Executive Licensing Panel - minutes

Centre 0307 (Complete Fertility Centre Southampton)

Renewal Inspection Report

Tuesday, 20 August 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Helen Crutcher Dina Halai	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Victoria Brown	Licensing Manager Inspector (Scientific) - Induction

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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that Complete Fertility Centre Southampton is located within the Princess Anne Hospital and has held a licence with the HFEA since 2008. The centre provides a full range of fertility services, including the storage of gametes and embryos.

1.3. The panel noted that, in the 12 months to 28 February 2019, the centre provided 657 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that HFEA register data for the period 1 February 2018 to 31 January 2019, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.5. The panel noted that in 2018, the centre provided 14 cycles of partner inseminations, with one pregnancy, and this is in line with the national average.

1.6. The panel noted that, between 1 February 2018 and 31 January 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 30 April and 1 May 2019.

1.8. The panel noted that at the time of the inspection, there was one critical area of non-compliance concerning medicines management. There were also five major areas of non-compliance relating to the safety and suitability of premises and facilities, laboratory accreditation, infection control, the Quality Management System (QMS) and equipment and materials. Five 'other' non-compliances regarding payments for donors, third party agreements (TPAs), egg sharing arrangements, confidentiality and privacy, and record keeping and document control were also identified.

1.9. Since the inspection visit, the Person Responsible (PR) has implemented all the recommendations made in the report in relation to the major and 'other' non-compliances. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure corrective actions have been effective.

1.10. The panel noted that the PR had given a commitment to fully implementing the critical non-compliance concerning medicines management.

1.11. The panel noted that due to the extent and nature of the non-compliances in the report, and in accordance with section 3.1 of the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 30 May 2019, to evaluate the findings of this renewal inspection report and to consider a proportionate course of action. It was concluded that the executive was not assured that the centre had robust systems in place to manage medicines and has therefore graded this as a critical non-compliance. It was agreed that the PR would be provided a copy of the draft inspection report and would be required to attend a telephone conference meeting with the Chief Inspector and the centre's inspector, to discuss the concerns related to medicines management and for the PR to provide assurances that the recommendations relating to medicines management are being, or will be, addressed as a priority. The telephone conference meeting took place on 2 July 2019 and the PR provided suitable assurances and plans to implement the recommendations related to medicines management, which is also reflected in the PR's response to this report.

1.12. The panel noted that the centre's success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet the target.

1.13. The panel noted that significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use this, to best effect, to monitor and improve the service provided. The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.14. The panel noted that 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.

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 expressed concern about the quantity and breadth of non-compliances identified in the renewal report and hoped to see an improvement at the interim inspection.

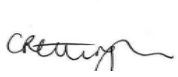
2.5. The panel recommended that patients are actively encouraged to provide feedback by means of the 'Choose a Fertility Clinic' facility, available on the HFEA website, noting that only nine patients had used this facility in the last 12 months, following treatment at the centre.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

23 August 2019

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: 30 April and 1 May 2019.

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage.

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

Inspectors: Sandrine Oakes (lead), Lesley Brown, Grace Lyndon, Polly Todd and Neil McComb.

ELP: 20 August 2019

Centre name	Complete Fertility Centre Southampton
Centre number	0307
Licence number	L/0307/3/b
Centre address	Princess Anne Hospital, Level G, Coxford Road, Southampton, SO16 5YA, United Kingdom
Person Responsible	Ms Julia Paget
Licence Holder	Dr Ying Cheong
Date licence issued	1 November 2015
Licence expiry date	31 October 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Complete Fertility Centre Southampton is located within the Princess Anne Hospital and has held a licence with the HFEA since 2008.

The centre provides a full range of fertility services, including the storage of gametes and embryos.

The current licence has been varied to reflect the following change:

- 4 August 2017 – Change of Licence Holder (LH)

The centre provided 657 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2019. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 February 2018 to 31 January 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 14 cycles of partner insemination with one pregnancy. This success rate is in line with the national average.

Multiple births[2]

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

Between 1 February 2018 and 31 January 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

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

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

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

Major areas of non-compliance:

- The PR should ensure that suitable premises are provided for staff and patients.
- The PR should ensure that laboratories are appropriately accredited to perform diagnostic tests to the relevant ISO standard.
- The PR should ensure compliance with infection control regulations.
- The PR should ensure that the quality management system (QMS) is effective and fit for purpose.
- The PR should ensure that each item of critical equipment is appropriately validated.

'Other' areas of non-compliance:

- The PR should ensure advertising and marketing materials used for the recruitment of donors are compliant with HFEA requirements and guidance.
- The PR should ensure that all third-party agreements (TPAs) are compliant with HFEA requirements.
- The PR should ensure that, if either the gamete provider or the recipient in a benefit in kind arrangement withdraws their consent to treatment or donation after preparation has begun, the centre should bear any financial loss it sustains as a result
- The PR should ensure that appropriate measures are in place to maintain patients' confidentiality.
- The PR should ensure record keeping and document control practices are compliant with HFEA requirements and guidance.

The PR has given a commitment to fully implementing the following recommendation:

Critical areas of non compliance:

- **The PR should ensure that medicines management practices are compliant with regulatory requirements and best practice guidelines.**

Due to the extent and nature of the non-compliances in this report, and in accordance with section 3.1 of the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 30 May 2019, to evaluate the findings of this renewal inspection report and to consider a proportionate course of action. It was concluded, following the management review, that the executive was not assured that the centre had robust systems in place to manage medicines and has therefore graded this as a critical non-compliance. It was agreed that the PR would be provided a copy of the draft inspection report and would be required to attend a telephone conference meeting with the Chief Inspector and the centre's inspector, to discuss the concerns related to medicines management and for the PR to provide assurances that the recommendations relating to medicines management are being, or will be, addressed as a priority. The telephone conference meeting took place on 2 July 2019 and the PR provided suitable assurances and plans to implement the recommendations related to medicines management, which is also reflected in the PR's response to this report.

Recommendation to the ELP

The centre has one critical, five major and five other areas of concern.

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

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided. The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team considered it proportionate, given the centre's history of compliance, to recommend the renewal of the centre's licence for a period of four years without any conditions.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

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

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

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

What the centre could do better

Payments for donors (Guidance note 13; General Direction 0001)
The inspection team noted that the centre's marketing banners placed an emphasis on financial gain rather than altruism for egg donation, which is not compliant with guidance (CoP Guidance 11.1; recommendation 7).

Suitable premises and suitable practices

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

What the centre does well

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

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

The premises of the centre's satellite facilities and 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 partially compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are not compliant with guidance.

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

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

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

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

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

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

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

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

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

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has not yet been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have not been made since the introduction of the ITE import certification scheme on 1 April 2018. The centre is therefore compliant with General Direction 0006.

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third-party agreements, are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

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

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
On inspection, the following were observed:

- a rectangular cut out hole is in the shower room and there appeared to be wires inside. This poses an electrical risk (SLC T2, DH Health Technical Memorandum 06-01 Electrical services supply and distribution (2017));
- not all doors are fitted with 'free/occupied' signs. The inspection team observed disturbances on numerous occasions with staff knocking at doors and then entering occupied rooms (CoP Guidance 25.9);
- the anaesthetist was observed checking her emails on her phone whilst her patient was having an egg collection under sedation. The inspection team was concerned this lack of attention to the sedated patient could compromise care and does not comply with the professional practice standards (SLC T2, Safe sedation practice for healthcare procedures, Standard and Guidance (2013));
- the theatre door has a window which is not frosted or screened with a privacy blind. There is also no sign on the door to say that the room is in use. The inspection team observed an egg collection during which several members of staff entered theatre, one of whom disturbed the anaesthetist whilst she was sedating a

patient. A privacy curtain is in place, which is pulled to offer screening, but the inspection team is concerned that the positioning of the couch in theatre (straight in front of the door) and interruptions from staff entering theatre, do not provide optimum privacy and dignity for patients (CoP Guidance 25.9).

Recommendation 2.

Laboratory accreditation (Guidance note 25)

Evidence was not available that the laboratory that performs sperm DNA damage testing for the centre's patients, or the test itself, is appropriately accredited. The testing laboratory states that the test is under performance evaluation and that each person tested is participating in ongoing performance evaluation. This is not made clear in the information about the test provided to patients (SLCs T21 and T58; recommendation 3).

Infection control (Guidance Note 25)

During the inspection, several non-compliances were identified:

- the sharps bin in theatre was placed directly on the floor and two other sharps bins did not have their temporary closure in use. Several sharps bins were stored in the dirty utility room rather than having been collected for disposal, as should occur daily according to the collection schedule (SLC T2, section 2 NHS Community Infection Prevention and Control Guidance for Health and Social Care, Sharps Management and Inoculation Injuries. Version 1.01 (2015));
- there were several items on the store room floor which prevented effective cleaning (section 3.105 DH Health Building Note 00-09: 'Infection control in the built environment' (2013));
- the seating in a men's production room was not made of an impermeable fabric and was unsuitable for cleaning with detergents and disinfectants (section 3.133 DH Health Building Note 00-09 'Infection control in the built environment (2013)');
- several bottles used to collect blood samples were out of date (SLC T2);
- staff were using out of date needles and syringes for demonstration purposes, which were stored alongside other needles and syringes for patient use. In addition to the concern that unsuitable equipment could be accidently used for a patient, the inspection team was concerned that staff were re-sheathing needles after demonstrating medicine administration (SLC T2, section 2 NHS Community Infection Prevention and Control Guidance for Health and Social Care, Sharps Management and Inoculation Injuries. Version 1.01 (2015);
- the anaesthetist had her backpack with her in theatre during a procedure, despite being provided with a private locker. This could pose an infection risk (part 3 section 1.1 The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (2015)).

Recommendation 4.

Medicines management (Guidance Note 25)

During the inspection, a significant number of non-compliances were identified:

- for two patients, there was a discrepancy between the amount of controlled drug (CD) administered recorded in the patients' records and in the CD register (section 4 The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' (2006));
- the sharing of fentanyl ampoules between patients was recorded in the CD register (recommendation 6 the AAGBI 'Controlled Drugs in Perioperative Care' (2006));

- drugs (including CD), were discarded in sharp bins for solid and non-hazardous waste and/or without a denaturing kit within it (section 7 the AAGBI 'Controlled Drugs in Perioperative Care' (2006));
- unidentifiable signatures were present in the CD register, which were not included in the signatory list (section 7.5 DH 'Safer Management of Controlled Drugs, A guide to good practice in secondary care (England)' (2007));
- several entries in the CD register were illegible (section 4.7 DH 'Safer Management of Controlled Drugs, A guide to good practice in secondary care (England)' (2007));
- the unit amounts of the CD administered and discarded were not recorded in the CD register; the centre is also using a CD register which is not suitable for the environment in which it is being used (section 4.11 DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007));
- during an egg collection, practitioners completed and signed the CD register to say a CD had been discarded before it had been (section 19 Misuse of Drugs (safe Custody) Regulations (2001));
- carry over amounts from one page to another had not been signed by two members of staff (section 4.7 DH 'Safer Management of Controlled Drugs, A guide to good practice in secondary care (England)' (2007));
- glucose injection in the resus trolley expired on the day of the inspection. The weekly trolley checks had been undertaken the day before the inspection and no replacement had been ordered. The inspection team was concerned that the process to document and check the shelf life of consumables and drugs within the resus trolley is not effective (SLC T2);
- the CD accountable officer (CDAO) had not applied to be registered on the register of CDAOs held by the CQC (section 10 DH: Controlled Drugs (Supervision of management and use) Regulation (2013)).

Recommendation 1.

Quality management system (QMS) (Guidance note 23)
During the inspection, several issues were identified:

- the counselling standard operating procedure (SOP) had not been reviewed within its specified review date, the ICSI SOP had not been updated in response to a corrective action resulting from an audit and two SOPs (production and witnessing) had discrepancies when describing the same procedure (SLC T33b);
- the counselling and legal parenthood SOPs incorrectly described the use of the PP consent form ('your consent to being the legal parent') by patients who were married or in a civil partnership, when it should have referred to the use of the PBR consent form ('your consent to being registered as the legal parent in the event of your death'). On discussion, staff were able to provide assurance that the WP, PP and PBR forms are correctly used in practice ('Consent forms: A Guide for Clinic Staff', HFEA (2019));
- for some incidents reviewed, investigation lacked robustness, as appropriate root cause analysis was not performed and corrective and/or preventive actions (CAPA) had not been identified or documented. Also, for some incidents, CAPA had not been closed within their scheduled closure dates (SLC T32, CoP Guidance 23.27 and 23.28);
- some audits lacked robustness, as they did not consider quality indicator monitoring data or document in response to non conformances, an appropriate

root cause analysis or CAPA with implementation dates (SLC T36, CoP Guidance 23.27 and 23.28);
- the following audits had not been performed within the last two years, contrary to HFEA requirements and the centre's annual audit schedule: IVF consent to treatment, IUI/DI consent, sperm donor recruitment and record keeping (SLC T36).

Recommendation 5.

Third party agreements (TPA) (Guidance note 24)
On inspection, five TPAs were reviewed. The content of the TPA with the European Sperm Bank (ESB) was not compliant with HFEA General Direction 0001 with regards to the compensation of overseas donors. The centre had also not re-evaluated the agreement to account for the new requirements for the screening of gamete donors, which came into force in October 2018. The inspection team noted however that no imports have taken place since the TPA was last reviewed in May 2018 (SLCs T53 and T112, General Direction 0001, Clinic Focus May 2018 and October 2018; recommendation 8).

Equipment and materials (Guidance note 26)
On inspection, the following non-compliances were identified:
- if a patient has no motile sperm, the laboratory uses a product in treatment which is CE marked for IVD use only. Patients are not informed that the product is not intended for use as a medical device and do not provide explicit consent to its use in treatment (SLCs T23 and T30, MHRA (2014) 'Off-label use of a medical device');
- staff were unable to provide evidence of validation for all critical equipment and, where present, some validation documents did not detail the critical operating parameters. One incubator had not been revalidated after a repair (SLC T24).

Recommendation 6.

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

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

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
This centre does not undertake embryo testing and therefore requirements related to their procedures were not relevant at this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only nine patients provided feedback in the last 12 months, giving an average four-star rating to the clinic.

This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it is important that every patient knows about the rating system. The inspection team discussed this with the PR. She explained this would be reviewed and agreed to address the issue. The inspection team was reassured that the PR will take appropriate actions to remedy the low feedback rate to the HFEA website.

The centre's own most recent patient survey responses (May 2018) were reviewed. The audit measured 'patient experience'. Of 118 patients who had returned the questionnaire, the average satisfaction scoring was 3.89 out of 4 (maximum score is 4 for excellent service).

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

- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are broadly 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 does not offer surrogacy treatments, therefore requirements related to its procedures were not relevant at this inspection.

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 broadly 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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
If patients in an egg-sharing agreement no longer wish to donate, the centre is charging them for the full cycle. This is not compliant with guidance which states 'if either the gamete provider or the recipient in a benefit in kind arrangement withdraws their consent to treatment after preparation has begun, the centre should bear any financial loss it sustains as a result' (SLC T58e, CoP Guidance 12.11).

It was also noted that egg sharing leaflets published by the centre in October 2018, advertised success rate information in percentages rather than raw numbers (CoP Guidance 4.8).

Recommendation 9.

Confidentiality and privacy (Guidance note 30)
The centre reported eight breaches of confidentiality to the HFEA in the last 12 months. Whilst these adverse incidents have been internally investigated, the inspection team is concerned that the investigation process is not robust enough, since any lessons learnt have not prevented further incidents from recurring (CoP Guidance 23.27, 23.28 and 30.1; General Data Protection Regulation (GDPR); recommendation 10).

Also see the non-compliance noted in the 'Safety and suitability of premises and facilities' section of this report and recommendation 2.

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/or donors are generally compliant with HFEA requirements, exceptions being noted in the 'egg sharing arrangements' and 'equipment and materials' sections 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 are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that three couples were affected by legal parenthood consent anomalies. All three couples have subsequently had their legal parenthood status established by the courts.

In May 2016, one case involving this centre was heard in the Family Division of the High Court, regarding the legal parenthood status of one couple, in which the centre was heavily criticised by the court. Following the judgement, the HFEA held a meeting with the PR, LH and key members of staff on 27 July 2016 to ascertain the details of the case and review the centre's actions since the incident and the judgement. As a result of the

meeting, the centre was required to conduct a full root cause analysis of the case, to consider the criticisms made by Sir James Munby and also to audit the effectiveness of the corrective actions taken. The root cause analysis was completed in November 2016 to the satisfaction of the Executive. An audit of legal parenthood was also provided which showed that corrective actions had been effective.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team at the interim inspection in May 2017 reviewed three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to consent and treatment in all cases. In summary, the inspection team considered the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

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

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

What the centre does well

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

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

The HFEA register audit team found no 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)
During the inspection, the following non-compliances were identified:

- staff visually identify patients and donors and a copy of their photographic ID is scanned onto their records; however, the staff member identifying patients and donors is not recorded in patient notes (SLC T46b);
- in three out of ten records reviewed, the inspection team observed poor scanning quality. On discussion, the issue has been identified by the centre and new equipment has been ordered. The inspection team is however concerned that the process for ensuring that all records are clear and readable is not sufficiently robust and may have serious implications (SLC T47).

Recommendation 11.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to two areas of major non compliance and one 'other' area of non compliance.

The PR provided information and evidence that all recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

Since the last inspection, the centre has not received any alerts relating to success rates.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Medicines management A significant number of non-compliances were identified: • there was a discrepancy in the amount of controlled drug administered recorded in two patients' records and in the CD register; • CDs in the register were not recorded in line with guidance; • fentanyl ampoules were shared between patients;	The PR should ensure that medicines management practices are compliant with regulatory requirements and best practice guidelines. Since the inspection, the PR has provided evidence that: the discrepancies in records of CD usage noted in the report have been reviewed; the sharing of fentanyl ampoules has been stopped; a suitable CD register has been sourced;	A root cause analysis and later a follow up summary report will be supplied as requested. The anaesthetist team have been fully sighted to this HFEA report and have reported that their practices have been routinely inspected and approved by the CQC throughout the Trust (ie. CDs in the register were not recorded in line with guidance,	The executive notes the PR's response and commitment to implementing this recommendation. The PR has confirmed that the centre will work to the appropriate standards and will be using the CQC self-assessment tool to further audit medicines management. The executive confirms receipt of the root cause analysis and

• drugs (including CDs), were not discarded in line with guidance; • the inspection team was concerned that the process to document and check the shelf life of consumables and drugs within the resus trolley is not effective; • the CDAO was not registered on the CQC register of CDAOs. SLC T2, The AAGBI 'Controlled Drugs in Perioperative Care' (2006), DH 'Safer Management of Controlled Drugs, A guide to good practice in secondary care (England)' (2007), Misuse of Drugs (Safe Custody) Regulations (2001), DH: Controlled Drugs (Supervision of management and use) Regulation (2013).	drugs are now disposed of in line with guidance; and the CDAO is now on the CQC CDAO register. The PR should conduct a root cause analysis into the circumstances which led to the discrepancies in CD records noted in this report, and also into the other failings in medicines management. This analysis should include corrective and preventive actions with timescales for implementation. A copy of the root cause analysis should be provided to the centre's inspector by 1 August 2019. The PR should seek an external review of the processes used to manage medicines, including actions to ensure their compliance with relevant legal requirements and best practice guidelines. A summary report of this review should be provided to the centre's inspector by 1 August 2019.	discard of drugs was not in line with guidance and fentanyl ampoules were shared between patients during a national shortage). We note the comments made by the Chief Inspector during the teleconference and agree that the fertility clinic intend to work to the appropriate standard. We are using the CQC self - assessment tool for further audits in addition to a booked external audit.	actions taken to address this non-compliance. The review has been discussed and reviewed at multi-disciplinary and nurse meetings. The PR provided suitable assurances during the teleconference meeting and has been proactive in implementing this recommendation. The executive has granted an extension for the submission of an external review related to medicines management now due by 1 September 2019. A summary report of a follow-up medicines management audit is now to be submitted to the centre's inspector by 1 December 2019. Further action required.

	Three months after the implementation of corrective actions, the PR should audit medicines management practice and procedures to ensure that corrective actions implemented, have been effective in achieving compliance. A summary report of this follow-up audit should be provided to the centre's inspector by 1 November 2019.		

Major area of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Safety and suitability of premises and facilities The following concerns related to the premises were observed: • there were exposed wires in the shower room, posing an electrical risk; • not all doors are fitted with 'free/occupied' signs; • the anaesthetist was observed checking her emails on her phone whilst her patient was having an egg collection under sedation; • theatre access is not restricted and several staff	The PR should ensure that suitable premises and facilities are provided. The PR should provide a report of their response to these concerns regarding the premises with planned actions and timescales for implementation, to the centre's inspector by 1 August 2019. The PR should investigate why a qualified medical practitioner was on her phone, instead of monitoring a sedated patient. A summary of the investigation, including any	The report will be provided.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a summary report of the actions taken in response to the safety and suitability of premises and facilities concerns. The PR has confirmed that all corrective actions have been implemented, staff training, and documentation updated where applicable.

entered the room whilst a patient was undergoing her procedure. SLC T2, CoP 25.9, DH Health Technical Memorandum 06-01 Electrical services supply and distribution (2017), Safe Sedation Practice for Healthcare Procedures, Standards and Guidance (2013).	corrective actions, with timescales, should be provided to the centre's inspector by 1 August 2019.		The PR has also confirmed that, as a preventive action, a telephone in theatre is to be installed to reduces disturbances. No further action required.
3. Laboratory accreditation Evidence was not available that the laboratory that performs sperm DNA damage testing for the centre's patients, or the test itself, is appropriately accredited. The test is under performance evaluation, and each patient tested is participating in ongoing performance evaluation. This is not made clear in the information about the test provided to patients. SLCs T21 and T58.	The PR should ensure that laboratories performing diagnostic tests, or the tests themselves, are appropriately accredited, and that accurate and effective information is provided to patients regarding diagnostic tests. The actions to be taken to implement this recommendation should be provided by the PR in the response to this report. The PR should provide a report of their response to these concerns regarding the laboratory accreditation with planned actions and timescales for implementation,	The clinic recommends sperm DNA fragmentation testing to a small number of patients based on very specific medical criteria, as outlined in our clinical SOP. We appreciate the feedback from the HFEA on this matter and have updated our clinical SOP to be explicit about the accreditation status of the test/ lab when counselling patients. We have also updated our patient information sheet accordingly. The clinic concurs that for this specific group of patients, the test can provide one element in a portfolio of information to assist decision-making	The executive notes the PR's response and commitment to implementing this recommendation. The PR has confirmed that the clinical SOP and patients' information sheet have been amended in response to this report. No further action beyond submission of the summary report due by 1 November 2019.

	to the centre's inspector by 1 November 2019.	regarding future treatment. Therefore we will continue to offer this test where the clinician feels it is beneficial, in conjunction with the appropriate information and counselling. The updated information sheet and SOP are now on QPulse waiting for Medical Director authorisation.	
4. Infection control Several non-compliances were identified related to infection control: • One sharps bin was placed directly on the floor, two sharps bins did not have their temporary closure in use and several full sharps bins were stored in a dirty utility room beyond the agreed collection schedule; • there were several items on the floor in the centre's store room; • the seating in a production room was porous and not of a suitable wipe clean fabric; • several bottles used to collect blood samples were out of date;	The PR should ensure compliance with infection control regulations. Since the inspection, the PR has provided evidence that all staff have individual lockers. The PR should investigate why personal belongings were brought into theatre, instead of being stored in the lockers provided. A summary of the investigation, including any corrective actions, with timescales for implementation, should be provided to the centre's inspector by 1 August 2019.	The report will be provided	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a summary report of the actions taken in response to the infection control issues. The PR has confirmed that all corrective actions have been implemented, training given, and documentation updated when appropriate. No further action.

• staff were using out of date needles and syringes for demonstration purposes, and re-sheathing after use. Out of date stock was being stored alongside in-use stock, without clear separation; • an outdoor backpack was brought into theatre during a procedure. SLC T2, NHS Community Infection Prevention and Control Guidance for Health and Social Care, Sharps Management and Inoculation Injuries. Version 1.01 (2015), The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (2015), DH Health Building Note 00-09: 'Infection control in the built environment' (2013).	The PR should consider the infection control issues identified in this report and should take actions to address them. A report of the PR's considerations including planned actions with timescales for implementation, should be provided to the centre's inspector by 1 August 2019.		
5. QMS Several issues were identified within the QMS: • several SOPs had not been reviewed within required time frames or were inaccurate or misleading or	The PR should ensure that the QMS is effective and fit for purpose. The PR should review and update the SOPs identified in this report as causing concern	The updated documents and the report will be provided.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a summary report of the actions

had not been appropriately updated; • investigation of some incidents lacked robustness; • some audits lacked robustness or had not been performed within documented timescales, or timescales set by the HFEA. SLCs T32, T33b, T35, T36, CoP 23.27 and 23.28, 'Consent forms: A Guide for Clinic Staff', HFEA (2019).	and provide a copy of the updated SOPs to the centre's inspector by 1 August 2019. The PR should review practice and processes with regards to investigating incidents and non-compliances found during audits. A summary report of this review, including corrective actions, with timescales for implementation, should be provided to the centre's inspector by 1 August 2019. The PR should ensure that audits which have not been performed within the scheduled timeframes are conducted. A summary report of these audits should be provided to the centre's inspector by 1 November 2019.		taken in response to the QMS concerns. The PR has provided an updated copy of all the relevant SOPs cited in this report. The PR has provided assurance that the legal parenthood SOP wording is being reviewed to meet compliance. The PR has confirmed that all corrective actions have been implemented, training scheduled as and when required, and documentation updated when appropriate. No further action beyond submission to the centre's inspector of a summary report of all outstanding audits identified in this report by 1 November 2019.
6. Equipment and materials On inspection, the following non-compliances were identified: • if a patient has no motile sperm, the laboratory uses a product in treatment which is CE marked for IVD	The PR should ensure that patient information clearly documents when products used in treatment are intended for IVD use only and are being used 'off label' for treatment purposes. The patients should be made aware of the	SpermMobil is a product used at our centre in the very small number of ICSI patients who have no motile sperm. We estimate this to be fewer than 10 patients per year. Although only licensed for IVD use, for this select group of patients it	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided the IVF Lab and pharmaceutical

use only. Patients are not informed that the product is not intended for use as a medical device and do not provide explicit consent to its use in treatment • staff were unable to provide evidence of validation for all pieces of critical equipment. SLCs T23, T24 and T30; MHRA (2014) 'Off-label use of a medical device'.	potential risks involved and should provide informed consent to the use in treatment of such products. The PR should ensure each item of critical equipment is appropriately validated. The PR should review critical equipment validation and identify items that are not appropriately validated. A summary of the review should be provided when responding to this report. Where validation records are deficient, appropriate validation records should be documented by 1 August 2019, at which time the centre's inspector will request a selection for review.	can make the difference between parenthood or childlessness and is therefore of significant clinical value. We have taken on board the feedback from our inspectors and we are creating a new information sheet and consent form explaining why SpermMobil may be recommended for use in their case. This will be provided to all SSR patients and patients who are freezing back up sperm samples due to poor motility prior to treatment. We will also update our fertilisation phone call checklist to ensure that patients are informed when SpermMobil has been used clinically. A review of critical equipment validation showed that in addition to the IVF lab fridge, one additional item of critical equipment had not been appropriately validated - the pharmaceutical fridge. (Relevant validation documents will be sent with this report). The lack of re-	fridges validations, which were satisfactory. The PR has provided a copy of the new patient information/ consent form to the use of SpermMobil and offered assurance that the comments cited in this report have been acted upon. The PR has provided a summary report of the root-cause analysis related to the lack of re-validation of the MINC. The PR has confirmed that all corrective actions have been implemented and the incubator has been validated. No further action.

		validation of the MINC incubator after repair will be reported as a non-conformity and investigated accordingly. KPI results and 24 our temperature monitoring have confirmed that this incubator has been operating without cause for concern since it was repaired.	

Other areas of practice that requires improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
7. Payments for donors The inspection team noted that the centre's marketing banners placed an emphasis on financial gain rather than altruism for egg donation, which is not compliant with guidance. CoP 11.1.	The PR should ensure advertising and marketing materials related to gamete donation are compliant with HFEA requirements and guidance. The PR should review all marketing materials relating to egg donors to ensure compliance. A summary report of this review, including any corrective actions, with timescales, should be provided to the centre's inspector by 1 August 2019. The centre's inspector should be informed of the actions taken to implement this recommendation by 1 August 2019.	All marketing material of this nature will be removed from display by 1st Aug 2019 and a report supplied.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a summary report of the review of all marketing materials. The PR has confirmed that all marketing materials have been removed following the inspection; all materials have been reviewed in response to this report: the amount of compensation has been removed from banners, patients' leaflets and the centre's website; where applicable, the centre now advertised 'donors will be compensated up to the permitted legal amount'.

			No further action.
8. TPAs The content of the TPA with ESB was not compliant with General Direction 0001 requirements regarding the compensation of overseas donors. The TPA and the service arrangement have also not been revised to incorporate the new requirements for the screening of gamete donors, which came into force in October 2018. SLCs T53, T112, General Direction 0001, Clinic Focus May 2018 and October 2018.	The PR should ensure that all TPAs are reviewed to ensure compliance with current HFEA requirements. A summary report of this review, including any corrective actions, with timescales for implementation, should be provided to the centre's inspector by 1 August 2019. The PR should update the TPA with ESB and should also review the compliance of ESB's activities with current HFEA requirements. A copy of the revised TPA and the compliance review should be provided to the centre's inspector by 1 August 2019. The PR should raise a non-compliance with ESB for failing to communicate with the centre regarding overseas donors' compensations changes. This non conformance should be investigated by ESB and,	The report will be provided. The ESB TPA has been updated and a copy will be provided. A non conformance with ESB has been raised.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a copy of the revised TPA with ESB and confirmation that a non-conformance has been raised with ESB. The PR has provided a summary report of the TPAs review which confirmed compliance. No further action.

	under the terms of the existing TPA, a copy of the incident investigation should be shared with the centre. The centre should provide the centre's inspector with the investigation report by 1 August 2019.		
9. Egg sharing arrangements If patients in an egg-sharing agreement no longer wish to donate, the centre is charging them for the full cycle. Egg sharing leaflets published by the centre in October 2018, advertised the success rate as a percentage, but did not provide raw numbers. SLC T58e, CoP Guidance 4.8 and 12.11.	The PR should ensure that, if either the gamete provider or the recipient in a benefit in kind arrangement withdraws their consent to treatment or donation after preparation has begun, the centre should bear any financial loss it sustains as a result. The PR should review practices and procedures relating to egg sharing arrangements to ensure their compliance with all HFEA requirements and Guidance. A summary report of this review, including any corrective actions, with timescales for implementation, should be provided to the centre's inspector by 1 August 2019.	A report will be provided.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a summary report of the review of the egg sharing arrangements concerns. The PR has confirmed that all corrective actions have been implemented, including the review of the clinic terms and conditions of treatment for egg sharers and success rates are now presented with raw figures alongside percentages. No further action.
10. Confidentiality and privacy	The PR should ensure that appropriate measures are in	A report will be provided	The executive notes the PR's response and commitment to

Eight breaches of confidentiality were reported in the last 12 months and the inspection team is concerned that the investigation process is not robust enough, since any lessons learnt have not prevented further incidents from recurring. CoP Guidance 23.27, 23.28 and 30.1; GDPR (2018),	place to maintain patients' confidentiality. The PR should investigate why eight breaches of confidentiality happened and highlight any possible trends allowing these incidents to recur. A summary of the investigation, including any corrective actions, with timescales for implementation, should be provided to the centre's inspector by 1 August 2019.		implementing this recommendation. The PR has provided a summary report of the review of the confidentiality breaches. No trend was identified. The PR has confirmed that all corrective actions have been implemented, further training has been scheduled for staff and breaches of confidentiality will be monitored to further ensure compliance. No further action.
11. Record keeping and document control During the inspection, some non-compliances were identified: • When recording the photo ID of patients and donors, the staff by whom the patient/donor has been reliably identified is not recorded; • in three out of ten records reviewed, the inspection team observed poor scanning quality.	The PR should ensure the staff member identifying patients and donors against photographic ID is documented in the records and is traceable. The PR should ensure that all records are legible and readable. Since the inspection, the PR has provided evidence that new equipment (scanners) have been purchased.	A report will be provided	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided a summary report of the review of the record keeping and document control concerns. The PR has confirmed that all corrective actions have been implemented, including a review of the process for traceability of patients' ID checks.

SLCs T46b and T47.	The PR should review practices and procedures relating to record keeping and document control, including, but not exclusively, the issues identified in this report. A summary report of this review, including any corrective actions, with timescales, should be provided to the centre's inspector by 1 August 2019.		No further action.

Reponses from the Person Responsible to this inspection report
We thank the inspectors for the feedback and will be providing all requested reports within the agreed timescales.