maintained and is fit for purpose;**

Major areas of non compliance:

- the PR should ensure that the disposal of sperm is witnessed;

'Other' areas that require improvement:

- the PR should ensure that the centrifuge used in the processing of each semen sample is traceable.

The PR has implemented the following recommendations and has committed to provide the required audits in due course:

Major areas of non compliance:

- the PR should ensure that the centre's multiple live birth rate does not exceed the 10% target;
- the PR should perform a comprehensive review of the effectiveness of the quality management system;
- the PR should audit their process for information provision to ensure that patients are fully informed about their treatment options and pathway;
- the PR should ensure that there is valid consent for all gametes and embryos in storage;
- the PR should ensure that patient records are traceable to the patient to whom they refer.

‘Other’ areas that require improvement:

- the PR should ensure that patients and their partners are screened in accordance with the timeframes specified by the Authority.

Recommendation to the Executive Licensing Panel:

The centre had one critical area of concern (corrected on the day of inspection) and six major areas of concern.

Some improvement is required in order for the centre to demonstrate the suitability of their practices.

The inspection team notes that the centre's success rates are consistent with the national average.

It is also noted that the centre’s multiple clinical pregnancy rate according to HFEA data is 22%. If it continues on this trajectory, the centre is unlikely to meet the current 10% live birth rate target. The PR is encouraged to continue to use the quality management system to best effect, to implement and monitor an effective strategy to reduce multiple birth rates to meet the target, so as to improve the quality of the service offered to patients.

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better
It was observed on inspection that the disposal of sperm not required for use in treatment is not witnessed. The centre's standard operating procedure (SOP) was amended on the day of inspection to include this witness step (SLC T71).
See recommendation 2.

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

Donor assisted conception (Guidance note 20)
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 suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and 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 single biggest risk of fertility treatment is a multiple pregnancy. 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.

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

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

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

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

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and there is enough information to permit the gametes and embryos to be stored or used in

treatment in a way that does not compromise their quality and safety.

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

Traceability (Guidance note 19)
The centre's procedures are 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;
- 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; General Direction 0010)
The centre does not conduct transport IVF. The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by transport or satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and most 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 is compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

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

centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Multiple births (Guidance note 7; General Direction 0003)
The PR was asked to review the centre's multiple birth minimisation strategy following the issue of alerts from the HFEA risk tool relating to high multiple clinical pregnancy rates.

The PR responded to the alerts, has revised the centre's strategy and has committed to monitor its effectiveness. The centre's own data seen on inspection indicates that the revised strategy is having a positive effect. However, HFEA data (three month lag) show the centre's multiple clinical pregnancy rate for treatments between 1 May 2014 and 30 April 2015 was 22% (SLC T2).
See recommendation 3.

Traceability (Guidance note 19)
The centrifuge used in the preparation of each individual semen sample is not recorded (SLC T99).
See recommendation 8.

QMS (Guidance note 23)
The QMS was considered by the inspection team to be non-compliant in several areas:

- There was no formal process in place for reviewing the performance of the quality management system to ensure continuous and systematic improvement (SLC T32).
- There was no formal system for the review of documents including SOPs and review dates were in some instances unclear to the centre team (SLC T34).
- Corrective actions following audits of activities were in some instances unclear and did not appear to address the actual non-conformance. In addition the implementation of corrective actions was not reviewed. For example corrective actions following an audit of consent were documented as 'nurse off sick' (SLC T36).
- The centre's methodology for audit did not appear to be comprehensive or robust. For example, the audit of provision of information to patients only questioned whether a letter sent to patients following consultation included a link to an online information booklet (SLC T36).

See recommendation 4.

Equipment and materials (Guidance note 26
The laryngoscope on the centre's emergency trolley did not have a battery and was therefore not fit for purpose in the event of an emergency (SLC T23).
See recommendation 1.

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 T/1145/7.

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

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection no patients elected to speak with members of the inspection team about their experiences. Five patients had however provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with three of the individuals providing written feedback to the HFEA commenting that they had compliments about the care that they received but two patients provided feedback commenting that not all treatment options were discussed and that there was not enough information provided before or during treatment.

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;
- provides patients with satisfactory facilities for their care

What the centre could do better

The inspection team acknowledges that patient comments received at the HFEA may not be representative of the majority of patients. However the patient information audit seen on inspection was not robust, the audit process only appearing to check that patients are provided with a link to a generic on-line leaflet. This on-line information described a number of treatment options and so was not patient specific. The inspection team was not assured that patients were being provided with sufficient information regarding their specific treatment (SLC T58 & T59).
See recommendation 5.

Treating patients fairly
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

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

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and/or donors are partially 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
See reference in patient feedback and recommendation 5.

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 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 patient identifying information, to researchers, with patient consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). 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 15;17)

The centre's procedures for screening patients are broadly 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, and 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

Screening of patients (Guidance note 17)

Patients are not being screened in accordance with the timeframes specified by the Authority. Male partners are being screened within three months of the first treatment cycle however female partners are not (SLC T51b).

See recommendation 9.

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved sperm for one patient and embryos for two couples (HF&E Act 1990 (as amended), Schedule 3, 8(1)).

The PR explained that all gametes and embryos are being stored within the statutory storage period but that extension to storage is being sought from one patient with sperm samples and one couple with embryos stored for the preservation of fertility.

The PR also explained that the second set of embryos stored is subject to a legal dispute where one gamete provider has withdrawn consent to store.

Having gametes/embryos in storage without consent would normally be classified as a critical non-compliance, however, the inspection team take into account the circumstances described by the PR and consider it proportionate to grade this non-compliance as a major. See recommendation 6.

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 does not use embryos for training staff.

What the centre could do better
Not applicable.

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 partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

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

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre operates a 'paper light' system. Where paper copies of consent or other documents are required, these are then scanned into the centre's patient information data base.

During an audit of patient files, it was observed that scanned documents did not have patient identifiers on each page and, in one instance, the history documented did not appear to correlate with other records in the file. For example, an allergy was noted but this was not referred to in any other part of the record, including the pre-operative assessment. The inspection team could therefore not be assured that all of the documentation on the scanned record did in fact relate to that patient (SLC T47).
See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to one area of major non compliance and three '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

The centre has not received any HFEA performance related alerts relating to clinical pregnancy rates following treatment, however, between May 2014 and September 2015 the centre received three alerts relating to multiple clinical pregnancy rates. In response to this the centre reviewed the effectiveness of their multiple births minimisation strategy (General Direction 0003; see section on multiple births).

The PR has given a commitment to keep the multiple birth strategy 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, General Direction 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 noncompliance 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 noncompliance 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 laryngoscope on the emergency trolley did not have a battery and was therefore not fit for use in the event of an emergency. It should be noted that this was corrected immediately (SLC T23).	The PR should review the process for ensuring key equipment is regularly inspected and fit for purpose, to identify if there are any barriers to this being done effectively. The centre's inspector should be advised of the measures taken to ensure that this happens when responding to this report.	This was corrected immediately. The list of all key equipment has been reviewed to ensure that the equipment is inspected and fit for purpose. The theatre nurse has been assigned responsibility for checking and signing off the checklist for all critical equipment in theatre and on the emergency trolley . The daily theatre record has been amended for anaesthetist to sign that equipment was checked.	The inspector acknowledges the PR's response. 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. The disposal of sperm not required for treatment is not witnessed (SLC T71).	The PR took immediate action to ensure that the disposal of sperm was witnessed on the day of the inspection and the centre's SOP was updated to reflect this. The PR should, after three months, audit compliance with these witnessing requirements, to ensure the corrective action has been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 1 February 2016.	The SOP has been revised Witnessing requirements will be audited and summary of audit provided to the centre's inspector by 01.02.2016	The inspector acknowledges the PR's response. Audit summary to be provided by 1 February 2016. Further action is required.
3. Between 1 May 2014 and 30 April 2015, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: this represents performance	The PR assured the inspection team that she had reviewed and revised the multiple birth minimisation strategy in response to alert emails from the HFEA risk tool, sent to the PR in response to the centre's high multiple clinical	The centre has audited the multiple clinical pregancy rate after the multiple birth minimisation strategy was revised at the end of February 2015 and our recent	The inspector acknowledges the PR's response and her commitment to monitor the centre's multiple clinical pregnancy rate. The PR is encouraged to review the centre's multiple birth

that is likely to be greater than the 10% multiple live birth rate target for this period (SLC T2).	pregnancy rate. The centre's own data indicates that the revised strategy is having a positive effect. The PR should continue to monitor the effectiveness of their multiple births minimisation strategy.	audit shows that the rate has reduced significantly. The HFEA data does not reflect this as it includes data before the strategy was revised. We will be monitoring the centre's clinical multiple pregnancy rate.	minimisation strategy again if the recent changes to the strategy prove unsuccessful. The centre's inspector will also continue to monitor the centre's multiple clinical pregnancy rate using the HFEA risk tool. Further action is required.
4. The quality management system was considered by the inspection team to be non-compliant in several areas as described in the body of the report (SLC T32, T34, T36).	The PR should conduct a review of the quality management system This should include a review of centre's SOPs and audit process. The PR should review audits conducted in the time since the last inspection, to ensure that findings and corrective actions are clearly documented and have been implemented. By 1 February 2016 the PR should provide a summary of the review and an action plan with time scales for corrective actions to be completed. Thereafter, the PR should provide a monthly update on progress with the action plan to the centre's inspector.	I appreciate the HFEA inspection team observations as there is always room for improvement. However I feel that our QMS is quite robust such that the feedback received from patients is positive, our success rates are in line with the national average, we receive very few complaints and non-conformances/adverse incidents/adverse events are minimal when compared with the number of patients treated at the centre. The documentation of CAPA and follow up may not have reflected correctly the purpose and standards of the audit. However our KPIs are	The inspector acknowledges the PR's response and her commitment to review the bring forward system for document review, in addition to providing staff training in audit methodology and management of corrective actions. Audit summary to be provided by 1 February 2016 in addition to monthly updates regarding the action plan to address any outstanding corrective actions. Further action is required.

		audited annually and in some instances half yearly and are compared with previous year's performance. This immediately informs us whether there has been improvement or not. Our local quality lead will create a bring forward system to review documents in a timely manner. Our document control SOP is being reviewed by the Quality Assurance Coordinator. To improve the process further we are organising staff training on Audit process, methodolgy and CAPA management. Audits conducted post-inspection will be reviewed and summary with action plan will be provided to the centre's inspector by 01.02.2016.	
5. Patient feedback received at the HFEA indicated that patients did not, in some instances, receive enough information (SLC T58 and	The PR should audit processes for giving information to ensure that patients are fully informed about their treatment options and pathway.	The number of patients giving feedback to HFEA was extremely small (five patients = 1% of total number of patients treated).	The inspector acknowledges that the patient feedback received at the HFEA was from a small percentage of patients who have attended

T59)	When responding to this report the PR should provide the centre's inspector with a plan of how they intend to conduct this audit, to ensure that it is comprehensive and will identify any gaps in the information process. Following review of the audit methodology, the PR should perform an audit of the patient information process and provide a summary of the audit, including corrective actions and their timescales for implementation, by 1 February 2016.	It is difficult to draw any reliable conclusions based on these very small numbers. The centre independently asks patients to reply anonymously to Survey Monkey questionnaire - this was presented to the inspection team. 132 patients provided treatment feedback over the past two years. The feedback analysis reported that less than 10% were either dissatisfied or very dissatisfied with explanation of treatment plan, purpose of medication, consents, procedures, risks, costs, etc. 26 patients have provided feedback after initial consultation from January to August 2015. Of these 23 patients felt that all available treatment options were discussed in great detail, understood what to expect from treatment and were happy with treatment/diagnosis offered.	the centre. The inspector also acknowledges that the centre's own patient survey indicates a high level of satisfaction with the information received regarding treatment options. The inspector also acknowledges the PR's commitment to document the information that is given to patients and to continually monitor patient satisfaction. The required audit should be provided by 1 February 2016. Further action is required.

		I am hence disappointed that the inspection team did not take this into consideration. Patients will be provided paper copies of treatment information and the pathway. Consultants will complete a check list for each patient. We will check medical records for details of discussion about treatment options and treatment pathway and whether checklist completed or not. We will continue to montor anomymous feedback through Survey monkey questionnaires.	
6. On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved sperm for one patient and embryos for two couples. This would normally be classified as a critical non compliance however the inspection team, taking into account the circumstances described in the body of the report,	The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent when responding to this report. In addition, 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.	Consents for extension of storage for cryopreserved sperm for one patient and embryos for one couple have been received. I am unclear why the 3rd case has been included - Cryopreserved embryos for one couple remain in storage as the embryos are 'in dispute'. Please refer to my long standing correspondence with senior	The inspector thanks the PR for this comprehensive update. The inspector also acknowledges the clarification regarding the embryos which remain in storage and are in the 'cooling off period'. No further action is required.

considered that this could reasonably be categorised as a major non compliance. HF&E Act 1990 (as amended), Schedule 3, 8(1).	The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	inspector Sara Parlett regarding this case. I received a written reply on 15.10.2015 to the query I sent on 11.09.2015 after receiving withdrawal of consent to storage. As per advice received from HFEA and having taken our own legal advice, the ex-partner who is the non-gamete provider as the 'interested party' has been informed of the withdrawal of consent to storage by the gamete provider. As yet, we have not received response from the ex-partner. The embryos are currently in the 'cooling-off' period. At the time of this report there are no other embryos/gametes in storage without effective consent in place.	
7. The centre has adopted a ‘paper light’ system with patient records being scanned and saved on computer.	The PR should ensure that patient records are fully traceable to the patient to whom they refer. The PR should review the process	The team have been sent an email reminding that each page of patient document should have patient name, date of birth and/or unique	The inspector acknowledges the PR’s response. Audit summary to be provided by 1 February 2016.

During an audit of patient files, it was observed that the scanned documents did not have patient identifiers on each page and in some instances the history documented did not correlate with other records within a file. Thus the inspection team could not be assured that all the documentation within a file did in fact relate to that patient (SLC T47).	to ensure that each document is identified as it relates to that patient. The PR should provide the centre's inspector with a copy of the review and any corrective actions when responding to this report. Three months after the implementation of any changes the PR should perform an audit of patient records to ensure that all sections of the patient record are traceable to the patient to whom they relate. The PR should provide a summary of the audit finding to the centre's inspector by 1 February 2016.	MRN number. This was also reiterated and minuted at the monthly team meeting chaired by our Medical Director. An audit will be carried out in January 2016 and findings submitted by 01.02.2016	Further action is 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
8. The centre does not record which centrifuge is used in the preparation of each individual semen sample (SLC T99).	The PR should take immediate action to ensure that the centrifuge which is used in the preparation of semen samples is documented. The PR should advise the centre's inspector of measures taken to ensure this happens when responding to this report.	The lab record and lab SOP have been amended and the lab sheet now records the centrifuge which is used in the preparation of individual semen sample.	No further action is required
9. Patients are not screened in accordance with the timeframes specified by the Authority. (SLC T51b).	The PR should review the patent/partner screening SOP to ensure that that it is compliant with current regulations. On completion of the review the PR should ensure that all staff are aware of current screening requirements. The PR should perform an audit of patient and partner screening three month after the review and implementation of any corrective actions.	The SOP has been reviewed and all staff are aware of current screening requirements for patient and partner. An audit will be conducted and findings submitted to the centre inspector by 01.02.2016	The inspector acknowledges the PR's response. Audit summary to be provided by 1 February 2016. Further action is required.

	The PR should provide a summary of the review and audit results to the centres inspector by 1 February 2016.		

Reponses from the Person Responsible to this inspection report