Executive Licensing Panel - minutes

Centre 0333 (Harley Street Fertility Clinic) – Inspection Report

Friday, 30 October 2015

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

Panel members	Juliet Tizzard (Chair) Hannah Verdin David Moysen	Director of Strategy & Corporate Affairs Head of Regulatory Policy Head of IT
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
Observers	None	

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. Background

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

1.2. Between 23 July 2014 and 31 May 2015, the centre provided 188 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre, however the centre does have the capacity to provide up to 800 cycles of treatment per year. It is anticipated that activity and staffing will progressively increase as the centre becomes more established.

1.3. The inspectorate conducted an unannounced inspection visit on 1 June 2015 and an announced full inspection visit on 1 and 2 July 2015 in response to patient feedback regarding the centre's medicines management procedures and concerns raised by the Care Quality Commission (CQC), following a complaint received from a patient regarding the centre's medicines management procedures. The full inspection visit was conducted to determine the centre's overall level of compliance since the initial licence was granted in July 2014.

2. Consideration of application

2.1. The panel considered the papers which included an inspection report and licensing minutes for the last year.

2.2. The panel noted the patient feedback regarding the centre's medicines management procedures and concerns raised by the Care Quality Commission (CQC) following a complaint they received from a patient regarding the same issue.

2.3. The panel noted that unannounced and announced inspections took place between June and July 2015 in response to the concerns raised about the centre.

2.4. The panel noted that the centre's licence is due to expire on 22 July 2016.

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

2.6. The panel noted that in 2014, the centre reported 19 cycles of partner insemination with no pregnancies. This represented performance that is likely to be consistent with the national average.

2.7. Between July 2014 and April 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 20%. This means that the centre's live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target.

2.8. The panel noted that at the time of the inspection, seven major and two other areas of non-compliance were identified. The panel noted in particular the non-compliances relating to medicines management, sedation practices and consent practices. The panel noted that the Person Responsible (PR) had been asked to take immediate action in relation to health care assistants (HCAs) performing venous cannulation and initiating intra venous therapy. The PR confirmed that this practice would stop with immediate effect. The panel endorsed the recommendation that the PR should commission an independent review of the centre's medicines management practices and of the provision of sedation to patients during operative procedures.

2.9. The panel noted that since the inspection, the Person Responsible (PR) has implemented four of the inspectorate's recommendations relating to three major and one other area of non-compliance. The PR has provided evidence that the outstanding recommendations are being implemented, some of which only require the further submission of a scheduled audit. The panel noted that the PR and her team have engaged fully with the HFEA since the inspection visits and that requests for further information and evidence of actions taken have been provided comprehensively and in a timely manner.

2.10. The panel noted that the centre has a QMS in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

2.11. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence without additional conditions subject to the outstanding recommendations made in this report being implemented within the prescribed timescales.

3. Decision

3.1. The panel had regard to its decision tree.

3.2. The panel was concerned about the non-compliances relating to consent and found the non-compliances relating to medicines management procedures and sedation practices troubling. The panel noted the progress the centre has made to date, but was concerned that the centre did not appreciate the serious consequences that failure to take proper consent might have on a patient. Taking this into account, the panel has requested that the inspectorate provides an update in January 2016 on how the centre is progressing in addressing the outstanding recommendations. The panel expects to see significant improvement and receive reassurance that all of the recommendations have been fully implemented by the time the renewal application is due to be considered.

3.3. The panel was satisfied that the centre was fit to have its treatment (including embryo testing) and storage licence continued.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

10 November 2015

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's performance and level of compliance since this initial licence was granted. An initial licence is usually granted for a period of two years. The Authority's Executive Licensing Panel (ELP) uses this report to decide on the continuation of the centre's licence and whether any additional conditions should be applied to the licence.

Date of inspection: 1 June 2015 and 1 and 2 July 2015

Purpose of inspection: This was a full inspection conducted to determine the centre's overall level of compliance subsequent to an unannounced visit made in response to concerns raised by the Care Quality Commission (CQC) following receipt of a complaint from a patient and patient feedback provided directly to the HFEA.

Inspection details: The report covers the performance of the centre since this licence was granted, findings from the unannounced inspection visit conducted on 1 June 2015, the announced full inspection visit conducted on 1 and 2 July 2015 and communications received from the centre during this period.

Inspectors: Unannounced inspection 1 June 2015: Sara Parlett and Gill Walsh
Announced full inspection 1 and 2 July 2015: Sara Parlett, Gill Walsh, Louise Winstone and Neil McComb

Date of Executive Licensing Panel: 30 October 2015

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	Dr 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:

The Harley Street Fertility Clinic is a stand-alone clinic in central London. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014 and provides a full range of fertility services. The centre was granted a licence for two years.

Between 23 July 2014 and 31 May 2015, the centre provided 188 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this currently equates to a small centre, however the centre's initial licence 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.

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

Background to this inspection

The CQC contacted the HFEA on 24 April 2015 following receipt of a complaint from a patient regarding the centre's medicines management procedures. In response to this and patient feedback provided directly to the HFEA regarding medicines, a management review was held on 15 May 2015 in accordance with the HFEA Compliance and Enforcement Policy. It was agreed that an inspection visit was warranted. Joint discussions were held with the CQC, following which it was agreed that the HFEA should conduct a focused on-site visit.

An unannounced inspection was conducted on 1 June 2015. The findings of that inspection visit are recorded within this report. In summary, a number of concerns were raised on the day, most significant of which related to medicines management and sedation practices at the centre. The Person Responsible (PR) was asked to take immediate action on the day in relation to health care assistants (HCAs) performing venous cannulation and initiating intra venous therapy. The PR confirmed that this practice would stop with immediate effect.

A second management review was conducted on 4 June 2015 at which the findings of the unannounced inspection were evaluated. It was agreed that informal action was appropriate at this stage. Further information was requested from the PR regarding staff training and supervision, the assessment of staff competence, professional body registration and appraisal/revalidation for staff in post and also current job descriptions for both registered nurses and HCAs. It was agreed that the PR should commission an independent review of the centre's medicines management practices and of the provision of sedation to patients during operative procedures.

It was also considered appropriate to conduct an announced, full inspection of the centre's activities to determine the current level of compliance in all areas.

Pregnancy outcomes[1]

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

In 2014 the centre reported 19 cycles of partner insemination with no pregnancies. This represents performance that is likely to be consistent with the national average.

Multiple births[2]

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

Between July 2014 and April 2015, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This means 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

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 seven major and two 'other' areas of non compliance.

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

Major areas of non compliance:

- The PR should provide a copy of the independent review of medicines management procedures to the HFEA for consideration before this report is considered by ELP.
- The PR should provide a copy of the independent review of sedation practices to the HFEA for consideration before this report is considered by ELP.
- The PR should ensure that the process for intra-cytoplasmic morphologically selected sperm injection (IMSI) is validated.

'Other' areas of non compliance:

- The PR should establish compliant third party agreements (TPAs) with its diagnostic laboratories.

The PR has provided evidence that the following recommendations are being implemented, some of which only require the further submission of a scheduled audit:

Major areas of non compliance:

- The PR should review the process for witnessing to ensure that the disposal of sperm or embryos not needed for treatment is witnessed. On receipt of gametes and embryos transferred from other licensed centres, both the signature of the person place the material into storage and the person witnessing it should be recorded.
- The PR should ensure that full and accurate records of care are maintained which are clear and unambiguous.
- The PR should ensure that only CE marked devices are used wherever possible.
- The PR should review the centre's procedures for obtaining consent to ensure the correct HFEA consent forms are completed and the process by which staff check consent forms after completion by the patients/donors to ensure that the documentation is complete and that the consent decisions are clear. The PR should review all information provided to patients to ensure it accurately reflects regulatory and CoP requirements.

'Other' areas of non compliance:

- The PR should review the implementation of the quality management system (QMS) to ensure that it is being used to best effect to improve the quality of care provided.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern however seven major areas of concern were identified on inspection. The ELP is asked to note that since the unannounced visit, the request for further information and the announced full inspection, the PR and her team

have engaged fully with the HFEA. Information requested and evidence of actions taken has been provided comprehensively and in a timely manner.

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

The centre has a 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 continuation of the centre's treatment (with embryo testing) and storage licence without additional conditions subject to the outstanding recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better
A review of witnessing records conducted on inspection showed that in a number of instances the signature of the second person witnessing the placing of gametes into storage following transfer from other licensed centres was not recorded (SLC T71, CoP Guidance 18.4h).

The disposal of sperm or embryos not needed for treatment is not witnessed or recorded (SLC T71, recommendation 1).

Donor selection criteria and laboratory tests

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

What the centre does well

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

Payments for donors (Guidance note 13; Directions 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
It was noted at the unannounced nspection visit that the centre was screening for syphilis but not at the time of donation (SLC T52). Between the first visit and the second visit the centre updated their donor screening procedures to comply with this requirement. No further recommendation is considered necessary regarding this.

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/or embryos (relevant third parties) are suitable.

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

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

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

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

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are partially 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; Directions 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all

gametes/embryos sent to other licensed centres within or outside the UK are:

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

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

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

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly 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; Directions 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 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 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 partially compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

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

What the centre could do better

Medicines management
At the unannounced inspection conducted on 1 June 2015 a number of concerns were raised relating to medicines management practices at the centre as follows:

Controlled drugs
The centre does not have a Controlled Drugs Accountable Officer (CDAO) registered with the CQC as the responsible body for England, nor could the centre provide evidence of a determination from the CQC confirming exemption (The Controlled Drugs (Supervision of Management and Use) Regulations 2013, SLC T2).

A review of the centre's controlled drugs register showed:

- The waste of any unused portion of a controlled drug drawn up but not administered was not witnessed or recorded. At the time of the inspection on 1 and 2 July 2015 the waste of any unused portion of a controlled drug drawn up was witnessed and recorded.
- A number of amendments to entries into the controlled drugs register were unclear (SLC T47; Misuse of Drugs Regulation 2001, schedule 20 (c)). Following the unannounced inspection, the PR provided assurance that staff have been advised to ensure records are clear and unambiguous and that entries in the controlled drug register would be audited.
- Although the balance number of ampoules being dispensed was checked at the time of use, no regular overall controlled drug stock checks were being conducted. Following the unannounced inspection daily stock checks have been initiated.
- The second person checking controlled drugs with the anaesthetist providing conscious sedation for operative procedures was routinely a HCA who had not received any formal training in controlled drugs management and was not working directly under the supervision of a registered nurse. Since the unannounced inspection this practice has changed and a registered nurse checks controlled drugs with the clinician (SLC T2).

See recommendations 2 and 3.

General medicines management
The centre provides the medicines required for >95% of patients treated at the centre.

Prescription and dispensing records reviewed on 1 June 2015 showed that medicines were routinely dispensed by one person without a second person checking what was actually provided to the patient. Records also showed that the person dispensing the medicines was commonly a HCA or registered nurse (RN). In four records seen it was not possible to determine who had dispensed the medicines as this had not been recorded. Following the unannounced inspection the PR gave assurance prescriptions are made up by a registered nurse and this is then checked by a second person but records reviewed on 1 July 2015 of medicines dispensed post 1 June 2015 showed this was not consistently being practiced and the signature of a second person checking the prescription was missing in a number of records. It was confirmed with staff present on inspection and with the PR that staff have not received specific training in the supply and dispensing of prescription medicines for self-administration (see recommendation 2 and 3).

Staff described that, where a full packet of a particular medicine was not required, a 'part box' was dispensed, the blister pack being labelled directly with the patient's name. In this instance the manufacturer's drug information leaflet is not being provided to the patient with the medicines. Following the unannounced inspection on 1 June 2015 the PR provided assurance that part packets would not be dispensed and an appropriate manufacturer's drug information leaflet would be supplied with all medicines dispensed for self–administration (see recommendation 3).

A tour of the centre during the 1 June 2015 inspection showed that some medicines were not being stored securely. Due to the volume of medicines held at the centre, medicines are stored in a number of locations. Drugs for subcutaneous and intravenous injection were stored in open supplier's boxes and a filing cabinet in the medical records store, all of which was unlocked on the day of inspection. The PR and staff were advised on the day that this practice was not acceptable. A tour of the centre during the announced inspection on 1 July 2015 confirmed that all medicines held at the centre are now stored securely. No further recommendation is considered necessary regarding this.

The centre has three cubicles designated for phlebotomy, this is also where the majority of medicines teaching sessions take place and prescriptions are filled from stock held in these areas. Staff described that this is usually were intravenous infusions were set up and administered to patients. From discussions it became apparent that HCAs were commonly performing venous cannulation, and 'putting up' intravenous infusions, commonly intralipid infusions, unsupervised. Following the unannounced inspection of 1 June 2015 the PR provided evidence of comprehensive training for the relevant HCAs and RN on staff in both phlebotomy and venepuncture. The Executive has been given assurance in writing by the PR that HCAs are no longer initiating intravenous infusions. No recommendation is considered necessary in relation to this activity following this change in practice.

Concerns raised overall regarding medicines management were such that a

recommendation was made to the PR that she should consider commissioning an independent review of medicines management practice at the centre by a suitably qualified and experienced pharmacist. The PR engaged fully with the HFEA regarding this and the report of this review is currently awaited (SLC T2, recommendation 3).

Pre-operative assessment and the surgical pathway
During the unannounced inspection on 1 June 2015 the clinical inspector observed practice during an egg collection procedure. During that procedure it was observed that the anaesthetist providing the sedation and analgesia to the patient was working without the assistance of a member of staff trained to support the anaesthetist in airway management or other life support procedures. It was observed that the level of sedation provided was deeper than that which could be considered 'conscious sedation' and as would be suitable in an isolated non-hospital setting as defined by the Academy of Medical Colleges publication 'Safe Sedation Practice for Healthcare Procedures – Standards and Guidance 2013'. The level of consciousness constituted 'deep sedation' which required a degree of airway management and some level of respiratory support. The level of sedation provided and the intended sedation target state for this setting and availability of a trained assistant was discussed with the anaesthetist providing care following this procedure.

As a result of concerns regarding the level of sedation observed, training of personnel working in the procedure room and the standard of record keeping relating to the surgical pathway (see section record keeping and document control) a recommendation was made to the PR that she should commission an independent review of sedation practice at the centre by a suitably qualified and experienced anaesthetist or sedation practitioner. The PR engaged fully with the HFEA regarding this and report of this review is currently awaited (SLC T2, recommendation 4).

Traceability (Guidance note 19)
The centre does not label tubes used at egg collection however any risk associated with this practice has been assessed. It was agreed on inspection that a further witnessing step would be added to document that a check has been made of all critical work areas and are cleared prior to egg collection. No further recommendation is considered necessary (SLC T101).

Quality management system (QMS) (Guidance note 23)
The centre is using a manual witnessing system as their electronic witnessing system is not yet operational. The centre's standard operating procedure (SOP) describes the use of an electronic witnessing system and therefore does not accurately reflect the centre's current witnessing procedures (SLC T33(b)).

The centre's laboratory SOP for egg collection states that tubes used for egg collection are to be labelled; therefore the SOP does not accurately reflect practice as described above (SLC T33(b)).

An audit of documentation relating to the surgical pathway conducted in March 2015 by the clinic identified a number of non compliances, similar to those noted by the inspection team during its own audit of the patient records (recommendation 2). This observation highlights that while the audit was effective in identifying anomalies, the process was ineffective in securing the necessary corrective actions (SLC T36, recommendation 8).

Third party agreements (Guidance note 24)
A sample of three TPAs was reviewed on inspection. The agreement with one of the centre's testing laboratories was not compliant with all requirements of SLC T114. For example it did not document how test results should be relayed to the centre, including sign off and confirmation that the result applies to the correct sample. In July 2014 the HFEA also recommended that such TPAs specify the third parties responsibilities to inform the centre if the testing laboratory adapts protocols for CE approved tests or if it receives a performance alert from UK NEQAS. These points were not covered in the centre's TPAs with its testing laboratories.

See recommendation 9.

Equipment and materials (Guidance note 26)
Pipettes and 5ml tubes used in the processing of gametes in the laboratory are not CE marked (SLC T30, recommendation 5).

Process validation (Guidance note 15)
The process for IMSI has not been validated (SLC T72, recommendation 6).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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 is broadly 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
During the unannounced inspection on 1 June 2015 it was noted that only one part time registered nurse was substantively employed by the centre. The inspection team had concerns that there was insufficient suitably qualified and experienced staff to provide safe care. There was also concern that HCAs were working beyond the scope of their training and job descriptions. Following this inspection the PR was asked to provide

evidence of training and job descriptions for a number of staff members, which she did promptly. Safe staffing levels were discussed with the PR and her team at the announced inspection. Assurance was provided that the centre would only conduct activity commensurate with the number and experience of staff available and that the centre had recently recruited additional registered nurses (due to start within the month). The PR confirmed that when not directly supervised by a registered nurse, HCAs were working under the direct supervision of the PR. Successful recruitment was confirmed at the inspection visit on 1 July 2015. Staffing and activity levels were discussed with the PR on both visits. The importance of ensuring safe and effective care by assessing an appropriate level of activity commensurate with the number and experience of staff available was stressed. No further recommendation is considered necessary at this time.

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryo is at a significant risk of having a serious 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 four patients who provided feedback on their experiences. A further two patients also provided feedback directly to the HFEA in the time since the licence was granted. Feedback provided in the course of the inspection was positive however the two individuals providing written feedback to the HFEA commented that they were in some part dissatisfied with the care that they received.

On the basis of this limited 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 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.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA

requirements. This is important to ensure that:

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

Surrogacy (Guidance note 14)
This centre has provided treatment involving surrogacy to date, however the centre's procedures for treatment involving surrogacy were discussed and are considered compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and/or donors are 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; CH(11)02)
It was noted from a record review conducted on inspection that the centre's own consent form for IVF/oocyte retrieval where the recipient is being treated with donor eggs or donor sperm, information provided on that form is inaccurate and possibly misleading regarding consent or withholding consent to legal parenthood. For example, it states that the female (donor egg recipient) can complete a withdrawal of consent form (WC) to use or storage of the eggs or embryos or her being the legal parent, or her partner being legal parent even though his gametes are used in treatment, both of which are incorrect (recommendation 7).

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 broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

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

What the centre could do better

Consent (Guidance note 5;6)
When reviewing patient records at the unannounced inspection visit, it was noted that a member of centre staff was signing the 'witness' section on the last page of patients' HFEA consent forms. This section is for use when the consent form is being signed at the direction of the person who cannot sign for themselves due to a physical illness, injury or disability. The PR was informed that centre staff should not be signing the form as evidence of witnessing the patient's own signature. Since the first unannounced inspection this practice has now changed and no recommendation is considered necessary.

The centre requires altruistic egg donors to complete both the WD and the GS HFEA consent forms. It is not clear what the purpose of completing both of these is. In one set of notes reviewed, the egg storage period consented to was different on the two consent forms. In two cases reviewed, the egg donor had also completed a WSG consent form. This form is designed solely for women who are commissioning a surrogacy arrangement and the inspection team is concerned that asking altruistic egg donors to complete this form could result in their having inaccurate information (SLC T57; recommendation 7).

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

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are partially 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 and accuracy of the centre's submission of data to the Register.

What the centre could do better
Record keeping and document control (Guidance note 31)
A review of patient records on inspection showed there to be poor record keeping with respect to a number of areas:

- the name of the person dispensing prescription medicines for self-administration was not recorded on all records seen;
- the controlled drugs register contained a number of alternations which were not clear or properly annotated;
- a review of a sample of records for six patients who have undergone egg collection showed in a number of instances documentation of the surgical care pathway was incomplete:
    - in one instance there was no record of the patient having received sedation or analgesia during the procedure or evidence of physiological monitoring (i.e blood pressure, pulse rate and oxygen saturation) during the procedure or recovery stage;
    - in one instance the record made by the doctor providing sedation and analgesia during the egg collection was illegible. The drugs administered or the dose provided could not be clearly determined from the record. The record of physiological monitoring during the procedure was incomplete;
    - in three of six records reviewed, the 'recovery' records and 'discharge' part of the patient record was incomplete.

It was noted overall that the medical record of sedation was consistently of a poor standard. Records were sometimes scant and were largely difficult to decipher (SLC T2, T46(c) and T47, see recommendation 2).

Obligations and reporting requirements (Guidance note 32; Direction 0005)

2% (2/85) of the IVF and 10% (1/10) of the DI treatments reviewed at inspection had not been reported to the HFEA (General Direction 0005, SLC T41).

82% (70/85) of the IVF and 60% (6/10) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.

At the time of inspection records showed there were three treatments using unregistered donors. These issues have already been rectified.

The centre had difficulties with installing EDI after the grant of its licence and there has been constant contact with the HFEA to attempt to resolve this. Full installation has only recently been completed and HFEA training in the use of EDI was due to be held the week following the inspection. Centre staff have given a commitment to resolving the issues noted and ensuring that all licensed activity is reported to the Authority within the timeframe required by General Direction 0005. As a result it is not considered proportionate to make a recommendation at this point. This will be reviewed at the next inspection due prior to the renewal of the centre's licence in July 2016.

Section 3: Monitoring of the centre's performance

Following the initial licence inspection in June 2014 one recommendation for improvement was made in relation to one area major non compliance. The PR provided information and evidence that this recommendation was fully implemented prior to the report being considered by the Licence Committee.

On-going monitoring of centre success rates

The centre has not received any HFEA risk based assessment tool (RBAT) alerts since this licence was granted.

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, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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. Witnessing A review of witnessing records conducted on inspection showed that in a number of instances the signature of the second person witnessing the placing of gametes into storage following transfer from other licensed centres was not recorded (SLC T71, CoP Guidance 18.4h). The disposal of sperm and embryos not needed for treatment is not witnessed or recorded (SLC T71).	The PR should review the process for witnessing to ensure that the disposal of sperm or embryos not needed for treatment is witnessed and recorded. The PR should review the process for receipt of gametes and embryos to ensure that the signature of both the person receiving the gametes or embryos and the person witnessing receipt is recorded. The PR should provide evidence of the implementation of this	We have revised our laboratory forms for the process for receipt of gametes and embryos to ensure that the signature of both the person receiving the gametes or embryos and the person witnessing receipt are present. [attachments: Oocyte Embryo Import Witness.pdf; Sperm Import witness.pdf] We have revised the lab SOP to ensure that disposal of any gametes no longer required for treatment is witnessed and recorded. [attachment: LABSOP17 Disposal of samples.pdf]	The Executive acknowledges the PR's actions to date and provision of documents described. A summary of the scheduled audit should be provided by 1 January 2016. Further action is required.

	recommendation to the centre's inspector by 1 October 2015. Three months after the implementation of any changes to practice an audit of witnessing procedures and documentation should be performed to evaluate the effectiveness of any actions taken. A summary of this audit should be provided to the centre's inspector by 1 January 2016.	We have also updated our laboratory form to indicate a wtiness must sign at the time of disposing of any unused sperm. [attachment: Andrology updated form.pdf]. Please note that disposal of any unused eggs (e.g. immature eggs unsuitable for ICSI) or embryos (e.g. degenerated embryos) was being suitably witnessed. Please refer to highlighted areas on attached lab form [attachment: embryology lab form.pdf]. We will perform an audit of these practices and provide our inspector with a summary by 1 January 2016 as requested.	
2. Record keeping Poor record keeping has been identified for a number of practices as detailed in the body of this report.	The PR should ensure that full and accurate records of care are maintained which are clear and unambiguous. The PR is to conduct a review	We will perform a review of the process by which medical records are completed and submit a summary of that report to our HFEA inspector by 1 October 2015 as	The Executive acknowledges the PR's actions to date. The PR has provided a copy of the review which includes details of actions taken in

SLC T46 and T47.	of the process by which medical reports are completed, with particular reference to the intra operative record and the surgical care pathway. The report should investigate any barriers to proper records being maintained and consider the professional responsibilities of the individuals accountable for making appropriate records of care provided. The outcome of this review and any resulting actions should be provided to the centre's inspector by 1 October 2015. Three months after the implementation of any changes an audit of surgical pathway records should be conducted to determine the efficacy of any changes made. A summary of this audit should be provided to the centre's inspector by 1 January 2016.	requested. We will also perform an audit of surgical records and care pathways to determine the efficacy of any changes implemented and submit a summary of that report to our inspector by 1 January 2016 as requested.	response to the review findings. A summary of the scheduled audit to determine the efficacy of these actions should be provided by 1 January 2016. Further action is required.

3. Medicines management Concern was raised regarding a number of areas of practice relating to medicines management at the centre. The PR was asked to consider and has agreed to commission an independent review of medicines management practices at the centre. SLC T2.	The PR should provide a copy of the independent review of medicines management procedures to the HFEA for consideration before this report is considered by ELP. This report will be updated to reflect the outcome of this review and any actions or recommendations as a result.	A copy of the independent medicines management review has been provided on 3 September 2015 to the HFEA for consideration.	The Executive acknowledges the PR's actions in commissioning this review. The PR has provided a copy of the independent review and the PRs response which includes evidence of actions taken to implement recommendations made. No further action is required at this time. This area of practice will be reviewed at the next inspection.
4. Pre-operative assessment and surgical pathway Concern was raised regarding a number of areas of practice relating to sedation practices at the centre. The PR was asked to consider and has agreed to commission an independent review of sedation practices at the centre. SLC T2.	The PR should provide a copy of the independent review of sedation practices to the HFEA for consideration before this report is considered by ELP. This report will be updated to reflect the outcome of this review and any actions or recommendations as a result.	A copy of the independent sedation practice review has been provided 24 August 2015 to the HFEA for consideration.	The Executive acknowledges the PR's actions in commissioning this review. The PR has provided a copy of the independent review and the PRs response which includes evidence of actions taken to implement recommendations made. No further action is required at this time. This area of practice will be reviewed again at the

			next inspection.
5. Equipment and materials Pipettes and 5ml tubes used in the processing of gametes in the laboratory are not CE marked (SLC T30).	The PR should ensure that only CE marked devices are used. The PR should conduct a review of all equipment and materials to determine whether the two items identified on inspection are the only non-CE marked products in use. The PR should provide a summary of the outcome of this review and a plan detailing when the non-CE marked products will be replaced by 1 October 2015. Any risk of a precipitous change to materials should be mitigated, it is however anticipated that all products in use should be CE marked devices wherever possible within six months of this inspection.	We will conduct a review of all equipment and materials with regards to use of non-CE marked products and submit a summary of that review by 1 October 2015 as requested.	The Executive acknowledges the PR's actions in providing a review of non-CE marked products currently in use. The Executive considers that CE marked alternatives are available for products in use which come directly in to contact with gametes or embryos. The PR is to provide the centre's inspector with an update regarding this by 1 December 2015. Further action is required.
6. Process validation The process for IMSI has not been validated (SLC T72).	The PR should ensure that the process for IMSI is appropriately validated. This validation may be based on	We will ensure the process for IMSI is appropriately validated and submit evidence of that validation to our HFEA	The Executive acknowledges the PR's action in implementing this recommendation. A copy of

	studies performed by the centre or on data from published studies or from well-established processing procedures or by retrospective evaluation of the clinical results. Evidence of process validation should be provided to the centre's inspector by 1 October 2015.	inspector by 1 October 2015 as requested.	the validation document has been provided for information. No further action is required.
7. Patient information and consent The centre's consent form for IVF/oocyte retrieval where the recipient is being treated with donor eggs or donor sperm contains information that is inaccurate and possibly misleading regarding consent or withholding consent to legal parenthood. The centre requires altruistic egg donors to complete both the WD and the GS HFEA consent forms. It is not clear what the purpose of completing both of these is. In one set of	The PR should review the centre's procedures for obtaining consent to ensure the correct HFEA consent forms are completed and the process by which staff check consent forms after completion by the patients/donors to ensure that the documentation is complete and that the consent decisions are clear. A summary report of the findings of the review including corrective actions and the timescale for implementation of corrective actions should be submitted	We will perform a review of our procedures for obtain consent and the process by which staff check consent forms after completion. We will provide a summary of that review, including any corrective actions, to our HFEA inspector by 1 October 2015 as requested. In the interim, we have revised the local consent form for ovum recipients and patients using donor sperm in order to address the concern raised [attachments: OR Consent37.pdf; Donor sperm	The Executive acknowledges the PR's action in implementing this recommendation. The PR has provided a copy of the review which includes details of actions taken in response to the review findings. Copies of the revised documents referred to have also been provided. A summary of the scheduled audit to determine the efficacy of these actions should be provided by 1 January 2016.

notes reviewed, the egg storage period consented to was different on both consent forms. In two cases reviewed, the egg donor had also completed a WSG consent form. This form is designed solely for women who are commissioning a surrogacy arrangement and the inspection team is concerned that asking altruistic egg donors to complete this form will give them inaccurate information SLC T57.	to the centre's inspector by 1 October 2015. 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 should be submitted by 1 January 2016. The IVF/oocyte retrieval consent form should be reviewed and revised and a copy submitted to the HFEA when responding to this report. The PR should review all information provided to patients, including that documented in local consent forms, to ensure it accurately reflects regulatory and CoP requirements. A copy of this review, including corrective actions taken, should be submitted to the centre's inspector by 1 January 2016.	reserve use consent39.pdf]. Similarly, we have revised the local consent forms for IVF/ICSI [attachment:IVF ICSI Consent08.pdf] and egg freezing [attachment: Egg Freezing Consent05.pdf]. We will perform an audit of corrective actions from the above review and submit that audit to our HFEA inspector by 1 January 2016 as requested. We will review all information provided to patients, including local consent forms, and provide a copy of that review, including corrective actions taken, to our HFEA inspector by 1 January 2016 as requested.	Further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
8. Quality management system An audit of documentation relating to the surgical pathway conducted in March 2015 identified a number of non compliances, as the inspection team noted (recommendation 4) but no corrective actions had been agreed or acted upon. SLC T36. Two of the centre's laboratory SOPs did not accurately reflect the current procedures performed. SLC T33(b).	The PR should ensure that following audit, any corrective actions are identified and implemented in a timely manner. Confirmation of this should be given when responding to the report. The PR should conduct a review of the centre's SOPs to ensure that, now the centre is becoming established, the SOPs accurately reflect current practice and regulatory requirements. The PR should confirm when this is completed and by 1 January 2016 at the latest.	Being a new clinic we were finding our feet with effectively implementing our QMS system. Initially, we had an external quality manger but we felt this was not operationally efficient. We have since appointed an internal quality manager to address this issue. We confirm audit findings are now being discussed at quarterly quality management meetings. Any required action is identified in that meeting and implemented in a timely manner. While the majority of our SOPs were reviewed this August, it being their 1 year anniversary. We will conduct a review of all SOPs by 1 January 2016 and provide confirmation upon completion.	The Executive acknowledges the PR's actions in implementing this recommendation. Documentation provided in response to this report has been of a high standard and presented in a timely manner. A further update regarding progress with the review of the centre's SOPs should be provided on or before 1 January 2016. Further action is required.

		Please find attached revised versions of the two SOPs mentioned in the reported. [attachments: LABSOP03 Oocyte Collection.pdf; LABSOP12 Laboratory Set-up.pdf]	
9. TPAs The agreement with one of the centre's testing laboratory was not compliant with all requirements of SLC T114. The HFEA recommended to the sector in July 2014 that such TPAs should also include informing the centre if the testing laboratory adapts protocols for CE approved tests or if it receives a performance alert from UK NEQAS. These points are not covered in the centre's TPAs with its testing laboratories.	The PR should conduct a review of its TPAs with its testing laboratories to ensure compliance with SLC T114 and the further requirements recommended by the HFEA in July 2014. These TPAs should be submitted to the centre's inspector by 1 October 2015.	We have submitted revised TPAs to our testing laboratories and will submit copies to our HFEA inspector by 1 October 2015 as requested.	The Executive acknowledges the PR's action in implementing this recommendation. A copy of the revised agreements have been provided for information. No further action is required.

Responses from the Person Responsible to this inspection report

We would like to thank the inspection team for their thorough and diligent inspection.

We would like to note that we had appointed a Controlled Drugs Accountable Officer (CDAO), Dr Suvir Venkataraman, at the time of being granted our licence to possess schedule 2 controlled drugs. However, we had not registered their details with the CQC as required. We have since submitted their details to be added to the register of CDAOs and expect the CQC to confirm this shortly.