Executive Licensing Panel - minutes

Centre 0314 (Leeds Fertility)

Renewal Inspection Report

Thursday, 8 November 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Research Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Hannah Carpenter	Policy Officer

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 Leeds Fertility has held a treatment (including embryo testing) and storage licence with the HFEA since 2010 and provides a full range of fertility services for NHS and privately funded patients.

1.3. The panel noted that, in the 12 months to 31 May 2018, the centre provided 1,951 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a large sized centre.

1.4. The panel noted that, between March 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4.7%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. The panel noted that, for IVF and ICSI, HFEA held register data, for the period March 2017 to February 2018, shows the centre's success rates are in line with national averages, with the exception of success rates for IVF treatments in women over 38 years old and ICSI treatments for women between 16 and 37, which are higher than average at a statistically significant level.

1.6. The panel noted that in 2018 the centre reported 70 cycles of partner insemination with 13 pregnancies; this represents a clinical pregnancy rate of 9%, which is in line with the national average.

1.7. An inspection was carried out at the centre on the 18th and 19th July 2018.

1.8. The panel noted that at the time of the inspection, there was one critical area of non-compliance regarding the storage of gametes and embryos. There were also eight major areas of non-compliance concerning safety and suitability of premises and facilities, infection control, medicines management, the Quality Management System (QMS), transport and satellite agreements, third party agreements, staff and information provided to patients.

1.9. Since the inspection, the Person Responsible (PR) has fully implemented the recommendations concerning the critical non-compliance and the major non-compliances relating to the safety and suitability of premises and facilities, infection control, medicines management, the QMS, transport and satellite agreements, third party agreements, and information provided to patients. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken have been effective. The PR has provided a commitment to investigating the barriers to staff completing Trust mandatory training.

1.10. The panel noted that significant improvement is required in order for the centre to reflect suitable practices. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their treatment, procedural and satellite processes and outcomes and the quality of the service offered to patients.

1.11. The panel noted that the inspectorate considered the progress made by the centre since the granting of the previous licence, where concerns were evident and a licence length of three years, rather than four, was granted. The inspection team had some concerns as to the number of non-compliances identified at this renewal inspection. The inspectorate noted the commitment of the PR to implementing the remedial actions without delay.

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

1.13. The panel noted that the inspection team 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 the report being implemented within the prescribes timescales.

2. Decision

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

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

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

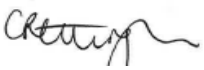
2.4. The panel expressed concern regarding the number of major non-compliances identified at the centre's renewal inspection. However, the panel recognised the PR's prompt engagement in implementing remedial action, noting that only one non-compliance, in connection with staff completing Trust mandatory training, remains outstanding. The PR was encouraged to work closely with the inspectorate to ensure fewer non-compliances are identified at the centre's interim inspection.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

13 November 2018

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (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: 18 and 19 July 2018

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: Grace Lyndon (lead), Janet Anderson-Pearce, Andy Glew, Danya Harris and Chris Hall. Observer for the second day; Samantha Hayhurst (Department of Health and Social Care (DHSC)).

Date of Executive Licensing Panel: 6 November 2018

Centre name	The Leeds Fertility
Centre number	0314
Licence number	L/0314/3/e
Centre address	Seacroft Hospital, York Road, Leeds, LS14 6UH,
Person Responsible	Mrs Karen Thompson
Licence Holder	Leeds Teaching Hospitals NHS Trust
Date licence issued	25/01/2016
Licence expiry date	24/01/2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Leeds Fertility has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2010 and provides a full range of fertility services for NHS and privately funded patients.

The centre provided 1,951 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2018. In relation to activity levels this is a large centre.

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

This current licence has been varied to reflect the following changes:

- change of Person Responsible (PR) was approved by an ELP in 13 January 2017;
- change of centre name was agreed by ELP on 21 April 2017, from The Leeds Centre for Reproductive Medicine to Leeds Fertility;
- variation of licence to include embryo testing on 18 October 2017.

Pregnancy outcomes[1]

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

- The success rates following IVF treatments in women over 38 years old and ICSI treatments for women between 16 and 37 are higher than average at a statistically significant level.

In 2018, the centre reported 70 cycles of partner insemination with 13 pregnancies. This represents a clinical pregnancy rate of 9%, which is in line with the national average.

Multiple births[2]

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

Between March 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4.7%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the (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 with the exceptions noted in this report;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical and eight major areas of non compliance.

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

Critical areas of non compliance:

- **The PR should ensure that patients consenting for storage have done so before the storage has commenced.**

Major areas of non compliance:

- The PR should ensure that fire exits are kept clear of obstructions at all times.
- The PR should ensure that the infection control measures and practices are compliant with regulatory and best practice guidance.
- The PR should ensure that medicines management procedures are followed in line with regulations and best practice.
- The PR must ensure that there is an effective and robust Quality Management System (QMS) in place to improve the quality and effectiveness of the service provided.
- The PR should ensure that the centre's transport and satellite agreements meet the relevant HFEA Code of Practice requirements.
- The PR should ensure that all third party agreements are reviewed and include the requirements set out by the HFEA.
- The PR should ensure that patients receive all necessary information in line with code of practice requirements.

The PR has provided a commitment to implementing the following recommendation within the required timescales:

Major areas of non compliance:

- The PR should investigate the barriers to staff completing Trust mandatory training as scheduled.

Recommendation to the Executive Licensing Panel

The centre has more than five major areas of non-compliance and one critical area of concern.

The inspection team notes that the success rates for IVF treatments in women over 38 years old and ICSI treatment for 16 to 37 year olds are above the national average at a statistically significant level and the centres multiple clinical pregnancy rate is below the recommended target and this is commended.

However, significant improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system in place. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their treatment, procedural and satellite processes and outcomes and the quality of the service offered to patients.

The inspection team considered the progress made by the centre since the granting of the previous licence, where concerns were evident and a licence length of three years, rather than the usual four, was granted.

The inspection team had some concerns as to the number of areas of concern identified at this inspection. At the same time, it took into account the commitment of the PR to the recommendations made in implementing the remedial actions without delay. The Executive note that only one recommendation remains to be completed, by February 2019.

As such, 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.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

In addition, the ELP is asked to note the time elapsed between the inspection and the report being made available to the PR for comment, and preparation of the report for consideration by the Panel, all longer than usual. This is due to staffing matters.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

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

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

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

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

Suitable premises and suitable practices

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

What the centre does well

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

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

The premises of the centre's satellite or transport 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/or 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 to be accredited by

CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are partially compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

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

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

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

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

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;

- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

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

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

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is 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 partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are partially compliant with HFEA requirements. This is important to ensure that activities performed by transport and 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 compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)

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

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

What the centre could do better
Safety and suitability of premises and facilities (Guidance note 25)
During the inspection, it was noted that there were storage boxes, Christmas trees with the accompanying decorations and metal crates within the corridors and leading up to and obscuring the fire exit.
There were coils of cables trailing on the floor and underneath the benches in the laboratory.

Recommendation 2.

Infection control (Guidance Note 25)
During the inspection, the following was noted;

- There were stores and drinks in the store room on the floor.
- Clinical and household waste for the day from the centre, was placed in the corridor late afternoon when patients were still attending the clinic for appointments.
- There were coils of cables trailing on the floor and underneath the benches in the laboratory.
- Some clinical rooms did not have wipe clean seating.
- One of the satellite centres (Yorkshire) does not have cleaning logs.

Recommendation 3.

Medicines management (Guidance Note 25)
On inspection, it was noted that;

- In the records reviewed, the amount of controlled drug recorded in the controlled drugs (CD) register as having been administered to the patient, did not match the amount recorded as being given in the patients' records.
- A review of the CD register showed that alterations were made by overwriting rather than using a method in line with the regulations; i.e. using a margin note or footnote, despite instructions displayed in the front of the controlled drugs register.
- There was some confusion about the disposal of controlled drugs. The inspector was informed that the disposal of controlled drugs was undertaken by squirting it into the theatre sink. The second comment was that to discard the excess controlled drugs, they were squirted into a plastic bag and lastly the waste was discarded into a sharps bin.
- Disposal of excess unused controlled drugs was not routinely witnessed by a second person;
- The controlled drugs audit lacks scope (see QMS section for further details).

- The CDAO (head of pharmacy) does not appear to have a clear overview of the clinic's medicines management practices. The controlled drugs audits undertaken by the CDAO and associates lacked in scope and failed to pick up the non compliances identified in this report. (Controlled Drugs (CD) audit did not pick up deficiencies in the completion of the CD Register, the administration or the discard).
- The controlled drugs audit lacks scope (see QMS section for further details).

Recommendation 4.

Quality management system (QMS) (Guidance note 23)
On inspection, it was found that;

- The dates that audits were carried out was not always recorded.
- The number of patients included in the audits was not always documented.
- In some audits recorded as being completed, it was unclear what, if any, action had been taken in response to non-compliances identified in the audit (witnessing and consent audit report 2018, audit grid May 2018 and case notes audit October 2017 for example).
- Once the non compliances were identified, the corrective actions were not routinely documented, and the action taken was routinely documented. This was evident in the audits mentioned above and would also include the RMU (medicines management for example).
- The timescale for completion of corrective actions was not documented on the centre's audits or those audits undertaken by the centre for their satellite centres.
- There were no documented quality indicators in the centre's audits. The quality indicators have not been established.
- There was no documented evidence or supporting information to show the non compliances at satellite centres had been addressed and signed off as complete.
- Definitions of 'compliance' in the centre's audits included 'part compliant', however, the part that was not compliant was not addressed in line with a non conformity.
- The controlled Drugs (CD) audit did not pick up deficiencies in the completion of the CD Register, and the administration or discard of controlled drugs.
- The centre does not include medicines management on their satellite centres' audit schedules (Orbit, Nobel and Yorkshire).
- Some satellite centres do not have a quality management system in place (Nobel and Orbit).

Recommendation 5.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The observations made during the inspection found that;

- Some satellite centres did not have a quality management system in place (Nobel and Orbit).
- Kynisi, a transport service company has not been audited by the centre.
- One satellite centre (Orbit) was last inspected over 2 years ago.
- The premises of the centre's satellite and transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) have not been audited in line with HFEA guidance.

Recommendation 6.

Third party agreements (Guidance note 24)
The third party agreements did not reflect the requirements of the HFEA;

- One of the agreements was out of the agreement timeline and required renewing (Cooper Genomics).
- No explanation was given as to how any test results are relayed to the commissioning centre, including sign off and confirmation that the results belong to the sample (Cryos).
- With the open-ended contracts, they are not reviewed two yearly to ensure the centre and the third parties requirements are still being met.

Recommendation 7.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

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

Staff (Guidance note 2)
The centre is partially 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
Staff (Guidance note 2)
The following was found during the inspection:

- Some staff members have not completed their yearly mandatory training in areas of their working practice such as safeguarding and CPR for example. There is not a mechanism in place to safeguard patients and staff members by not placing them in the high-risk areas and a close review of the staff without the competencies in these areas are not monitored closely. This was a non compliance during an inspection at the centre in 2015 and was not in line with the centre's own SOP.
- The PR did not have the awareness of the training the medical staff had undertaken to ensure they were competent and working within their sphere of practice. This was identified in the centre's own audit and no action was taken.
- The dissemination of information is not planned, and staff meetings occur on an ad hoc basis. Some disciplines have been informed by email of their discipline's non compliances. Management are not assured if all staff have received or taken the advice on board.

- The PR nor centre staff were aware of the Hepatitis A recommendation discussed in the Clinic Focus article in August 2017 and it was therefore not discussed with patients, documented in the patient information or discussed as a part of the counselling process.

Recommendation 8.

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing
Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

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

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

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. The centre's most recent patient survey responses collected between April 2018 and June 2018 were reviewed. The feedback from these patients was generally very positive.

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

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

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

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
Th area of practice was not reviewed during the inspection as it is an area of practice that this centre does not participate in.

Surrogacy (Guidance note 14)

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

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter (CH(11)02)
The centre's procedures for providing information to patients 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
Information (Guidance note 4; Chair's Letter (CH(11)02)
On inspection, it was observed that the information provided to patients was not documented in their records. The centre does not have an SOP for the provision of information to patients.;

The centre's website is not compliant with HFEA regulations;

- The data relating to activity, pregnancy rates and live birth rates was more than three years old.
- The national rate; the like for like for the maternal age groups, treatment types with reflective time frame was not available on the centres website.

Recommendation 9.

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

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

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

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

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

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

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

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

Screening of patients and Storage of gametes and embryos

What the centre does well

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

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

What the centre could do better
Storage of gametes and embryos (Guidance note 17)
It was discovered in a set of donor patient's notes that a cycle of sperm donation was completed before the consent to freeze form was completed by the patient. The consent form was completed approximately a year after the initial donation.

Recommendation 1.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors. However, there have been some historic difficulties in submitting data, of which the HFEA is aware and is working with the centre to resolve. The centre has assured the Executive that the back log of data submissions should all be completed by the end of August. The PR will keep the centre's inspector updated with progress. As this issue is outside of the centre's control, no recommendation has been made at this time.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register. However, within the data quality review, a small number of minor data quality issues were identified. The centre is now aware of them and will make corrections where necessary.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to three areas of major 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

Leeds Fertility is a large centre and they are to be commended for their multiple birth rate which was below the national average at 4.7%.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Storage of gametes and embryos It was discovered in a set of donor patient's notes that a cycle of sperm donation was completed before the consent to freeze form was completed by the patient. The consent form was completed approximately a year after the initial donation. Schedule 3 HF &E Act 1990 (as amended).	The PR should ensure that patients consenting for storage have done so before the storage has commenced. The PR should review consenting practice and relevant standard operating procedures (SOPs) to ensure they are compliant with statutory and regulatory requirements.	During a check of sperm donor notes for LCRM001, it was noted that the date of the MD form was after the donor had started donating - see below 7.4.11: First screening tests 2.9.11: Signed CD form 2.9.11: Donor gave his first sample for donation 7.9.12: Signed MD form and final screening	This non-compliance relates to the findings of the inspection team on the day(s) of the inspection. As there was no evidence at that time to indicate that valid storage consent was in place for this patient's samples, a critical non-compliance has been issued. The Executive acknowledges the PR's response and commitment to investigating

SLC T57.	The PR should provide a summary report of this review, including corrective actions taken, when responding to this report. The PR should seek a legal opinion as to whether continued storage of the gametes identified in this report, is lawful, given that consent was obtained after they were stored. A summary report of this opinion should be provided to the centre's inspector by 18 January 2019. The PR should ensure that if this consent anomaly was not reported to the HFEA as an incident, at the time, a retrospective incident report is submitted. The PR should confirm to the centre's inspector when this incident has been reported to the HFEA.	This was obviously of concern as it appeared that the donor had not consented for donation before donating. Upon closer inspection of the notes and the freeze summaries for this donation, there was an expiry date (of 10 years) on all the summary sheets which had then been crossed out and changed to 55 years (time period on consent form in the notes). This seemed to indicate that the donor had changed the consent to 55 years at the time of his final screening test but there is no record of an original MD form. I spoke with the technician (no longer works with us) who seemed to recall him updating consent for length of storage, but obviously could not say for sure due to it being a long time ago. I therefore contacted the donor to see if he had his copy of the original MD form. The donor told us he had updated his consents and	this non-compliance and is reassured by the findings. No further action required.

		when he checked his records found the original MD form which had been signed on the 7.4.11 which was prior to the freeze (in addition to the updated consent form) which he has now scanned and sent to me for our records. This is reassuring to know that lawful consent was indeed in place before donation began and therefore legal opinion has not been sought regarding storage nor has an incident form been sent. It is unclear however, why a copy of this form was not in the records, and the likelihood it was removed at the time the consent forms were updated. I contacted the inspector on 26.7.18 (one week post inspection) via email to inform of this update. This has been discussed with the whole team as a follow up to your inspection and it was reiterated that if consents are updated then old consents should be voided and not removed. It is also the case	

		that the consent audit performed this year did not show any issues regarding consents. I therefore ask that this is considered by the ELP with a view to not recording this as a critical non conformance as although the consents not being in the notes is not good, a valid consent was actually in place at the time of donation and a copy of this is now in the notes.	

Major area of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Safety and suitability of premises and facilities During the inspection, it was noted that there were storage boxes, Christmas trees with the accompanying decorations and metal crates within the corridors and leading up to and obscuring the fire exit. There were coils of cables trailing on the floor and underneath the benches in the laboratory. Regulatory Reform (Fire Safety) Order 2005.	The PR should ensure that fire exits are kept clear of obstructions at all times. The PR should address the issues identified in this report and inform the centre's inspector of the actions taken to ensure ongoing compliance when responding to this report.	At the time of the inspection, several boxes were in the corridor leading to the fire escape. In additon there was the CSSD trolley (containing used equipment for sterilisation). We accept that another place should be found for the boxes and these were moved. The CSSD trolley was against the wall (a few metres from the fire doors). When this was highlighted as a risk on the day of inspection, we did demonstrate that a bed/trolley was able to get	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The Executive has removed the non-compliance relating to satellite and transport centres from this recommendation as it is actioned in recommendation 6. The Executive acknowledges receipt of the laboratory risk assessment dated April 2018. No further action required.

		past to enable exit from the fire door if required. Lockers which were also on this corridor have now been removed so that the CSSD trolley can be pushed closer to the wall making even more space, however we do feel this trolley needs to be close to the theatres so we are not carring "used and dirty" equipment too far as this poses an infection risk. An inspection was carried out by the Trust fire officer on 25.9.18 and he deemed that Leeds Fertility met all fire regulations including clear exits. As a big busy clinic, we have a lot of incubators and other equipment and each incubator has independent monitoring probes connected to our alarm monitoring system (a HFEA requirement and direcly impacts patient safety). This unfortunately means the laboratory does have a lot of cables. We cannot get away	

		from this fact however we feel we have managed this as best we can by using cable ties to attach these to bench legs and all of the cables are behind and under the benches which are out of the way and minimise any risk (see risk assessment for lab attached). The clinic will be looking to upgrade the alarm system in the next couple of years and strong consideration will be given to wireless alarms for the incubators to minimise the number of cables in the lab. See recommendation 6 for response on satellite and transport audit.	
3. Infection Control During the inspection, the following was noted; • There were stores and drinks in the store room on the floor. • Clinical and household waste for the day from the centre, was placed in the corridor late afternoon when patients were still	The PR should ensure that the infection control measures and practices are compliant with regulatory and best practice guidance. The PR should review the premises in relation, but not exclusively, to the issues identified in this report.	Store room: There are some boxes on the floor in the store room, generally of sharps bins. The bottles of drinks were not on the floor but on a shelf sealed in plastic and in a box. The clinic will ensure that these are kept in a more appropriate food storage place (such as resource room or in cupboard below coffee machine). These were moved	The Executive acknowledges the PR's response and commitment to implementing this recommendation, and receipt of the review of infection prevention and control practice and procedures. No further action beyond submission of an audit of infection prevention and

attending the clinic for appointments. • There were coils of cables trailing on the floor and underneath the benches in the laboratory. • Some clinical rooms did not have wipe clean seating. • One of the satellite centres (Yorkshire) does not have cleaning logs. DH Health Building Note 00-09: 'Infection control in the built environment' 2013.	The PR should provide a summary report of this review, including the actions taken to achieve compliance and timeframes for implementation to the centre's inspector by 19 September 2018. Three months after the implementation of corrective actions, an audit should be undertaken. The audit summary should be sent to the centre's inspector by 19 December 2018.	on the day of inspection and have not been kept there since that date. The cleaners start cleaning the unit from 4pm when clinics are almost finished though there are some patients still there. The clinical waste bags were piled in one area near where patient clinic rooms were. The cleaners have been informed by the PR that when emptying waste bins during clinical hours they must put all bags in a cage and keep out of clinical areas before taking to big clinical waste bins (dumpsters) in the designated clinical waste room in the entrance of the unit. This is with immediate effect The laboratory staff have also been informed to take clinical waste bags directly to the clinical waste bin at end of the day rather than leave on the corridor for the cleaners with immediate effect.	control practice due by 19 December 2018.

		The issue of the cables on the floor in the laboratory has been addressed in the previous section, as unfortunately we cannot get away with the number of cables nor can they be unplugged. The lab is monitored monthly with settle plates and every 6 months externally by pharmacy QC to look at air quality and particles. No areas of concern have been raised with infection control in the laboratory. The lab is deep cleaned and everything moved (during christmas shut down) but cleaned around this best we can at other times. Wipe clean seating: The scan room in the clinical area, ie couch and seat behind curtain including where a patient would be undressed and the clinician would be seated all had wipe clean seats. The seats at the other side of the room where the patient would be dressed and clinican seated had some chairs with fabric, though no clinical	

		examination happens at this side of the room. The clinic however take on board the HFEA recommendations and have ordered vinyl seating. Target date 21st December 2018. An audit of the above actions will be provided to the inspector by 21st December 2018.	
4. Medicines Management On inspection, it was noted that; • In the records reviewed, the amount of controlled drug recorded in the controlled drugs (CD) register as having been administered to the patient, did not match the amount recorded as being given in the patients' records. • A review of the CD register showed that alterations were made by overwriting rather than using a method in line with the regulations; i.e. using a margin note or	The PR should ensure that medicines management procedures are followed in line with regulations and best practice. The PR should review medicines management practices and address the issues identified in this report. The PR should provide a summary report of the review, including corrective actions taken and timescales for implementation, to the centre's inspector by 19 October 2018.	The PR and nurses involved in the inspection challenge the statement that the amount of controlled drugs given to the patient as recorded in the controlled drug record book (CDRB) did not match those recorded in the patient records. One record was documented in the CDRB but had not been recorded on the anaesthetic record or in the patient notes. Therefore no discrepancies in recording but one omission in documentation was found. Leeds Teaching Hospitals NHS Trust Controlled Drug	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of an audit of medicines management practice due by 19 January 2019.

footnote, despite instructions displayed in the front of the controlled drugs register. • There was some confusion about the disposal of controlled drugs. The inspector was informed that the disposal of controlled drugs was undertaken by squirting it into the theatre sink. The second comment was that to discard the excess controlled drugs, they were squirted into a plastic bag and lastly the waste was discarded into a sharps bin. • Disposal of excess unused controlled drugs was not routinely witnessed by a second person. • The controlled drugs audit lacks scope (see QMS section for further details). • The CDAO (head of pharmacy) does not appear to have a clear overview of the clinic's medicines management practices. The controlled drugs audits undertaken by	Within three months of the implementation of corrective actions, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the centre's inspector by 19 January 2019.	standard operating procedure (SOP) CDSOP 2.8 (Management of Controlled Drugs in Theatres) requires that controlled drugs given in theatre must be recorded in the CDRB and appropriate patient specific records. The PR accepts that the recording of controlled drugs in the patient notes did not demonstrate best practice or adherence to the SOP and since the inspection has put corrective actions in place which will be reported in the requested review. One alteration was found, which was over written by scoring through but was not obliterated, the original entry was still legible. Staff have been reminded of the current correct procedure for corrections made in CDRBs (LTHT SOP ref CD 2.8) a copy of which will be provided with the requested review. There was some confusion in the inspection discussion of how the disposal of controlled	

the CDAO and associates lacked in scope and failed to pick up the non compliances identified in this report. (Controlled Drugs (CD) audit did not pick up deficiencies in the completion of the CD Register, the administration or the discard). SLC T12, and T36. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. Misuse of Drugs (safe Custody) Regulations 2001. Controlled Drugs (Supervision of Management and Use) Regulations 2013.		drugs was conducted. The PR confirms that unrequired controlled drugs for destruction are disposed of into pharmaceutical waste disposal sharps bins which contain appropriate absorptive or denaturing kit material (as per LTHT SOP ref CD1.6 Destruction of Controlled Drug Preparations) and this was shown to the inspector on the second day of the inspection. The requested review will include an assessment of whether the disposal of unused Controlled Drugs (CDs) is appropriately witnessed The PR is looking into the issue that the inspector raised regarding the view that the locally conducted controlled drugs audit lacked scope with the Trust CD Accountable Officer. The scope and quality control of the Trust quarterly audit programme are currently being reviewed. In the meantime the unit pharmacist, lead nurse and PR	

		have put several 'best practice' rules in place for the staff to follow and the unit will be audited against these additional criteria as part of the existing Quarterly CD audit programme review process. The audit report will be submitted to the inspector by January as requested.	
5. Quality Management System On inspection, it was found that; • The dates that audits were carried out was not always recorded. • The number of patients included in the audits was not always documented. • In some audits recorded as being completed, it was unclear what, if any, action had been taken in response to non-compliances identified in the audit (witnessing and consent audit	The PR must ensure that there is an effective and robust QMS in place to improve the quality and effectiveness of the service provided. The PR must complete a comprehensive review of the QMS, to include, but is not exclusively the issues identified in this report The PR should provide a summary report of this review, including staff training requirements and timescales for implementation of corrective actions	The PR and QM have reviewed the quality manual and quality management system and feel that this is suitable for purpose, however some improvements can be made in line with recommendations following the inspection. In addition, Leeds Fertility have had ISO accrediation for quality management for over 10 years and so therefore are independently audited . A recent ISO inspection in September 2018 of our quality management system recommended re-certification with no non conformances identified.	The Executive acknowledges the PR's response and receipt of the QMS review and ISO report. No further action required.

report 2018, audit grid May 2018 and case notes audit October 2017 for example). • Once the non compliances were identified, the corrective actions were not routinely documented, and the action taken was routinely documented. This was evident in the audits mentioned above and would also include the RMU (medicines management for example). • The timescale for completion of corrective actions was not documented on the centre's audits or those audits undertaken by the centre for their satellite centres. • There were no documented quality indicators in the centre's audits. The quality indicators have not been established.	implemented, to the centre's inspector by 19 October 2018. The PR should ensure that audits are robust and address (but not exclusively), issues identified in this report A summary report of the actions taken should be provided to the centre's inspector by 19 October 2018.	The PR however does take on board the recommendations made during the recent inspection and will aim to respond to the issues identified in this report regarding the quality management system particularly surrounding the audit process and documentation and completion of corrective actions. The PR will send a separate report, entitled Leeds Fertility Quality Management review along with this response which will address these issues and include the ISO inspection report. Documentation: A report was reviewed which did not include the date, though this was a summary finding and the original raw audit did include this. Another audit report the samples size was not clear. The QM has in response to these findings has developed a standard proforma for all unti	

• There was no documented evidence or supporting information to show the non compliances at satellite centres had been addressed and signed off as complete. • Definitions of 'compliance' in the centre's audits included 'part compliant'; however, the part that was not compliant was not addressed in line with a non conformity. • The controlled Drugs (CD) audit did not pick up deficiencies in the completion of the CD Register, and the administration or discard of controlled drugs. • The centre does not include medicines management on their satellite centres' audit schedules (Orbit, Nobel and Yorkshire). • Some satellite centres do not have a quality		audits which include aim, date, sample size, findings, KPI targets, corrective actions, target date, re-audit)If necessary) and sign off date to ensure that this is a more smooth process. Proforma document forwarded with report. The majority of the actions and completion dates were completed on the audit matrix (see attached) though agreed that the actions weren't always clear in each audit. The PR and the QM team have also set more defined KPI which would then make it much clearer whether actions are required or not and whether re-audit was required. Satellite centres The PR accepts that it is not clear whether actions from insopections of satellite centres had been completed or not. Following the inspection, the PR will follow up on actions raised and	

management system in place (Nobel and Orbit). SLC T32, T35 and T36		whether thse have been completed. Part compliance was used as a definition, in line with the HFEA SAQ, which has this as an option and used in terms of the process may need further development, and these will be documentsed in follow up satellite report. The PR will redsign the satellite SAQ and audit proforma to ensure it is clearer whether units are compliant and what the actions are including target dates for completion. (See separate quality management report) Medicines management of satellite centres: Medicines management assessment is not included in the satellite audits as no drugs are kept or dispensed at these units. Medicines are dispensed by pharmacy directly to the patient. The patient is then shown how to do the relevant injections by the nursing staff according to the SOP.	

		In addition clincial staff have had medicines management training in their local induction Satellite centre cleaning logs are kept as well as service records. Patient information provision SOP is addressed in section 9 The controlled drugs (CD) audit deficiencies is addressed in section 4.	The non-compliance relating to satellite cleaning logs is addressed in recommendation 3. The non-compliance relating to patient information has been removed from this recommendation and is addressed in recommendation 9.
6. Transport and satellite agreements The observations made during the inspection found that; • Some satellite centres did not have a quality management system in place (Nobel and Orbit). • Kynisi, a transport service company has not been audited by the centre; • One satellite centre (Orbit) was last inspected over 2 years ago. • The premises of the centre's satellite and transport facilities and laboratories conducting tests that impact on the	The PR should ensure that the centre's transport and satellite agreements meet the relevant HFEA Code of Practice requirements. The PR should ensure that all satellite centres and transport services are audited. The PR should provide a summary report of the audits including corrective actions undertaken, to the centre's inspector by 19 January 2019.	Satellite centre QMS. Noble hospital: The satellite centre at Noble hospital consists of one senior referring consultant, who sees all the patients, does her own paperwork and filing etc. Noble does have a quality management system which demonstrates SOP and document version control, however there is not a quality manual but there is a quality management SOP. Audit of notes are performed. Satellite inspection reports including corrective actions will	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The Executive confirms that the documents received relating to the receipt or transfer of gametes or embryos is enough to satisfy the requirements of auditing the relevant third party. No further action beyond submission of the outstanding audits due by 19 January 2019.

quality and safety of gametes and embryos (relevant third parties) have not been audited in line with HFEA guidance. SLCs T111-T116.		be submitted in the report in January 2019. Orbit Fertility did not have a QMS at time of last inspection (May 2016) though they had document and SOP version control and were developing their own QMS. Since this inspection the PR at Leeds Fertility has changed. The current PR and lead nurse will attend Orbit on 2.11.18 to perform inspection and the results, including actions recommended/completed to be sent to the inspector on 19th January. Kynisi (transport service) is continually audited - we have log of all patients who transfer gametes/embryos in and out of the unit (see transport log - anonomised for confidentiality). Please note that donor sperm import from external centres use their own courier service for which they have their own agreements.	

		When transports happen the checklist is completed (attached with this report EmbDoc 009 -012) for sending/receiving gametes and embryos which include checking the labelling of the shipper and shipper temperature. Samples are not sent/received if these are not completed and acceptable. Therefore the log is an account of an ongoing audit, please confirm if this is acceptable, as this can be formally written if required.	
7. Third party agreements The third party agreements did not reflect the requirements of the HFEA; • One of the agreements was out of the agreement timeline and required renewing (Cooper Genomics). • No explanation was given as to how any test results are relayed to the commissioning centre, including sign off and confirmation that the results belong to the sample (Cryos).	The PR should ensure that all third party agreements are reviewed and include the requirements set out by the HFEA. The PR should ensure that the agreements are updated. A copy of the updated agreements should be sent to your centre inspector by 19 October 2018.	The 3rd party agreement for Cooper Genomics is now signed and attached with this report. In relation to Cryos, the PR does not remember this question being raised at inspection, however can provide an explanation of this process. Once a donor is selected, the donor bank sends all information regarding the donor via secure transfer to the centre for approval. This	The Executive acknowledges the PR's response and receipt of the updated third party agreement. No further action required.

• With the open ended contracts, they are not reviewed two yearly to ensure the centre and the third parties requirements are still being met. SLC T111 and T112		includes, consents, screening results, SEC codes and freeze dates of samples and the patient to who the sperm will be allocated (unit number) These are all checked by the embryology team before approving these to be imported. The SOP(EmbSOP Import of sperm from outside of the UK) and documentation completed prior to receiving the sample (EmbDoc 053 Donor cryopreservation summary (from another centre)) is attached. Other open ended agreements have been reviewed and it is agreed that the terms are still applicable to date and do not need to be changed.	
8. Staff The following was found during the inspection; • Some staff members have not completed their yearly mandatory training in areas of their working practice such as safeguarding and CPR for example. There is not a mechanism in place to	The PR should investigate the barriers to staff completing Trust mandatory training as scheduled. The PR should review staff training requirements and ensure that all staff completes their mandatory training. The PR should provide a summary report of this review	Monthly mandatory training reports are sent to the team leaders detailing which staff are due which mandatory training. The leader will then inform the individual staff member to arrange this training. Unfortunately the number of available places on CPR training in the Trust does not meet demand (as the Trust	The Executive acknowledges the PR's response. No further action beyond submission of staff competency assessments as they are completed and by 19 February 2019.

safeguard patients and staff members by not placing them in the high-risk areas and a close review of the staff without the competencies in these areas are not monitored closely. This was a non compliance during an inspection at the centre in 2015 and was not in line with the centre's own SOP. • The PR did not have the awareness of the training the medical staff had undertaken to ensure they were competent and working within their sphere of practice. This was identified in the centre's own audit and no action was taken. • The dissemination of information is not planned, and staff meetings occur on an ad hoc basis. Some disciplines have been informed by email of their disciplines non compliances. Management are not assured if all staff have	including timescales for completion of training, to the centre's inspector by 19 October 2018. The PR should ensure that all staff have been assessed as competent to undertake the activities relevant to their role. The PR should review staff competencies and complete competency assessments where required. It is expected that all staff will have had their competency assessed by 19 January 2019. Evidence of completed assessments should be provided to the centre's inspector by 19 February 2019.	suggest an annual refreshers) and dates are only released 6 weeks in advance and book up very quickly. The PR has escalated this to the Trust risk register, however would like to note that since the 2015 inspection provision of mandatory training throught the Trust has improved. Once it is identified if an individual CPR training is involved then they would be taken from high risk areas such as theatre or recovery. Please see more detailed staff compliance report. Staff must have practical competency assessments completed prior to their annual appraisal. Additional monitoring such as ICSI fertilisation and pregnancy rates for individual embryologists and pregnancy rates for embryo transfer operatives (medical or ANP) are also monitored. Staff must have practical competency assessments	

received or taking the advice on board. The PR nor centre staff were aware of the Hepatitis A recommendation discussed in the Clinic Focus article in August 2017 and it was therefore not discussed with patients, documented in the patient information or discussed as a part of the counselling process. SLC T12 and T15a. Clinic Focus August 2017**.** Code of Practice guidance note 2.4	The PR should ensure that the information regarding Hepatitis A is disseminated throughout the required disciplines and the staff SOP, patient information, counselling documentation etc includes this information. Assurance this has been completed should be sent to your centre's inspector by 19 October 2018.	completed prior to their annual appraisal. Additional monitoring such as ICSI fertilisation and pregnancy rates for individual embryologists and pregnancy rates for embryo transfer operatives (medical or ANP) are also monitored. Medical training: The PR was questioned on the day regarding the process of assessing clinican competency. It was explained at that time by the PR that they had a very documented training process which was overseen by the clinic lead, and she didn't know the minutaie of this. The medical training and competency assessment process is described in the attached report. The PR would also like to state that she has absolute confidence in the clinical lead assessment of clinician competence and she also monitors performance (success rates) of each regularly.	

		Medical training had been raised on a previous audit as described in this report as we did not have access to the records of one of the sub speciality doctors. Action was taken however (contrary to what is stated in this report) - the QM addressed this point in a follow up with the clinical lead who explained that there was an electronic record of sub speciality training (specialist registrar training) with the deanery and that ongoing competencies were uploaded and assessed annually for appraisal. Team meetings and dissemination of information: Whole team meetings and senior team meetings are not ad hoc and planned for every other Friday (see attached standard agendas). Staff are expected to attend if present or read the minutes (all saved under team minute folder on the shared drive) if they are not in that day.	

		The individual group meetings are always a little bit more ad hoc by nature as it will depend on unit activity. In the lab for example, we cannot have a meeting if we are too busy clinically and unfortunately we do not know this until 2 days in advance (ie egg collections planned 2 days in advance timed with HcG injections). All meetings held are minuted. With a large team such as as Leeds Fertility the quickest and easiest way to disseminate information is by email as not all staff are able to attend meetings. Staff are reminded that they have a professional responsibility to check their individual emails and read team minutes and question if they do not understand any aspect of this information. When informing staff of actions following an audit for example, the date of the email is documented on the audit matrix. The inspector during	

		our recent ISO Quality management inspection commended us on our dissemination of information to staff. The PR would like to thank the inspector for highlighting the updated guidance on hepatitis A as this was missed on the clinic focus. The viral policy is being updated and this will be disseminated to the team when completed. Staff will be asked to sign to confirm they understand the new recommendations. It was also discussed at the team meeting on the 28th September. Medical illustration have been informed to modify the sperm donation patient information booklet to include updated requirement to screen for Hepatitis A in some sperm donors and the sperm history booklet in the notes has been modified to include Hepatitis A for high risk donors.	

9. Information provided to patients On inspection, the information provided to patients was not documented in their records. The centre does not have an SOP for the provision of information to patients. The centre's website is not compliant with HFEA regulations because; • The data relating to activity, pregnancy rates and live birth rates was more than three years old. • The national rate; the like for like for the maternal age groups, treatment types with reflective time frame was not available on the centres website. SLC T58, T60. Chairs letter: (CH(11)02 Responsible use of websites: the duty of centres. Code of Practice guidance note 4.	The PR should ensure that patients receive all necessary information in line with code of practice requirements. Appropriate changes should be made and a summary document describing the changes provided to the centre's inspector by 19 October 2018.	Some of the patient written information at the time of inspection was unavailable as it was at the print unit waiting to be printed. An overhaul and update of the information given to patients has been completed over the last year which has been a mammoth task. If written patient information booklets were not available whilst waiting to be printed, patients were directed to the website where the electronic copies were available. The PR confirms that patient information will be available for patients in both formats. In regards to the giving of patient information, it isn't always given at first clinic appointment as it is not always known at that time what treatment they may be having as not all investigations may be completed. At the time of the inspection the notes reviewed were for someone who had been seen for first appintment but not yet	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required.

		had the follow up nurse consulatation. At nurse consultation the HFEA record of information form is completed. This has been modified before print to include specific patient information (see attached) boxes to tick for each type of information. The PR has reviewed the SOP's and will ensure a clear SOP on the provision of information for different treatment types is completed as currently the provision of information is embedded in other SOPs. Website: Currently the Leeds Fertility website sits on the LTHT website and is not particularly easy to navigate or make amendments which is primarily why a decision was made to move forward with a stand alone website. The target date for the launch of this website was the beginningJuly (which the PR did mention to the inspector	

		prior to the inspection), but unfortunately this appears to have been an optimistic time frame for development and was not completed. The proposed go live date is now mid October. The new website has up to date information on success rates including a reference to the national success rates (HFEA website).	

Other areas of practice that requires improvement

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

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

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

Reponses from the Person Responsible to this inspection report

The PR has responded to this inspection report to the best of her ability within the statutory 10 day timeframe given including supplementary reports and/or audits prior to the ELP to provide evidence of compliance. The PR was disappointed with the classification of some of the issues raised and feel that these should be perhaps classified not as major areas of non conformance, but minor areas of non-conformance or room for improvement, particularly the sub sections on the safety of premises and infection control. The PR does however take all the points raised on board and is working with her team to address these issues fully to ensure the very best in patient care.