Executive Licensing Panel - minutes

Centre 0321 (NewLife Fertility Centre) Renewal

Friday, 17 June 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that NewLife Fertility Centre, centre 0321 is located in Epsom, Surrey. The centre provides a full range of fertility services including embryo testing. In relation to activity levels this is a small centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 2011.

1.4. The panel noted that in the 12 months to 31 January 2016, the centre performed 254 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 November 2014 to 31 October 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2015 the centre reported 22 cycles of partner insemination with four pregnancies. This is likely to be consistent with the national average.

1.7. Between November 2014 and October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 19%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target.

1.8. The panel noted that at the time of the renewal inspection on 23 and 24 February 2016, two critical, ten major and five other areas of non-compliance were identified. In particular, the panel noted the two critical areas of non-compliance and that some areas of non-compliance were recurring from previous inspections. The panel noted that since the inspection the Person Responsible (PR) has confirmed that nine of the non-compliances, including the two critical areas of non-compliance have been addressed. The PR has also committed to fully implementing all of the outstanding recommendations within the prescribed timescales.

1.9. The panel noted that given the nature and number of non-compliances and the centre's recent licensing history, a management review was held on 29 March 2016 in accordance with the HFEA Compliance and Enforcement Policy. The panel noted the outcome of the management review and the inspectorate's concern that some recurring non-compliance may indicate a lack of learning. However, the inspectorate considered that there has been significant staff changes at the centre in the last 12 to 18 months and this may have impacted on the centre's ability to demonstrate compliance. The centre has now replaced two key members of staff with people who are suitably trained and competent. A new Licence Holder has also been appointed. The inspectorate considered that the PR was fully engaged with the HFEA throughout the inspection process, the PR provided a detailed response to the draft report and evidence of actions taken and the PR also committed to implementing all of the remaining recommendations within the prescribed timescales.

1.10. The panel noted that significant improvement is required in order for the centre to reflect suitable practices.

1.11. The panel noted that, having considered the PR's responses and actions, the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the standard four.

1.12. The inspectorate also recommends that an interim inspection, focused on the implementation of the recommendations, alongside the current interim themes, is conducted within one year of the licence coming into force.

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 her duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel urged the PR to ensure that learning is embedded and part of induction for new staff. The panel also urged the PR to maintain a good level of engagement with the inspectorate and fully implement the outstanding recommendations.

2.5. The panel had regard to its guidance on periods for which new or renewed licences should be granted and agreed to renew the centre's treatment (including embryo testing) and storage licence for a period of three 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

30 June 2016

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: 23 and 24 February 2016

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 (lead), Karen Conyers, Polly Todd and Gill Walsh.

Date of Executive Licence Panel: 17 June 2016

Centre name	NewLife Fertility Centre
Centre number	0321
Licence number	L/0321/2/b
Centre address	The Parade, The Pines, Epsom, Surrey, KT18 5DH , United Kingdom
Person Responsible	Dr Amin Gafar
Licence Holder	Karen Badger
Date licence issued	3 August 2013
Licence expiry date	2 August 2016
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

NewLife Fertility Centre has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2011 and provides a full range of fertility services.

The centre performed 254 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a small centre.

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

This centre has a relatively poor history of compliance. It was inspected in March 2013 for renewal of the licence; eight major and ten 'other' non compliances were identified. The ELP which considered the inspection report was concerned that in the two years since the centre's initial licence had been granted, a significant number of non compliances had developed. The panel endorsed the inspection team's recommendation that the centre's licence should be renewed for a period of three years, rather than the usual four, and that a targeted unannounced interim inspection should be performed within 12 months of the licence renewal date.

A targeted interim inspection was therefore performed in February 2014, which identified seven major non compliances. The ELP which considered the inspection report endorsed the inspection team's recommendation that a further unannounced inspection is conducted within 12 months and, in the event that suitable progress with the implementation of recommendations could not be demonstrated, the inspection findings be referred back to the ELP with recommendations for regulatory action.

Consequently, a further inspection was conducted in November 2014. The inspection team considered that the centre could demonstrate progress and improvement and only one major non compliance was identified.

This current licence was varied in November 2014 to reflect a change of Licence Holder.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2014 – 31 October 2015 show the centre's success rates are in line with national averages.

The centre reported 22 cycles of partner insemination with four pregnancies in 2015. National data has yet to be analysed, but this success rate is likely to be consistent with the national average.

Multiple births[2]

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

Between November 2014 and October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Summary for licensing decision:

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented:

Critical area of non compliance:

- **the PR should ensure that donors are screened in accordance with standard licence conditions and professional body guidelines.**
- **the PR should ensure that the correct consents are in place before any treatment is undertaken.**

Major areas of non compliance:

- the PR should ensure compliance with the requirements of General Direction 0006 when importing gametes and embryos;
- the PR should ensure that all critical equipment is validated and is regularly serviced and calibrated;
- the PR should ensure that all relevant incidents and adverse events are reported to the HFEA;
- the PR should ensure that centre staff are suitably trained and competent for the tasks they perform;

'Other' areas that require improvement:

- the PR should ensure that processes are in place to ensure the safety and suitability of the premises;
- the PR should establish a summary log of cases where multiple embryos have been transferred to patients who meet the criteria for single embryo transfer;
- the PR should ensure that shipping labels used when transporting gametes and embryos are completed appropriately;

Since the inspection visit the PR has given a commitment to fully implementing all remaining actions relating to the following recommendations in the prescribed timescales:

Major areas of non compliance:

- the PR should ensure that the disposal of sperm not used in treatment is witnessed;
- the PR should ensure that the laboratory which undertakes diagnostic semen analysis can demonstrate equivalence to Clinical Pathology Accreditation (UK) Ltd (CPA) accreditation;
- the PR should ensure that practices relating to the safe storage and handling of controlled drugs and general medicines management are compliant with regulatory guidance and professional practice standards;
- the PR should review the quality management system (QMS) to ensure that standard operating procedures (SOPs) are established for all activities authorised by the centre's licence and other activities carried out in the course of providing treatment services and that audits of these activities are robust and comprehensive;
- the PR should ensure that welfare of the child (WoC) assessments are completed for all relevant parties involved in treatments;
- the PR should ensure that patient consent to disclosure decisions are accurately submitted to the authority.

'Other' areas that require improvement:

- the PR should ensure that written agreements are established with all third parties who provide goods or services and that these agreements all accurately reflect the identity of the person at the centre responsible for managing the agreement;
- the PR should ensure that the centre's website and patient information is compliant with requirements.

Recommendation to the Executive Licensing Panel:

The centre has two critical areas of non compliance, ten major areas of non compliance and five 'other' areas of practice that require improvement.

The inspection team notes that the centre's success rates are consistent with the national average and their multiple clinical pregnancy / live birth rates are likely to meet the target.

Significant improvement is required in order for the centre to reflect suitable practices.

Given the number and variety of non compliances noted at this inspection and the centre's recent licencing history, in accordance with the HFEA Compliance and Enforcement Policy, a management review was held on 29 March 2016 to consider the implications of the findings of this report and to assess any risks they may pose. The management review found that the non compliances identified at this inspection relating to consent to treatment and to disclosure of identifying information, WoC assessment and the QMS have also been reported on earlier inspections. Although they were not issues at the last inspection in November 2014, they have now recurred. Whilst this may indicate a lack of learning, there have been significant staff changes at the centre in the last 12 to 18 months, which the inspection team consider may have impacted on the centre's ability to demonstrate compliance. The management review also noted that the non compliances in consent, donor screening and WoC assessment, including the two critical non compliances, were only seen in two cases and were not considered to represent systemic failures in the centre's processes. Taking into account the centre's

history of compliance and the findings of this inspection, the management review considered that the centre may be showing signs of a fluctuating ability to demonstrate an acceptable level of compliance.

Since the management review the PR has informed the centre's inspector that two key members of staff have left employment at the centre however the positions have been filled by suitably trained and competent staff. As one of the staff who have left the centre also held the position of Licence Holder the PR has submitted an application to vary the licence to reflect a change of Licence Holder.

The PR has provided detailed responses to the draft report, a commitment to implementing all remaining actions within the timescales prescribed, evidence of actions taken and has been fully engaged with the HFEA throughout. Having considered the PR's responses and actions the inspection team recommends the renewal of the centre's treatment and storage licence for a period of three years, rather than the standard four, and that an interim inspection is conducted within one year of this licence coming into force. The interim inspection should focus on the implementation of the recommendations made here alongside the current interim themes.

The centre's inspector will continue to monitor the centre's performance closely. Failure to implement the recommendations relating to these outstanding areas of non compliance within the prescribed timescales may result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better

Witnessing (Guidance note 18)
The centre team do not witness the discard of sperm (SLCT71) (Code of Practice 18.4) recommendation 3).

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 not 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

Screening of donors (Guidance note 11)
The inspection team reviewed three records of treatments involving egg donation. The following non compliances were observed:

- One egg donor had not been screened for antibodies against hepatitis B core antigen, cystic fibrosis mutations or karyotype (SLC T52; recommendation 1).
- Blood samples for screening tests had been taken from one egg donor four months prior to the egg collection, rather than at the time of donation (SLC T53(b); recommendation 1). It is acknowledged that it may not be practical to perform screening tests on the day of oocyte collection. The centre team could not however provide a rationale as to why the screening performed ensured a level of safety equivalent to that provided if the donor had been screened 'at the time of donation', in accordance with the requirements of the European Union Tissues and Cells Directive 2006/17/E explained within the Clinic Focus article on 28 March 2013.

Suitable premises and suitable practices

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

What the centre does well:

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are partially compliant with HFEA requirements for accreditation by CPA or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

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

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

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are broadly 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;
- if 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 broadly compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has no transport or satellite agreements and therefore this guidance note is not relevant.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. Some 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 partially compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and

procedures to follow if equipment malfunctions.

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports some 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

Safety and suitability of premises and facilities (Guidance note 25)
The label on the fire extinguisher outside the complementary therapy area indicated that it had not been included in the annual inspection of fire extinguishers since 2014. Two small oxygen cylinders located in a corridor near the recovery area were not appropriately secured, nor was the oxygen cylinder on a patient trolley during transfer from theatre to recovery (SLC T17; recommendation 13).

Laboratory accreditation (Guidance note 25)
The centre undertakes diagnostic semen analysis, however the laboratory is not accredited by CPA and could not demonstrate equivalence (SLC T21; recommendation 4) due to the following:

- the process for diagnostic semen analysis has not been validated;
- the SOP for diagnostic semen analysis has not been reviewed against World Health Organisation (WHO) guidelines;
- the laboratory participates in the UK National External Quality Assessment Service (NEQAS) programme for andrology, and had been sent a performance alert three months previously. No corrective actions have been considered or developed in order to review performance in this area.

Infection control
The integrity of the surface of the scrub sink in the procedure room appeared to be compromised (stained). The inspection team considered that this could be a risk to infection control. Whilst this was corrected the day following the inspection it was of concern that the centre had not taken action prior to the inspection visit (SLC T17; recommendation 13)

Medicines management
A number of non compliances relating to medicines management were observed (SLCs T15 and T47, Nursing & Midwifery Council (NMC) 'Standards for medicines management 2010; Controlled Drugs (Supervision of Management and Use) Regulations 2006; recommendation 5):

Controlled drugs

- entries in the controlled drugs (CD) register are commonly unclear and in a number of instances illegible, where only the patient's name is recorded and no other unique identifier, making traceability problematic;

- entries in the CD register showed single use ampoules are frequently shared between patients;
- the running total stock level was not correct after an ampoule had been removed for use (this error was not identified by the two practitioners checking the drug out);
- the CD register and CD practice has not been audited;
- at the time of the inspection the centre did not have a Controlled Drugs Accountable Officer (CDAO) nor had an application been made to the Care Quality Commission (CQC) for an exemption. The application process was commenced on the day of the inspection.

General medicines management
Medicines required for treatment are prescribed by the treating clinician and delivered directly to the patient by a home delivery pharmacy. Nursing staff will on occasion dispense small amounts of 'top up' medicines as prescribed from stock held at the centre. It was noted that:

- the nurses have not received specific training in the dispensing of medicines for self-administration;
- medicines are dispensed against the doctor's prescription but are not checked by a second person before being supplied to the patient;
- medicines dispensed by the centre are labelled with the patient's name only, the label provides no detail of who supplied the drug, the date on which it was supplied or the person dispensing the medicine.

(SLCs T15 and T47, Nursing & Midwifery Council (NMC) 'Standards for medicines management 2010; Controlled Drugs (Supervision of Management and Use) Regulations 2006; recommendation 5).

It was noted that the log recording the monitoring of the temperature of the medicines fridge showed that where the temperature had fallen outside the usual range for safe use, no corrective action or explanation was recorded (SLC T24; recommendation 8).

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA) as an intravenous nutritional supplement for adults and children.

Some healthcare professionals consider intralipid therapy has an effect on the immune system and may be beneficial to a particular subset of women having IVF. Intralipid is not licensed for use in fertility treatment. If prescribed in this context, this represents 'off-label' use.

Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence. In April 2015 the President of the Royal College of Obstetricians and Gynaecologists (RGOC), published concerns regarding the evidence base for the use of this medicine in IVF in terms of its safety and efficacy. In July 2015 the HFEA published guidance to centres regarding the prescribing of intralipid or other 'off label' therapies to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care.

The centre's procedure for monitoring patients during intralipid infusion was reviewed and considered to be suitable. It was noted however in one patient record that intralipid had

been provided to the patient against a document headed 'private prescription'. This document was in fact a list of equipment and materials required to administer intralipid and was not a prescription or direction to provide the medication (SLC T2; recommendation 5).

Multiple births (Guidance note 7; General Direction 0003)
The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets their criteria for single embryo transfer (General Direction 0003; recommendation 14).

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The labelling of the shipping container used in the transport and distribution of gametes and embryos does not include all the details required by SLC T107 (b, c and d) (recommendation 15).

Imports and exports (Guidance note 16; General Direction 0006)
Four sets of records where sperm or embryos had been imported into the centre were reviewed. In one case the gamete provider had not been tested for antibodies against hepatitis B core antigen, cystic fibrosis mutations or karyotype. In addition the centre team was unable to provide evidence of the accreditation status of two of the exporting centres. Subsequent to the inspection, the centre team forwarded to the inspector documents regarding the accreditation of the laboratories where blood tests had been performed. These documents were considered by the inspection team to not provide sufficient evidence of accreditation (SLCs T52 and T53a; General Direction 0006; (recommendation 6).

Quality management system (QMS) (Guidance note 23)
There were a number of issues relating to the QMS noted on inspection:

- the centre does not have SOPs for the following activities: donor assessment and screening; patient and partner screening; surrogacy;
- the SOP directing the transfer of samples between centres does not fully describe how to ensure compliance with General Direction 0006 prior to import or export, or the conditions of shipping as per SLCs T105-T110.
- some SOPs had not been updated to reflect a change of author and other SOPs had passed their review dates without review.
- the robustness of the centre's audit programme was considered inadequate as a number of audits did not identify issues which were subsequently identified by the inspection team (SLCs T33, T34 and T36; recommendation 7).

Third Party agreements (Guidance note 24)
There is no third party agreement in place with a local hospital where surgical sperm retrievals are performed under the centre's licence, prior to transporting and storing the gametes at the centre. In addition, some third party agreements named the person responsible for managing the agreement as a member of staff who was no longer employed at the centre (SLCs T111 and T114b; recommendation 16).

Equipment and materials (Guidance note 26)
A review of the centre's critical equipment management process noted the following:

- the Gilson pipettes have not been serviced, calibrated or validated;
- the egg collection suction pump has not been validated;

- the centre uses external temperature probes which have not been calibrated against a traceable standard.

(SLC T24; recommendation 8).

Adverse incidents (Guidance note 27)
A review of the centre's incident reports showed that the centre did not notify the HFEA of four HFEA-reportable adverse events (SLCs T120 and T121; recommendation 9).

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/1185/8).

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)
Whilst examples of competency assessments and training for some activities were seen on inspection the inspection team were concerned that considering the non-compliances related to donor screening, consent and medicines management centre staff may not have received adequate training and assessment of competencies prior to undertaking these activities (SLCsT12and T15) (see recommendation 10).

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 partially 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

Welfare of the child (Guidance note 8)
Where a woman who is to be a surrogate has a partner, both she and her partner are to be assessed for welfare of the child. In one instance, no WoC assessment had been completed for the surrogate's partner. A review of patient records also showed that in one instance the WoC assessment form had been signed by the practitioner but the assessment criteria checklist had not been completed (SLC T56; Guidance note 8.3; 8.4; recommendation 11).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (PGS) (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 lead inspector spoke to one patient who provided positive feedback on her experiences. A further six patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with three of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not provide egg sharing treatment, therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)

The centre's procedures for treatment involving surrogacy are partially 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

Surrogacy (Guidance note 14)
In one case, no WoC assessment was completed for the partner of a surrogate, as described in the section 'Welfare of the Child' above (recommendation 11).

There is no SOP to direct the process involved in surrogacy agreements, as described in the 'QMS' section above (see recommendation 7).

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are broadly 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)
Written information provided to patients offered intralipid therapy was comprehensive but does not specify that, if prescribed to this group of patients, the drug is being prescribed 'off label' (SLC T2, Clinic Focus July 2015; recommendation 17).

The centre's website does not provide the live birth rate per treatment cycle (Chair's Letter (11)02, CoP guidance 4.5; recommendation 17).

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are partially compliant with HFEA requirements.

Legal parenthood
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 PR provided a summary of the audit findings which indicated that there was effective consent to legal parenthood for all patients who had been treated with donor gametes.

As the impact of legal parenthood consent failures came to light, the HFEA wrote again to centres in October 2015 requiring that, by 17 November 2015, PRs should provide the Authority with assurance that their initial audit process was comprehensive and that the centre's processes for staff training and ongoing audit of consent to legal parenthood processes are robust. The PR responded to this request within the required timescales.

The inspection team were assured that the centre's current procedures for obtaining consent to legal parenthood are compliant. Due to the small number of patients treated at the centre no relevant records were available for audit by the inspection team, however the centre provided two recent audits of consent to legal parenthood in which no non compliances were identified.

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

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

What the centre could do better

Consent (Guidance note 5;6)
A review of patient records showed that in one instance a woman consenting to donate

her eggs had completed an ED (consent to embryo donation) form instead of completing a WD (consent to egg donation) form. This had not been identified by centre staff during the woman's treatment (SLC T57; recommendation 2).

Consent to disclosure (General Direction 0005)
Four discrepancies were found between 25 completed patient/partner disclosure consent forms within patient files and the related consent data submitted for inclusion on the register. In one of these instances the patient had not consented to disclosure to researchers however the decision communicated to the HFEA was that they had consented. The centre's procedures have therefore failed to ensure that the HFEA holds an accurate record of consents to disclosure. These failings lead to a risk that the HFEA may release patient identifying information, to researchers, without the consent of the patient (General Direction 0005; recommendation 12).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities:

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified on this inspection.

▶ **Use of embryos for training staff** (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32 ; 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 accuracy of the centre's submission of data to the Register.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in November 2014, recommendations for improvement were made in relation to one area of major non compliance. The PR provided evidence that he had complied with this recommendation.

On-going monitoring of centre success rates

In 2015, the centre did not receive any performance related alerts regarding their success rates.

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The inspection team reviewed three records of treatments involving egg donation: • One egg donor had not been screened for antibodies against hepatitis B core antigen, cystic fibrosis mutations or karyotype. • Blood samples for screening tests had been taken from one egg donor four months prior to the egg collection, rather than at the time of donation.	The PR should ensure that donors are screened in accordance with HFEA requirements and professional body guidelines. The PR should ensure that a SOP describing compliant donor screening practices is in place. The PR should provide a copy of the updated SOP to the centre's inspector when responding to this report. The PR should provide the centre's inspector with	The centre has implemented SOPs detailing compliant donor screening practices. (See attached SOPL40 Import of donor sperm eggs and embryos/SOPC51 Known Sperm Donation Assessment and Screening/SOPC52 Egg Donor Assessment and Screening/SOPC53 Known Surrogacy Assessment and Screening.) Nursing staff have received updated training since inspection in donor screening	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector has received the updated SOPs, evidence of staff training and audit of practice as requested. Following, receipt of this audit, the inspector sought further clarification on the centre's processes for donor screening and has been provided with additional evidence of their

SLCs T52 and T53(b); Clinic Focus 28 March 2013.	evidence of staff training regarding donor screening requirements and the implementation of the donor screening SOP when responding to this report. The PR should perform an audit of all egg donation cycles that have been performed at the centre to ensure that the donors have been screened appropriately. The PR should provide the centre's inspector with a summary report of the audit by 24 May 2016.	practices.See attached statement confirming application of the donor screening SOPs and staff training. The centre has conducted an audit of all egg donation cycles and will provide the centre's inspector with a summary report of the audit findings by 24 May 2016.	review of practice and corrective actions taken to ensure compliance with requirements relating to screening of egg donors. No further action is required.
2. One egg donor had completed an ED (consent to embryo donation) form instead of completing a WD (consent to egg donation) form. HF&E Act 1990 (as amended) Schedule 3(b)	The PR should ensure that the correct consents are in place prior to treatment or donation. The PR should review the process for obtaining consent to donation to identify whether there are any barriers to this being conducted effectively. The PR should provide a summary of this review when responding to this report including detail of any actions required in response to the	The PR has conducted a review of the SOP for obtaining consent to donation. Longer nurse consultation appointments are now available in the afternoons to ensure consenting processes are conducted effectively. (See attached SOPC35 - Provision of Information) Staff will receive updated training in the correct use of consent forms for all treatment options available. This training	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The PR has confirmed that he has been in contact with the egg donor and the correct consent forms are now in place, albeit retrospectively. The inspector has received the requested review, evidence of staff training in consent

	reviews findings. The PR should ensure that all staff are appropriately trained in the correct use of consent forms for all treatment options available at the centre. The PR should provide the centre's inspector with a summary report of training undertaken by staff in relation to consenting patients by 24 May 2016. The PR should perform an audit of the consent decisions recorded in all egg donation and surrogacy treatments that have been performed at the centre and provide the centre's inspector with a summary report of the audit by 24 May 2016.	has been planned for week commencing 16/05/2016. The PR will provide a summary of the report of training undertaken by staff by 24 May 2016. The centre has conducted an audit of consent decisions recorded in all egg donation and surrogacy treatments and will provide the centre's inspector with a summary report of the audit findings by 24 May 2016.	requirements and the audit of consent decisions. 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
3. Centre staff do not witness the discard of sperm. SLC T71, Code of Practice 18.4.	The PR should take immediate action to ensure that the discard of sperm is witnessed. The PR should inform the centre's inspector of actions taken to implement this recommendation when responding to this report. Three months after corrective actions are implemented; the PR should audit the witnessing of the discard of sperm to assess compliance with this recommendation. The PR should provide the centre's inspector with a summary report of the audit by 24 May 2016.	The PR has taken immediate action to ensure that the discard of sperm is witnessed. A review of processes surrounding the discard of sperm has been undertaken. Sperm discard witnessing is now recorded after each cycle, within the IVF Witness Final Report. Revised SOPs have been implemented and issued to laboratory staff in relation to Witnessing and Fertilisation Checks. (See attached SOPL35 Witnessing/SOPL14 Fertilisation Check) The PR will ensure that an audit of the witnessing of the discard of sperm is conducted	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation and has received the SOP. Subsequent to completion of the draft report the inspector agreed with the PR that as the audit is to be performed three months after implementation of the recommendation and that a summary report is to be provided to the inspector by 24 July 2016. Further action is required.

		three months after corrective actions were implemented.The PR will therefore provide the centre's inspector with a summary report of the audit by 24 July 2016.	
4. The centre undertakes diagnostic semen analysis, however the laboratory is not accredited by CPA and the centre team could not provide satisfactory evidence of equivalence as described below: • the SOP for diagnostic semen analysis has not been reviewed against professional (WHO) guidelines; • there is no process validation for diagnostic semen analysis; • corrective actions have not been developed in response to a recent alert from NEQAS regarding the centre's performance in quality assurance testing. SLC T21.	The PR should ensure the centre's semen analysis service is working to a standard equivalent to CPA accreditation. Evidence of this should be provided to the centre's inspector by 24 May 2016.	The centre will review the SOP for diagnostic semen analysis to include more detailed referencing against WHO guidelines. The centre will develop protocols for the process validation for diagnostic semen analysis. Haemocytometer will be used for NEQAS reporting. Laboratory staff performing semen analysis will submit their data for the next NEQAS distribution and and their results will be compared to the national average. Comptetency assessments will be undertaken where results deviate from the national averages. Makler counting chambers will be introduced for routine semen analysis.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector has agreed with the PR that due to staff changes in the laboratory and the recruitment of a new laboratory manager the time frame for implementing this recommendation will be extended to 24 July 2016. The inspector is concerned with the PR's implication that a different method for semen analysis (haemocytometer) will be used for their NEQAS participation to that used during day-to-day practice (Makler). The inspector will seek further clarification regarding the different methodologies used for

		Evidence will be provided to the centre's inspector in this regard by 24 May 2016.	diagnostic semen analysis and that used for the NEQAS for external quality assurance. The updated SOP has been provided and further information and evidence is awaited by 24 July 2016. Further action is required.
5. There were a number of non compliances relating to medicines management noted on inspection: <u>Controlled drugs</u> • Entries in the CD register are commonly unclear and in a number of instances illegible, where only the patient's name is recorded and no other unique identifier, this makes traceability problematic; • entries into the CD register showed single use ampoules are frequently shared between patients; • the running total stock level was not correct after an ampoule had been	The PR should conduct a comprehensive review of the centre's medicines management procedures relating to both controlled drugs and general medicines to ensure compliance with regulatory requirements and best practice guidance. In conducting this review, the PR should seek guidance from a registered pharmacist on best practice regarding the dispensing of medicines. The review and action plan should include measures to address the issues noted on inspection. The PR should provide a summary of the review and action plan, with time scales for	The PR has ensured that a comprehensive review of medicines management procedures is being undertaken. This relates to both the management of controlled drugs and general medicines. The review will ensure the engagement of a registered pharmacist in order to comply with regulatory and best practice guidance. The PR will provide a summary of the review to the centre's inspector by 24 May 2016. Immediate action was taken following inspection to ensure the following improvements were made to the management of controlled	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The PR has provided a detailed review of processes, confirmed implementation of several corrective actions, evidence of staff training and an audit of CDs. Subsequent to completion of the draft report the inspector agreed with the PR that the time frame for those actions requested by 24 May 2016 will be extended to 24 July 2016 in order to arrange a comprehensive review of the

removed for use; • the CD register and CD practice has not been audited; • at the time of the inspection the centre did not have a Controlled Drugs Accountable officer (CDAO) in place nor had application been made to the Care Quality Commission (CQC) for an exemption. <u>General medicines management</u> It was noted that: • nurses have not received specific training in the dispensing of medicines for self-administration; • medicines are dispensed against the doctor's prescription but are not checked by a second person before being supplied to the patient; • medicines dispensed by the centre are labelled with the patient's name only, the label provides no detail of who supplied the drug	implementation, to the centre's inspector by 24 May 2016. The PR should ensure that any prescription required for intralipid therapy meets the requirements of best practice pharmaceutical and General Medical Council guidance. The PR should ensure that information provided to patients concerning intralipid treatment includes that the drug is being prescribed 'off label'. The revised information should be provided to the centre's inspector when responding to this report. The PR should audit compliance with all aspects of this recommendation and provide the centre's inspector with a summary of the audit results by 24 August 2016.	drugs: All staff have been provided with updated guidance on the requirements related to the completion of the CD register. Additional unique identifiers i.e patients' clinical record ID, are now used to improve patient traceability. Legibility has now improved. Single use ampoules are no longer shared between patients. Stock levels are now consistently correct. A programme of ongoing audit of the CD register and CD practice will be implemented. The centre submitted an application to CQC following inspection and has received confirmation of exemption from the need to register a Controlled Drugs Accountable Officer. (See attached email 'Controlled Drugs Exemption Confirmation'.) Immediate action was taken following inspection to ensure the following improvements	centre's medicine management procedures by a suitably qualified person. Further action is required.

(the centre), the date on which it was supplied or the person dispensing the medicine; • intralipid therapy is being administered without a written prescription. SLCs T2, T12, T36 and T47; Nursing & Midwifery Council (NMC) 'Standards for medicines management 2010; Controlled Drugs (Supervision of Management and Use) Regulations 2006. Clinic focus July 2015.		were made to general medicines management processes: Nurse training is planned in the dispensing of medicines for self-administration. A programme of regular review of nurse competencies in relation to medicines management will be implemented. Dispensing processes have been reviewed and amended to ensure dispensed medicines are checked by a second nurse before being supplied to the patient. Labelling of dispensed medicines now includes 2 patient unique identifiers, the date of dispensing and the signatures of 2 nurse checkers. Protocols which support the prescribing of Intralipid therapy have been reviewed to ensure they meet best practice, pharmaceutical and GMC guidance. Information provided to patients	

		concerning intralipid therapy has been reviewed and revised. (See attached NDF02 - Intralipid Private Prescription/PI73 Intralipid Infusion Information & Consent). The PR will conduct an audit of compliance and will provide a summary of the audit to the centre's inspector by 24 August 2016.	
6. Four sets of records where sperm or embryos had been imported into the centre were reviewed: • in one case the gamete provider had not been tested for antibodies against hepatitis B core antigen, cystic fibrosis mutations or karyotype. • the records did not in all cases include appropriate evidence of the accreditation status of the laboratories where blood tests had been performed • the records did not in all cases contain appropriate	The PR should ensure compliance with all requirements of General Direction 0006 prior to the import or export of any gametes or embryos. The PR should perform a root cause analysis to identify how the samples came to be imported without sufficient evidence that the requirements of General Direction 0006 had been met. The analysis report should include appropriate actions to prevent recurrence. The PR should review all	The PR has performed a root cause analysis to identify the circumstances surrounding the importing of samples without sufficient evidence that the requirements of General Directions 0006 had been met. The PR has ensured that the centre has conducted a review of all gametes and embryos that have been imported by the centre and has produced a summary of the review. The PR will provide a summary of the review and a report of the root cause	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. A copy of the root cause analysis and summary report of a review and audit of all imported gametes and embryos has been provided. No further action is required.

evidence of the licensing certification status of the exporting centres. SLCs T52 and T53a; General Direction 0006.	gametes and embryos that have been imported by the centre to ensure that the requirements of General Direction 0006 have been met for each import. The PR should provide a summary of the review and a report of the root cause analysis to the centre's inspector by 24 May 2016.	analysis to the centre's inspector by 24 May 2016.	
7. The following non compliances regarding the centre's QMS were noted: • the centre does not have SOPs for: donor assessment and screening; patient and partner screening and surrogacy; • some SOPs had not been updated to reflect a change of author; • the review dates had expired on a number of SOPs; • the robustness of the audit programme was considered inadequate to satisfy regulatory requirements, since a	The PR should perform a comprehensive review of the centre's QMS to ensure its effectiveness and to address the issues noted on inspection. The PR should provide a summary of the review and an action plan with time scales for implementation to the centre's inspector by 24 May 2016. The PR should forward a copy of the outstanding SOPs when responding to the report.	The PR has ensured that a comprehensive review of the centre's QMS is underway. The robustness and effectiveness of the audit programme will be assessed as part of that review Oustanding SOPS have been developed and implemented in relation to donor assessment and screening, patient and partner screening and surrogacy. (See attached) All SOPs are in the process of being reviewed to ensure their currency and to reflect the change of author where applicable. This will include a	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector has received copies of the SOPs and a summary of the findings of the review of the QMS. It has been agreed with the PR that in recognition of the recruitment of a new quality manager that the time frame for implementing this recommendation will be extended to 24 August 2016.

number of audits performed by the centre did not identify issues which were subsequently identified by the inspection team. • the SOP directing the transfer of samples between centres does not effectively describe how to ensure compliance with General Direction 0006 prior to import or export, or the conditions of shipping as per SLCs T105-T110. SLCs T33(b),T34 and T36.		review of the SOP directing the transfer of samples between centres. The PR will produce a summary of the review plan and an action plan with time scales for implementation to the centre's inspector by 24 May 2016. The PR wishes to propose that with the recent appointment of a new General Manager and a new Laboratory Manager within the centre, a comprehensive review of all Quality Management Systems be undertaken over a 3 month period and completed by 24 August 2016.	Further action is required.
8. A review of the centre's critical equipment management process noted the following: • the Gilson pipettes have not been serviced, calibrated or validated; • the egg collection suction pump has not been validated; • the centre uses external	The PR should review the centre's equipment validation, revalidation and calibration programme to ensure that it meets HFEA requirements. The PR should provide the centres' inspector with a plan as to how he will address the individual issues relevant to this non compliance noted on	The centre is conducting a review of all equipment validation, revalidation and calibration. The centre will produce a summary of the review and an action plan. The centre will produce an equipment maintenance schedule for all areas of the clinic.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. A summary of the review of centre's equipment validation, revalidation and calibration programme has been provided. The inspector notes

temperature probes which have not been calibrated against a traceable standard; • no corrective action or explanation was documented in the log recording the temperature of the medicines fridge when the fridge temperature fell outside the usual range for safe use. SLC T24.	inspection. The PR should provide a summary of the review and action plan, with time scales for implementation, to the centre's inspector by 24 May 2016.	The centre has arranged for servicing, calibration and validation of all equipment identified as requiring such at inspection. New Gilson pipettes have been purchased which have been calibrated and validated. Arrangements have been confirmed for the original Gilson pipettes to be serviced and calibrated. The egg suction pump is undergoing a validation process. Thermometers have been calibrated against a calibrated thermocouple and correction factor, date of calibration and the due date of the next calibration have been attached to each thermometer. A central calibration record has been implemented. A daily laboratory monitoring document has been amended to ensure the recording of the	that this programme forms part of the actions outlined in the review of the QMS and will be followed up as necessary through that recommendation. No further action is required

		temperature of each thermometer on a daily basis (See attached SDLab33 Daily Incubator Monitoring). The centre is in the process of undertaking a review of their Medicines Management Policy to include a cold chain protocol and ensure appropriate action is taken in response to fridge temperatures which fall outside the usual range for safe use. The centre will ensure nursing staff are aware of the reporting and risk management processes for such incidents. Immediate action has been taken to provide clear information and instruction to nursing staff to manage temperature fluctuations. (See attached 'SOPC54 Drug Fridge Temperature Monitoring'). The PR will provide a summary of the review and action plan to the centre's inspector by 24 May 2016.	
9. The centre did not notify the HFEA of four HFEA-	The PR should ensure that all significant adverse events and	Four incidents had been recorded internally within the	The inspector acknowledges the PR's response and the

reportable adverse events. SLCs T118, T120 and T121.	serious reactions are reported to the HFEA. The PR should ensure that all staff are aware of their responsibility to report serious adverse events and serious reactions to the HFEA. The PR should provide a summary report of the actions taken to meet these regulatory requirements to the centre's inspector by 24 May 2016.	12 month period leading up to inspection. These were comprehensive records which detailed the corrective action taken and the learning from each incident. However, the incidents had not been reported to HFEA. This was due to a lack of clarification within the clinic as to which level of incidents were reportable to HFEA. A review of protocols supporting serious adverse event reporting has been undertaken. Staff awareness of incident reporting procedures is being improved. The PR will produce a summary report of the actions taken to meet these regulatory requirements to the centre's inspector by 24 May 2016.	actions he has taken towards compliance with this recommendation. The PR has provided a detailed review of adverse incident reporting processes and related SOPs and has confirmed implementation of corrective actions. It has been agreed that these incidents do not need to be reported to the HFEA retrospectively. No further action is required.
10. Whilst an example of competency assessments and training for some activities were seen on inspection the inspection team were concerned that considering the non-	The PR should ensure that centre staff are suitably trained and competent for the tasks they perform. The PR should review the areas of non-compliance noted on	The PR has taken action following inspection to ensure that staff receive updated training and competency assessment related to donor screening and consent processes.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector has received a

compliances related to donor screening, consent and medicines management centre staff may not have received adequate training and assessment of competencies prior to undertaking these activities. SLCT12 and SLCT15.	inspection to identify if there are additional training needs for the centre team. The PR should provide the centre's inspector with a summary of the review, corrective actions identified and confirmation of staff training where applicable by 24 May 2016.	Nursing staff will undergo training and competency assessment relating to medicines management processes prior to 24 May 2016. The PR will provide a summary of the review, corrective actions taken and confirmation of staff training by 24 May 2016.	summary of the review, evidence of staff training related to medicines management, donor screening and consent processes. No further action is required.
11. In one record a WoC assessment had not been completed for the partner of a surrogate. In another patient record, the WoC form had been signed by the practitioner but the assessment criteria checklist had not been completed. SLC T56; Guidance note 8.3; 8.4.	The PR should review the process for the assessment of WoC to ensure that it is conducted appropriately in all cases. The PR should provide the centre's inspector with a summary of the review by 24 May 2016. The PR should conduct an audit of WoC assessment in patient and partner records for treatments in the last year. A summary of the audit findings should be provided to the centre's inspector by 24 August	The PR has reviewed processes to ensure Welfare of Child Assessments are conducted appropriately. A summary of the review will be provided by 24 May 2016. The centre will conduct an audit of WoC assessment in patient and partner records for treatments over the last year. A summary of the audit findings will be provided by 24 August 2016.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector has received a summary of the review and an updated SOP. The audit is to be provided by 24 August 2016. Further action is required.

	2016.		
12. Four discrepancies were found between 25 completed patient/partner disclosure consent forms within patient files and the related consent data submitted for inclusion on the Register. In one of these instances the patient had not consented to disclosure to researchers however the decision communicated to the HFEA was that they had consented. The centre's procedures have therefore failed to ensure that the HFEA holds an accurate record of consents to disclosure. These failings lead to a risk that the HFEA may release patient identifying information, to researchers, without consent. General Direction 0005.	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms documented by the patients. The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time the inspection report is considered by a licensing committee and the inspector informed of the results of the review and actions taken. The PR should conduct an audit six months after implementing corrective actions to identify if they have been effective. The PR should provide the centres inspector with a summary of the audit by 24 August 2016.	Discrepancies identified within patient/partner disclosure consent forms at the time of inspection have since been corrected. The PR has undertaken a review of procedures to ensure that the disclosure consent information supplied to HFEA accurately reflects that recorded on disclosure consent forms. The PR has ensured that additional checks are undertaken by nursing staff to ensure that correct information is supplied to HFEA. The PR will conduct an audit six months after implementing corrective actions in order to ensure their effectiveness and will provide the inspector with a summary of the audit by 24 August 2016.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The PR has confirmed correction of the incorrect submissions, has provided an audit of consent to disclosure submissions, and a repeat audit is to be provided as requested by 24 August 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
13. The following issues were observed regarding the safety and suitability of the premises: • oxygen cylinders in the procedure and recovery area were not secured; • the label on the fire extinguisher located outside the complementary therapy area indicated that it had not been checked since 2014; • the integrity of the surface of the scrub sink in the procedure room, appeared to have been compromised (stained). SLC T17.	The PR should ensure all equipment is checked and appropriately maintained. The PR should provide the centre's inspector with a detailed plan as to how this is to be achieved in his response to the report. The PR should ensure that medical gas cylinders are properly stored and provide confirmation of this to the centre's inspector when responding to this report. The PR should ensure that the fire extinguishers are checked and provide confirmation of this to the centre's inspector when responding to this report.	The PR has undertaken a review to ensure that all equipment is checked and appropriately maintained. The centre is in the process of confirming a full inventory of equipment and a revised maintenance plan will be put in place in conjuntion with the review of all third party agreements. Immediate action was taken following inspection to address the findings relating to the equipment specified. Oxygen cylinders in the procedure and recovery areas have been safely secured. A review of all fire extinguisher checks has been undertaken and the omitted extinguisher has been checked and maintained. The scrub sink surface in the procedure room has been	The inspector acknowledges the PR's response and the actions that the he has taken towards compliance with this recommendation. No further action is required.

		improved. (See attached Fire Equipment Servicing Record/Theatre sink images/O2 cylinder storage image).	
14. The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. General Direction 0003.	The PR should establish a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. The PR should confirm the establishment of this log when responding to this report.	The centre has, since inspection, established a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. No further action is required.
15. The labelling of the shipping container used in the transport and distribution of gametes and embryos does not include all the details required by SLC T107. SLC T107.	The PR should ensure that shipping labels used when transporting gametes and embryos are completed in compliance with SLC T107. The PR should inform the centre's inspector of actions taken to comply with this recommendation when responding to this report.	The centre has sought clarification from the inspection team in this regard. The centre does not use their own shipping container. An identified courier is used by the centre who provides their own shipping labels at the point of collection of gametes and embryos from the centre. However, the centre has reviewed the SOP and checklist relating to the transport of gametes to ensure that the courier dry shipping	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector acknowledges the PR's confirmation of the processes to be used when shipping samples and has received a further revised copy of the labels to be used by the centre when transporting gametes or embryos. No further action is required.

		label fulfills the required criteria. (See attached SDLab45 Export of cryopreserved embryos or gametes checklist). Transport labels are available within the centre if urgently required for ransport via the centre's dry shipper. (See attached SDLab74 Transport Label 2016).	
16. The centre does not have a third party agreement with a local hospital where surgical sperm retrievals are performed under the centre's licence. Third party agreements in some instances named the person responsible for managing the agreement as a member of staff who was no longer employed at the centre. SLCs T111 and T114(b).	The PR should ensure that appropriately completed agreements are in place with all third parties who provide goods or services that influence the quality and safety of gametes and embryos. The PR should provide the centre's inspector by 24 May 2016 with a copy of the third party agreement with the local hospital where surgical sperm retrievals are performed. The PR should develop a time line as to when the relevant third party agreements will be updated or reviewed and provide the centre's inspector	The centre is in the process of establishing a third party agreement with the local hospital where surgical sperm retrievals are performed. It is anticipated that this may not be finalised by 24 May 2016. Therefore the PR has ensured that this service is suspended whilst the required third party agreement is confirmed. A timeline for the review of all other third party agreements will be provided to the centre's inspector by 24 May 2016.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector notes the suspension of the specific services until completion of the third party agreement and has received the timeline for the review of third party agreements. The inspector will follow up to ensure completion of these, and a copy of the specified agreement is awaited. Further action is required.

	with a copy of the timeline by 24 May 2016.		
17. The written information provided to offer intralipid therapy does not specify that, if prescribed to this group of patients, the drug is being prescribed 'off label'. The centre's website does not include information regarding live birth rate per treatment cycle at the centre. SLC T2, Clinic Focus Chair's Letter (11)02, CoP guidance 4.5	The PR should ensure that the written information for patients prescribed intralipid therapy specifies that if prescribed to this group of patients the drug is being prescribed 'off label'. The PR should ensure that information regarding the centre's live birth rate per treatment cycle is provided on the centre's website. The PR should inform the centre's inspector of the actions taken to comply with this recommendation by 24 August 2016.	Written information for patients prescribed intralipid therapy has been revised. (See attached PI73 Intralipid Infusion Information & Consent) Information regarding the centre's live birth rate will be provided on the centre's website. The PR will inform the centre's inspector of the actions taken to comply with this recommendation by 24 August 2016.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector acknowledges receipt of the amended patient information and expects an update of further actions taken to comply with this recommendation to be provided by 24 August 2016. Further action is required.

Reponses from the Person Responsible to this inspection report