Executive Licensing Panel - minutes

Centre 0333 (Harley Street Fertility Clinic) Renewal Inspection Report

Friday, 20 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Anjeli Kara	Director of Strategy & Corporate Affairs Technical Report Developer Regulatory Policy Manager
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, executive update and licensing minutes for the last three years.

1.2. The panel noted that Harley Street Fertility Clinic (centre 0333) is located in central London. The centre provides a full range of fertility services including embryo testing. The panel noted that in relation to activity levels this is a small centre, however the centre has the capacity to provide up to 800 cycles of treatment per annum and it is anticipated that activity and staffing will progressively increase as the centre becomes more established.

1.3. The panel noted that the centre was granted an initial two-year licence in 2014.

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

1.5. The panel noted that between 1 January and 31 December 2015, the centre provided 229 cycles of treatment (excluding partner intrauterine insemination).

1.6. The panel noted that in 2015 the centre reported 30 cycles of partner insemination with two pregnancies. This is likely to be consistent with the national average.

1.7. Between October 2014 and September 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 26%. This represents performance that is likely to be consistent with the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that an unannounced inspection was conducted in June 2015 in response to a patient complaint to the Care Quality Commission, regarding the centre's medicines management procedures and patient feedback provided directly to the HFEA on the same matter. A number of concerns were raised by the unannounced inspection, the most significant of which related to medicines management and sedation practices for surgical procedures at the centre. In accordance with the HFEA Compliance and Enforcement Policy, a management review was conducted at which the findings of the unannounced inspection were evaluated. It was considered appropriate to conduct an announced, full inspection of all the centre's activities to determine the current level of compliance in all areas. This was carried out in July 2015. Seven major areas of non-compliance were identified on these inspections. The Person Responsible (PR) and her team engaged fully with the HFEA and information requested and evidence of actions taken were provided in a comprehensive and timely manner.

1.9. The report of both of these inspections was considered by the Executive Licensing Panel in October 2015. The panel was concerned about the non-compliances relating to consent, medicines management and sedation practices. The panel noted the progress the centre had made (four of nine recommendations had been fully implemented) but considered that the centre may not fully appreciate the serious consequences failing to take proper consent might have. Taking this into account, the panel requested that the executive provide an update in January 2016 regarding the centre's progress in implementing the outstanding recommendations. The update was provided in January 2016. The PR provided evidence that the majority of the outstanding recommendations had been fully implemented. The panel noted the centre's progress in addressing the non-compliances and urged the PR to address the remaining recommendations within the prescribed timescales.

1.10. The panel noted that, in consideration of the inspection history of this centre, the level of engagement and commitment to achieving compliance and because a comprehensive inspection of all licensable activities had been performed in July 2015, a standard licence renewal inspection was not considered necessary at this time. Instead, this inspection visit focused on continuing compliance with the recommendations that were made in the previous inspection report.

1.11. The panel noted that the report of the renewal inspection made five recommendations for improvement. Three of these recommendations were due to be completed, or had elements that were due to be completed by 17 May 2016. All recommendations have now been implemented and the PR will provide evidence of further audit to demonstrate the effectiveness of the corrective action by 17 August 2016.

1.12. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a Quality Management System (QMS) in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.13. The panel noted that the centre has made significant improvement in compliance with regulatory requirements since the last inspection visits in June and July 2015.

1.14. The panel noted that the inspectorate 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.

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 endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this 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

Juliet Tizzard

Date

3 June 2016

Executive Update for Executive Licensing Panel
20 May 2016

Centre number	0333
Centre name	Harley Street Fertility Clinic
Person Responsible	Geetha Venkataraman

Update to renewal inspection report

Background

1. Centre 0333's renewal application is being considered by this Executive Licensing Panel (ELP).

2. The report of the renewal inspection of centre 0333 made five recommendations for improvement. Three of these recommendations were due to be completed, or had elements that were due to be completed by 17 May 2016.

3. Annex 1 provides an update on the implementation of these three recommendations.

4. All recommendations have now been implemented. The PR will provide evidence of further audit to demonstrate the effectiveness of the corrective action by 17 August 2016.

Sara Parlett
Inspector

Annex 1: Recommendations that required further action

Note: Only recommendations that were due to be implemented by 17 May 2016 have been included in the list below. The original numbering for non-compliances from the inspection report has been retained.

▶ Critical area of non compliance

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

▶ Major area of non compliance

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Donor screening In one set of egg donor notes reviewed, the donor had been screened for syphilis but not at the time of donation. A similar non compliance was noted at the unannounced inspection in June 2015. Assurance was provided subsequent to the 2015 inspection that corrective action had been implemented however this was clearly not effective.	The PR should ensure that donor screening is performed within the timeframes specified by the Authority. The PR should conduct a review of the centre's donor screening procedures and this should include staff training requirements. The findings of the review, including further corrective actions with timescales for implementation, should be	We will perform a review of our donor screenning procedures, including staff training requirements. We shall provide a report of that review, including corrective action and timescales for implementation, to our inspector by 17 May 2016. As requested, we will perform an audit of our donor screening three months after implementation of corrective action to	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation. The PR will be providing a summary of the review of donor screening practices to the centre's inspector by 17 May 2016. **Update 16 May 2016:** The PR has provided a copy of the centre's comprehensive

SLC T53b.	submitted to the centre's inspector by 17 May 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these further corrective actions have been effective. This audit should be submitted by 17 August 2016.	ensure that those corrective actions were effective.	review of donor screening procedures which includes details of actions taken in response to the review findings. A summary report of the audit to determine the effectiveness of this corrective action to be submitted to the centre's inspector by 17 August 2016.

Other areas of practice that requires improvement

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. CE marking A pre-mixed heparinised saline solution is used for flushing follicles during oocyte collection. This solution is CE marked, but not for the purpose for which it is being used. SLC T30.	The PR should ensure that wherever possible CE marked medical devices are used and that these are used for the manufacturer's intended purpose. The PR should source a suitable alternative solution for flushing follicles and this should be in use no later than 17 May 2016.	We will provide confirmation of use of a CE marked solution that is intended for follicle flushing before 17 May 2016 as requested.	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation. **Update 16 May 2016:** The centre has confirmed that they have discontinued use of the heparinised saline solution on 12 May 2016. A CE marked media specific

	Confirmation of this should be provided to the centre's inspector.		for oocyte aspiration is now in use. No further action required.
5. Data submission Thirty five percent (35/100) of the IVF and 50% (6/12) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for delayed submissions. A summary report of the findings of the review including corrective actions and the timescale for implementation of corrective actions should be submitted to the centre's inspector by 17 May 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions	We will perform a review of the procedures used within the clinic to submit data to the Authority. We will provide a report of that review, including corrective action, to our inspector by 17 May 2016. We will audit the clinic's data submissions three months after implementation to ensure those actions have been effective.	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation. The PR will be providing a summary of the review of data submission procedures to the centre's inspector by 17 May 2016. **Update 16 May 2016:** The PR has provided a copy of the centre's comprehensive review of data submission procedures which includes details of actions taken in response to the review findings. A summary report of the audit to determine the effectiveness of this corrective action to be submitted to the centre's

	have been effective. This audit should be submitted by 17 August 2016.		inspector by 17 August 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: 17 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 inspection visits in 2015 and 2016 and communications received from the centre.

Inspectors: Sara Parlett (Lead), Gill Walsh and Neil McComb

Date of Executive Licensing Panel: 20 May 2016

Centre name	Harley Street Fertility Clinic
Centre number	0333
Licence number	L/0333/1/a
Centre address	134, Harley Street, London, W1G 7JY
Person Responsible	Geetha Venkataraman
Licence Holder	Mr Lawrence Ashford
Date licence issued	23 July 2014
Licence expiry date	22 July 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Harley Street Fertility Clinic is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014. This initial licence was granted for two years. The centre provides a full range of fertility services.

Between 1 January and 31 December 2015, the centre provided 229 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this currently equates to a small centre, however the centre's renewal application states that the facilities have capacity to provide up to 800 cycles of treatment per annum. It is anticipated that activity and staffing will progressively increase as the centre becomes more established.

This inspection visit would more usually be the first visit to a new centre after an initial two year licence was granted. However, an unannounced inspection was conducted in June 2015 in response to a complaint to the Care Quality Commission from a patient regarding the centre's medicines management procedures and patient feedback provided directly to the HFEA on the same subject.

A number of concerns were raised by the unannounced inspection, the most significant of which related to medicines management and sedation practices for surgical procedures at the centre. In accordance with the HFEA Compliance and Enforcement Policy, a management review was conducted at which the findings of the unannounced inspection were evaluated. It was considered appropriate to conduct an announced, full inspection of all the centre's activities to determine the current level of compliance in all areas. This was carried out in July 2015. Seven major areas of non-compliance were identified on these inspections. The Person Responsible (PR) and her team engaged fully with the HFEA; information requested and evidence of actions taken were provided in a comprehensive and timely manner.

The report of both of these inspections was considered by ELP in October 2015. The panel was concerned about the non-compliances relating to consent, medicines management and sedation practices. The panel noted the progress the centre had made (four of nine recommendations had been fully implemented) but considered that the centre may not fully appreciate the serious consequences failing to take proper consent might have. Taking this into account, the panel requested that the executive provide an update in January 2016 regarding the centre's progress in implementing the outstanding recommendations.

This update was provided to ELP in January 2016. The PR provided evidence that the majority of the outstanding recommendations had been fully implemented. The panel noted the centre's progress in addressing the non-compliances and urged the PR to address the remaining recommendations within the prescribed timescales.

In consideration of the inspection history of this centre, the level of engagement and commitment to achieving compliance demonstrated by the centre team and because a comprehensive inspection of all licensable activities had been performed in July 2015, a standard licence renewal inspection was not considered necessary at this time. Instead,

this inspection visit focused on continuing compliance with the recommendations that were made in the previous inspection report.

Pregnancy outcomes[1]

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

In 2015 the centre reported 30 cycles of partner insemination with two pregnancies. National data for this year has not yet been analysed, but it is likely that this will be consistent with the national average.

Multiple births[2]

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

Between October 2014 and September 2015, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%. This mean's that the centre's live birth rate is likely to be consistent with 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;
- 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 there were a number of areas of practice that required improvement, including two major and three 'other' areas of non-compliance.

In responding to the report the PR has provided evidence that the following recommendations have been implemented:

Major areas of non compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.

'Other' areas that require improvement:

- The PR should review the written information provided to patients about treatment with intralipid to ensure it accurately reflects the requirements of guidance.

Since the inspection the PR has also given a commitment to fully implement the following recommendations within the prescribed timescales:

Major areas of non compliance:

- The PR should ensure that donor screening is performed within the timeframes specified by the Authority.

'Other' areas that require improvement:

- The PR should ensure that wherever possible CE marked medical devices are used and that these are used for the manufacturer's intended purpose.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has two major areas of concern, one of which has been fully addressed since the inspection visit. The inspection team notes that the success rates are consistent with the national average and the centre's multiple clinical pregnancy rates are likely to meet the live birth rate target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales. In recommending this, the inspection team notes the significant improvement in compliance with regulatory requirements that the centre has achieved since the last inspection visits in June and July 2015.

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 were considered partially compliant with HFEA requirements at the last inspection. Full compliance was noted at this inspection. 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)
It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos. The centre's procedures for screening donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures were considered compliant with HFEA requirements at the last inspection 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 were considered to be compliant with HFEA requirements at the last inspection to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
One set of egg donor records reviewed on this inspection showed that the donor had been screened for syphilis but not at the time of donation (SLC T53b). A similar non compliance was noted at the unannounced inspection in June 2015. Assurance was provided subsequent to the 2015 inspection that corrective action had been implemented, however this was clearly not effective (recommendation 1).

Suitable premises and suitable practices

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

What the centre does well

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

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

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) were considered compliant with HFEA requirements at the last inspection.

The centre was considered compliant with HFEA requirements at the last inspection to process gametes and 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, were considered compliant at the last inspection with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that were considered compliant with guidance at the last inspection.

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.

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 (RCOG), 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 by:

- recording the reasons for prescribing this medicine in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The centre's procedures are considered compliant with these requirements. However, the patient information provided by the centre regarding intralipid is not considered to be compliant with the guidance issued.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that were considered partially compliant at the last inspection with professional body guidelines for pre-operative assessment and management of the surgical pathway. Full compliance was noted at this inspection. 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 were considered compliant with HFEA multiple births minimisation strategy requirements at the last inspection 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 were considered compliant with HFEA requirements at the last inspection 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 were considered compliant with HFEA requirements at the last inspection. 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 were considered compliant with HFEA requirements at the last inspection. 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 were considered compliant with HFEA requirements at the last inspection.

Traceability (Guidance note 19)
The centre's procedures were considered compliant with HFEA traceability requirements at the last inspection. 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 was considered broadly compliant with HFEA requirements at the last inspection. Full compliance was noted at this inspection, with one exception noted below (see 'medicines management' section). 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 were considered broadly compliant with HFEA requirements at the last inspection. Evidence of full compliance has since been provided.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite IVF arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that were partially compliant with HFEA requirements at the time of the last inspection. Some of the equipment and materials used in licensed activity were seen at the last inspection to be designated for the purpose and appropriately maintained in order to minimise any hazard to patients and/or staff. Full compliance was noted at this inspection, with one exception described below.

The centre was considered fully compliant with HFEA requirements to validate critical equipment at the last inspection. 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 were considered partially compliant with HFEA requirement to validate critical processes at the last inspection. Evidence of full compliance has since been provided. 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 were considered compliant with HFEA requirements at the last inspection. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Medicines management
This was a critical area of concern at the last inspection and was a focus at this inspection. The inspection team considers that there has been a significant improvement in the management of medicines at the centre. However, following a review of the controlled drugs register, a number of concerns were noted:

- the name, strength and volume of each drug is not always recorded on the top of each page, e.g. the entry would state Fentanyl but does not include the strength or ampoule size;
- the signature of the person administering the drug was missing in two cases;
- where two patients were treated on the same day, one ampoule of Fentanyl was used for both patients;
- when the full amount of one ampoule of controlled drug is not used, the waste portion is not usually recorded. Centre staff are aware of this requirement and are sourcing a new register to make it easier to record;
- only the patient name is recorded in the register and the hand written entries are frequently hard to read and not easily legible for traceability purposes. Centre staff explained that patient details could be established using other records. But the inspection team considered that the primary record should include all details necessary for traceability, which ideally should include an additional identifier to the patient name.

The centre's quarterly audits of its controlled drugs procedures failed to identify non compliance with regulatory requirements as noted above (SLC T36).

(Misuse of Drugs Regulations 2001, Controlled Drugs in Perioperative Care 2006, Controlled drugs (Supervision of management and use) Regulations 2013 and NMC Standards for medicines management 2010).

See recommendation 2.

Prescription of intralipid 'off label'
Written information provided to patients offered this treatment states that intralipid is designed to combat factors that may affect fertility. The inspection team considered this to be misleading because this is not what the supplement was designed for. The information does not explain that the intralipid has been prescribed 'off-label', what this means, or that there is currently little evidence to support its use (SLC T58; recommendation 3).

Equipment and materials (Guidance note 26)
A pre-mixed heparinised saline is used for flushing follicles during oocyte collection. This reagent is CE marked, but not for the purpose for which it is being used (SLC T30, recommendation 4).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1243/81).

Staff (Guidance note 2)
The centre was considered broadly compliant with HFEA requirements at the last

inspection 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. Full compliance was noted at this inspection.

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

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

Welfare of the child and safeguarding

What the centre does well

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

Safeguarding
The centre's procedures were considered compliant with safeguarding guidance at the last inspection. 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 were considered compliant with HFEA requirements at the last inspection. 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 three patients who provided feedback on their experiences. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with three of the individuals providing feedback to the HFEA commenting that they have compliments about the care that they received. Feedback was similar to that received at the last inspection.

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 sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures were considered compliant at the last inspection with the HF&E Act 1990 (as amended) requirements, 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 were considered compliant at the last inspection 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 were considered compliant with HFEA requirements at the last inspection. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

The centre's procedures for egg sharing arrangements were considered compliant with HFEA requirements at the last inspection. This is important to ensure that:

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy were considered compliant with HFEA requirements at the last inspection. 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 were considered compliant at the last inspection 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 were considered compliant at the last inspection 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 and donors were considered broadly compliant with HFEA requirements at the last inspection. Full compliance was noted at this inspection, with the exception noted in the intralipid section of this report. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent were considered broadly compliant with HFEA requirements at the last inspection. Full compliance was noted at this inspection. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood
Where a couple to be treated with donated gametes or embryos are 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 October 2015, the HFEA's Chief Inspector asked all newly licensed 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 provided evidence of a comprehensive audit identifying no issues and evidence that their procedures for obtaining consent to legal parenthood are robust.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of patient notes on this inspection, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. The centre's procedures are compliant with legal parenthood consent 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 assisted reproductive technology (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 were considered compliant with the requirements of the HF&E Act 1990 (as amended) at the last inspection. 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 were considered compliant with HFEA requirements at the last inspection. 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 were considered compliant with HFEA requirements at the last inspection. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

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

Use of embryos for training staff (Guidance note 22)
Use of embryos for training staff (Guidance note 22) The centre does not currently use embryos for training staff in embryological procedures.
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 were considered at the last inspection partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Significant improvement in record keeping was noted at this inspection, with exceptions noted in the medicines management section of this report. 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 broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

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

What the centre could do better

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
Thirty five percent (35/100) of the IVF and 50% (6/12) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005 (recommendation 5).

Section 3: Monitoring of the centre's performance

Following the inspections in 2015, recommendations for improvement were made in relation to seven major and two 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented. A repeat of one non compliance in the area of medicines management (recommendation 2) was seen on this inspection, although the inspection team notes the overall significant improvement that has been achieved.

On-going monitoring of centre success rates

The centre has not received any success rate risk tool alerts since it was licensed.

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
None			

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
1. **Donor screening** In one set of egg donor notes reviewed, the donor had been screened for syphilis but not at the time of donation. A similar non compliance was noted at the unannounced inspection in June 2015. Assurance was provided subsequent to the 2015 inspection that corrective action had been implemented however this was clearly not effective. SLC T53b.	The PR should ensure that donor screening is performed within the timeframes specified by the Authority. The PR should conduct a review of the centre's donor screening procedures and this should include staff training requirements. The findings of the review, including further corrective actions with timescales for implementation, should be submitted to the centre's inspector by 17 May 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that	We will perform a review of our donor screenning procedures, including staff training requirements. We shall provide a report of that review, including corrective action and timescales for implementation, to our inspector by 17 May 2016. As requested, we will perform an audit of our donor screening three months after implementation of corrective action to ensure that those corrective actions were effective.	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation. The PR will be providing a summary of the review of donor screening practices to the centre's inspector by 17 May 2016.

	these further corrective actions have been effective. This audit should be submitted by 17 August 2016.		
2. **Medicines management** Following a review of the controlled drugs register, a number of areas of concern were noted: • the name, strength and volume of each drug is not always recorded on the top of each page e.g. the entry would state Fentanyl, but does not include the strength or ampoule size; • the signature of the person administering the drug was missing in two cases; • where two patients were treated on the same day, one ampoule of Fentanyl was used for both patients; • where the full amount of one ampoule of controlled drug is not used, the waste portion is not usually recorded. Centre staff are aware	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should conduct a review of the centre's medicine management procedures and this should include staff training requirements. The findings of the review including corrective actions and timescales for implementation of the corrective actions should be submitted to the centre's inspector by 17 May 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. The PR should ensure that this audit is sufficient in scope to identify any issues with the management of controlled drugs. This audit should be	We have conducted a review of the clinic's medicines management with regard to use of controlled drugs. The report of that review is enclosed with this report. Corrective action has been taken based on the findings of the review. As requested, we will perform an audit of our medicines management with regard to use of controlled drugs three months after implementation of corrective action to ensure that those corrective actions were effective.	The centre has provided a copy of its comprehensive review of medicines management procedures and details of the corrective actions that have been implemented. The PR will be performing an audit to ensure that these corrective actions have been effective and will be providing a copy of this audit to the centre's inspector by 17 August 2016.

of this requirement and are sourcing a new register to make it easier to record; • only the patient name is recorded in the register and the hand written entries are frequently hard to read and not easily legible for traceability purposes. Centre staff explained that patient details could be established using other records. But the inspection team considered that the primary record should include all details necessary for traceability, which ideally should include an additional identifier to the patient name. SLC T2, Misuse of Drugs Regulations 2001, Controlled Drugs in Perioperative Care 2006, Controlled drugs (Supervision of management and use) Regulations 2013 and NMC Standards for medicines management 2010.	submitted by 17 August 2016.		

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. **Intralipid** Written information provided to patients states that intralipid is designed to combat factors that may affect fertility. The inspection team considers this to be misleading because this is not what the supplement was designed for. The information does not explain that the intralipid has been prescribed 'off-label', what this means, or that there is currently little evidence to support its use. SLC T58; Clinic Focus article, July 2015.	The PR should review the written information provided to patients about treatment with intralipid to ensure it accurately reflects the requirements of guidance issued. A copy of the revised patient information should be submitted to the centre's inspector by 17 May 2016.	We have reviewed the written information provided to patients, please find the revised version enclosed with this report.	The centre has provided a copy of its revised patient information which explains what the supplement was designed for, that it is being prescribed 'off-label' and what this means and that there have been no published randomised controlled trials assessing its efficacy. No further action is required.
4. **CE marking** A pre-mixed heparinised saline solution is used for flushing follicles during oocyte collection. This solution is CE marked, but not for the purpose for which it is being	The PR should ensure that wherever possible CE marked medical devices are used and that these are used for the manufacturer's intended purpose.	We will provide confirmation of use of a CE marked solution that is intended for follicle flushing before 17 May 2016 as requested.	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation.

used. SLC T30.	The PR should source a suitable alternative solution for flushing follicles and this should be in use no later than 17 May 2016. Confirmation of this should be provided to the centre's inspector.		
5. **Data submission** Thirty five percent (35/100) of the IVF and 50% (6/12) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for delayed submissions. A summary report of the findings of the review including corrective actions and the timescale for implementation of corrective actions should be submitted to the centre's inspector by 17 May 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit	We will perform a review of the procedures used within the clinic to submit data to the Authority. We will provide a report of that review, including corrective action, to our inspector by 17 May 2016. We will audit the clinic's data submissions three months after implementation to ensure those actions have been effective.	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation. The PR will be providing a summary of the review of data submission procedures to the centre's inspector by 17 May 2016.

	should be submitted by 17 August 2016.		

Reponses from the Person Responsible to this inspection report