Licence Committee - minutes

Centre 0357 (Thames Valley Fertility)
Renewal Licence

Thursday, 11 July 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Eve Piffaretti	Blake Morgan LLP
Specialist Adviser		
Observers	Alistair Robertson	Solicitor (Induction)

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Renewal Inspection Report
- Application form
- Previous licensing minutes for the last three years:
    - 30 June 2017 - Executive Licensing Panel (ELP) - Initial Inspection Report
    - 10 October 2018 - Executive Licensing Panel (ELP) - Change of Person Responsible
    - 10 October 2018 - Executive Licensing Panel (ELP) - Interim Inspection Report
- Importing Tissue Establishment (ITE) Import Certificate

1. Background

1.1. Thames Valley Fertility is located in Maidenhead, Berkshire. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2017 and provides a full range of fertility services.

Current Licence

1.2. The centre's current licence was issued for a period of 2 years with no additional conditions. An Initial treatment (including embryo testing) and storage licence would normally be offered for up to two years as there would be no history of compliance to support a longer licence.

1.3. The centre's licence was varied to reflect a change of Person Responsible (PR) in 2018.

1.4. The current licence expired on 10 July 2019. The committee noted that the Executive Licensing Panel granted Special Directions for the continuation of the centre's licensed activities during the licensing process.

The Fertility Partnership Group

1.5. Thames Valley Fertility is part of The Fertility Partnership corporate group of seven HFEA licensed centres which includes:

- Oxford Fertility, centre 0035
- Nurture, centre 0076
- IVF Hammersmith, centre 0078
- GCRM Glasgow, centre 0250
- Boston Place, centre 0327
- Simply Fertility, centre 0336
- Thames Valley Fertility, centre 0357

1.6. Quality management across the group is coordinated, notably regarding audits, quality indicator (QI) monitoring and working policies. However local standard operating procedures (SOPs) can vary from the group policies depending on local conditions. Audit findings, QI monitoring data, SOPs and centre forms and other documents are exchanged between the centres, as is knowledge via coordinated sharing of experienced staff.

1.7. As centres in The Fertility Partnership group do not currently operate under common practices and procedures across all areas, this renewal inspection was not undertaken using the HFEA's 'group approach' methodology.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the treatment (including embryo testing) and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 31 January 2019, the centre provided 491 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is small centre.

2.4. The committee noted that HFEA-held register data for the period 1 January 2018 to 31 December 2018 for IVF and ICSI, showed the centre's success rates were in line with national averages.

2.5. The committee noted that in 2018, the centre reported six cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

2.6. Between 1 January 2018 to 31 December 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 10%, which is in line with the 10% maximum multiple live birth rate target.

2.7. The committee noted that the renewal inspection took place on 27 and 28 February 2019. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there was one critical, two major and three other areas of non-compliance identified:

Critical areas of non-compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory requirements.

Major areas of non-compliance:

- The PR should ensure that the centre has an effective and robust QMS, compliant with CoP requirements and guidance;
- The PR should ensure that all staff members receive training and that their competence to undertake their designated tasks is assessed.

Other areas of non-compliance or poor practice:

- The PR should ensure that all patients have their baseline vital signs assessed and documented pre-operatively;
- The PR should review the centre's third party agreements to ensure that they meet CoP requirements;
- The PR should ensure that all licensed treatment activity is reported to the Authority as required by General Direction 0005.

2.8. The committee noted that since the inspection visit, the PR has committed to fully implementing all of the recommendations.

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

2.10. The centre has a Quality Management System (QMS) and the PR is encouraged to continue to use it to monitor and improve its success rates and the quality of the service offered to patients.

2.11. The Executive has confirmed that the Fertility Partnership as a whole has put surrogacy on hold with the exception of those already in treatment, to review their practices.

2.12. The committee noted that the inspectorate will continue to monitor the centre's performance and the implementation of the recommendations within the required timescales.

Management review meeting - 4 April 2019

2.13. The Executive held a management review meeting on 4 April 2019 in accordance with the HFEA's Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation for the renewal application.

2.14. It was concluded that the issues of concern were significant, posed direct risks to patients and were not compliant with the HF&E Act 1990 (as amended) and other relevant legal requirements, notably concerning medicines management practices and the QMS.

2.15. The Executive considered whether the PR has failed to discharge his duty under section 17(1)(d) and (e) of the HF&E Act 1990 (as amended) because he has failed to ensure that suitable practices were used in the course of activities. The PR had been in post for approximately three months prior to the inspection, therefore the Executive accepted that this was not adequate time for the PR to detect the areas of concern and to correct them. However, the Executive expects that, if the PR is to discharge his duty appropriately, he will fully engage in implementing the recommendations of this report and will ensure the centre's full compliance at the next inspection.

Recommendations

Licence

2.16. Taking all of the issues into account, the Executive recommended that the centre's licence should be renewed for three years, rather than the usual four, providing that the PR develops and implements effective action plans to address all of the non-compliances. This recommendation would allow a targeted interim inspection to be performed within one year of the Licence Committee's decision, when the implementation of the recommendations and the centre's general compliance will be assessed.

Importing Tissue Establishment (ITE) Import Certificate

2.17. The committee noted that centre 0357 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The committee noted that the inspectorate recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Mr Jon Taylor

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge his duties under section 17 of the HF&E Act 1990 (as amended).

3.4. The committee had some concerns about whether the character of the proposed PR is such as is required for supervision of the licensed activities, however the committee noted that the PR had only been in the post for a short period before the inspection took place and this was not adequate time for the PR to detect the areas of concern and to correct them. The committee noted that the implementation of the recommendations and the centre's general compliance will be assessed at the next inspection. The committee expects the PR to discharge his duty appropriately and engage with the Executive. It is hoped that the PR will have full knowledge and understanding of his role and responsibilities and of the staff working within the team, and will have developed systems through which he is able to lead the centre in a compliant manner.

Proposed Licence Holder (LH) – Ms Judith Fleming

3.5. The committee was satisfied that the proposed LH is suitable.

Activities

3.6. The committee was satisfied with the suitability of the activities applied for.

Premises – Clarion House, Ground Floor, Norreys Drive, Maidenhead, Berkshire, SL6 4BY

3.7. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.8. The committee was satisfied that the third-party premises are also suitable.

Licence

3.9. The committee had regard to the HFEA Guidance on licensing and considered the duration of licence it should offer. The committee considered the number and nature of non-compliances identified and the impact on the quality of service provided by the centre. Carefully weighing all factors in the balance, the committee agreed that a three-year licence, subject to the implementation of the recommendations outlined in the renewal inspection report, was appropriate. If no representations regarding the proposed decision or any other information is received within 28 days, the committee agreed for the final licence to be issued.

3.10. The committee agreed that the inspectorate should complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance. The committee also asked that the group situation with regard to surrogacy is reviewed at the next inspection.

Importing Tissue Establishment (ITE) Import Certificate

3.11. The committee endorsed the Executive's recommendation to renew the Importing Tissue Establishment (ITE) import certificate.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

31 July 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 Licensing Committee (LC) 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: 27 and 28 February 2019

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

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

Inspectors: Grace Lyndon (lead), Louise Winstone, Katie Best and Polly Todd (observer)

Date of Executive Licensing Panel: 21 May 2019

Centre name	Thames Valley Fertility
Centre number	0357
Licence number	L/0357/1/b
Centre address	Clarion House, Ground Floor, Norreys Drive, Maidenhead, Berkshire, SL6 4BY, United Kingdom
Person Responsible	Mr Jon Taylor
Licence Holder	Judith Fleming
Date licence issued	11 July 2017
Licence expiry date	10 July 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Thames Valley Fertility is situated in Maidenhead and has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2017. The centre provides a full range of fertility services.

The centre provided 491 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2019. In relation to activity levels this is small centre.

The Centre submitted an application for the variation of Licence for the change of PR which was successful and granted in October 2018.

Thames Valley Fertility is part of The Fertility Partnership corporate group of HFEA licensed centres, which includes Boston Place (0327), Oxford Fertility (0035), IVF Hammersmith (0078), GCRM Glasgow (0250), Nurture (0076) and Simply Fertility (0336). Quality management across the group is coordinated, notably regarding audits, quality indicator (QI) monitoring and working policies, however local standard operating procedures (SOPs) can vary from the group policies depending on local conditions. Audit findings, QI monitoring data, SOPs and centre forms and other documents are exchanged between the centres, as is knowledge via coordinated sharing of experienced staff. As centres in The Fertility Partnership group do not currently operate under common practices and procedures across all areas, this inspection was not undertaken using the HFEA's 'group approach' methodology.

Pregnancy outcomes[1]

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

In 2018, the centre reported six cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between 1 January 2018 to 31 December 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%, which is in line with the 10% multiple live birth rate target.

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

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

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) 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 his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The LC 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, two major and three 'other' areas of non compliance.

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

Critical areas of non compliance:

- **The PR should ensure that medicines management practices at the centre are compliant with regulatory requirements.**

Major areas of non compliance:

- The PR should ensure that the centre has an effective and robust QMS, compliant with CoP requirements and guidance;
- The PR should ensure that all staff members receive training and that their competence to undertake their designated tasks is assessed.

'Other' areas that require improvement:

- The PR should ensure that all patients have their baseline vital signs assessed and documented pre-operatively;
- The PR should review the centre's third party agreements to ensure that they meet CoP requirements;
- The PR should ensure that all licensed treatment activity is reported to the Authority as required by General Direction 0005.

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

Recommendation to the Executive Licensing Panel

The centre has one critical, two major and four other non compliances or poor practice.

Given the critical and major non compliances identified during this inspection, the executive held a management review meeting on 4 April 2019 in accordance with the HFEA's Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application. The management review found that the issues of concern were significant, posed direct risks to patients and reflected non compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements, notably concerning medicines management practices and the quality management system (QMS). Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR should use it to monitor and improve the service provided.

The management review considered if the PR has failed to discharge his duty under section 17(1)(d) and (e) of the HF&E Act 1990 (as amended) because he has failed to ensure that suitable practices are used in the course of activities. The management review noted that the PR had been in post for approximately three months prior to the inspection and accepted that this was not adequate time for the PR to detect the areas of concern and to correct them. The management review expects however that the PR, if discharging his duty appropriately, will fully engage in implementing the recommendations of this report and will ensure the centre's full compliance at the next inspection.

Taking the above into account, the management review concluded that the centre's licence should be renewed for three years. This recommendation is conditional on the PR developing and implementing effective action plans to address all non-compliances in the centre's activities. If the inspection team considers that the PR's responses to this report are unsuitable, this licensing recommendation may be changed.

In conclusion, the executive recommends the renewal of the centre's treatment (with embryo testing) and storage licence for a period of three years, rather than the usual four. This recommendation will allow a targeted interim inspection to be performed within one year of the LC decision, at which the centre's compliance generally, and with regard to the implementation of this report's recommendations, will be assessed.

Thames Valley Fertility has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

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)
This area was not reviewed during the inspection as our priority was to review the critical non compliance found during the inspection.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are 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 transport facilities and laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by 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 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 requirements.

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 broadly 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 and 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. This centre has been allocated an ITE import certificate and all recent imports of gametes and embryos from outside the EU/EEA have been from TCSs specified in the import certificate. 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 (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, including those associated with ITE/TCS import certificates, are broadly compliant with HFEA requirements.

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all 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 (Guidance Note 25)
The following non compliances were observed:

- One ampoule of 'Fentanyl' was not accounted for and further immediate investigation was required;
- The Controlled Drugs Accountable Officer (CDAO) has access to the controlled drugs supply and handles controlled drugs;
- The drugs prescribed post operatively were not always signed for by the prescriber;
- A patient's identity was not always documented consistently between the patient notes and the controlled drugs register;
- There is not a registered and trained member of staff in theatre to routinely check the controlled drugs with the anaesthetist, or to witness the supply, administration or destruction of the controlled drugs;
- Non standard abbreviations were used to document drugs in the patient's records;
- The full drug name, strength, concentration and unit is not always documented.

An entry in the controlled drugs register was missing the patient name and identifier yet the responsible person and witness had both signed that controlled drugs had been given to this 'patient'. No amounts were documented for the drug supplied, administered or discarded. The prescription sheet in this patient's records included the amount of drug administered to the patient, but this was not signed by the prescriber. The lead nurse was advised to document these findings as an incident and report it to the HFEA.

The controlled drugs register contained some entries which were not dated, properly witnessed or clearly legible, or where the patient was not properly identified or alterations made in accordance with best practice guidance. Entries were also sometimes not in date order, suggesting that some entries were not made contemporaneously. New pages sometimes did not include the 'carried forward from' page number, the signatures of both the responsible person and the witness and the carried forward stock balance.

Due to the severity and number of non compliances related to medicines management seen at this inspection, and the recurrence in one case, this non compliance was graded as a critical. (SLC T2; T15(a); CoP 25.21; 25.23; Controlled Drugs (Supervision of Management and Use) Regulations 2013; The Misuse of Drugs Regulations, 2001; Section 2); see recommendation 1).

Considering the significant non compliance in medicines management practices, the inspection team discussed with the PR ways to safeguard patients and staff. The PR agreed to immediately:

- Find out who the 'un-named' ampoule of medication had been given to. The centre reviewed treatments and located the patient that had treatment that day. The patient notes were reviewed and the amounts given and discarded reflected that of the controlled drugs register;
- Archive the controlled drugs register and commence with a new controlled drug register;
- Instruct staff to comply with the centre's policies regarding documenting the use of controlled drugs;
- Instruct staff that only those who have signed the controlled drug register signature log should give or witness the administration or destruction of controlled drugs.

The PR also agreed to:

- Undertake an independent review of the centres medicines management systems and provide staff with appropriate training in the use and management of controlled drugs;
- Ensure staff are appropriately trained and competent, before undertaking the receipt, storage, administration and disposal of any controlled drugs;
- Review the audit process to ensure the audits assess the compliance of practices against all legal requirements and best practice guidance;
- Ensure there are adequately trained staff in theatre to witness the supply, administration and discard of controlled drugs;
- To audit the new processes and provide the HFEA with a summary of the audit within three months.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The pre-operative vital signs are not always documented in a patient's notes or using the pre operative assessment pathway record sheet, before procedures are undertaken. This leads to a risk that pathological deviations in vital signs will not be quickly identified, undermining patient care (SLC T2; see recommendation 4).

Quality Management System (Guidance note 23)
The inspection team noted that:

- Regulatory requirements are not audited against;
- The monthly audits of medicines management are not robust and had not detected the multiple non compliances seen by the inspection team in this area of practice;
- The counselling audit was not robust and was limited in its scope as it only contained numbers of patients that had taken up counselling;
- The welfare of the child (WoC) audit did not review the content of the WoC form, but only checked the presence of the form in the medical records;
- The anaesthetist holds the controlled drugs keys during the morning procedures, contrary to the centre's SOP regarding the management of the controlled drugs keys.

The centre has not audited the following areas of practice in the last two years:

- Provision of information;
- Donor recruitment, assessment and screening;
- Record keeping;
- Submission of data to the HFEA.

The centre does not have SOPs to cover the following areas of practice:

- Provision of information;
- Record keeping – how long files are stored, and the processes for destruction or recall of stored or electronic patient notes, are not included;

The SOP and patient information sheet describing the process by which patients can access their records and other data, need to be revised. This is because these documents state there is a £25 charge if a copy of the patient record is requested, yet this charge has not been levied since May 2018.

The centre has not established quality indicators in the following areas of practice;

- Record keeping;
- Medicines management;
- Infection control.

SLC T32; T33b; T34; T35 and T36; see recommendation 2.

Third party agreements (Guidance note 24)
A review of a selection of the centre's third party agreements showed that their content did not meet HFEA requirements. For example, the third party agreement with The Doctor's Laboratory did not discuss the centre's requirements or specifications for the service to be provided, e.g. how the centre will receive test results and the timescales within which tests should be performed (SLC T113; see recommendation 5).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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

The PR's leadership was considered by the inspection team, in light of the volume and severity of the non compliances noted within this report. The PR had been in the role for three months at the time of the inspection. The inspection team accepted that he had not been in post for long enough to identify the non compliances and make changes. The PR's leadership will be a key focus at the next inspection. It is hoped that the PR will have full knowledge and understanding of his role and responsibilities as PR and of the staff working within the team, and will have developed systems through which he is able to lead the centre in a compliant manner.

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

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

What the centre could do better

Staff (Guidance note 2)
On inspection it was noted that:

- The competence of staff to undertake treatments involving surrogacy arrangements, to perform WoC assessments and to guide patients providing consent to disclosure, has not been assessed;
- The quality manager could not provide evidence of an assessment of their competence to perform the role;
- As discussed above in 'Medicines Management', a qualified and competent nurse is not available in theatre during oocyte retrieval, to witness the administration and disposal of controlled drugs

SLC T12, T14 and T15; see recommendation 3.

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

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

The centre ensures that people seeking embryo testing are given written information and 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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 44 patients have provided feedback in the last 12 months regarding their treatment at Thames Valley Fertility, giving an average 4.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting the personal service at the clinic.

The centre's most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

During the inspection the inspectors spoke to one patient who also provided positive feedback on their experiences.

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

- treats patients with privacy and dignity;
- 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)
This area of practice was not reviewed as the centre does not undertake egg sharing arrangements.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are 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
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.

While the focus on legal parenthood consenting has been in place since February 2014, this centre only opened in July 2017. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing.

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 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 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 broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better
Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. To do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

4% (4/112) of the IVF treatments reviewed post inspection had not been reported to the HFEA (General Direction 0005).

The donor insemination (DI) data provided by the centre for post inspection review was found to be incomplete. The centre's data set provided 21 DI cycles, however, the HFEA register data contained only 14 DI cycles.

With respect to the treatments within our sample, 94% (102/112) of the IVF and 93% (13/14) of the DI treatments reviewed post inspection had been reported to the HFEA within the period required by General Direction 0005.

These findings indicate that the centre's procedures for submitting information about licensed activities, to the Authority are broadly compliant with HFEA requirements.

General Direction 0005; SLC T41; see recommendation 6.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to one 'other' non compliance related to medicines management.

The PR provided information and evidence that the recommendation had been fully implemented, however, significant medicines management non compliances were seen at this inspection and have been graded as a critical non compliance.

On-going monitoring of centre success rates

The centre has only been providing treatments for approximately two years and monitoring of success rates using the risk tool will not have been reliable in the first year of treatment due to low activity, but also because of the slow treatment data submission. The centre has assured the inspection team that they will review the procedures for the provision of treatment information and that they are committed to keeping their success rates under review.

Areas of practice requiring action

This 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 number of concerns were identified in medicines management practice, as detailed in the main body of the inspection report. A catalogue of inaccuracies and non compliances was observed, giving the inspection team little reassurance that medicines are effectively managed, in line with the	The PR should ensure that medicines management practices at the centre are compliant with regulatory requirements. The PR should carry out a thorough review of the practices used to manage controlled and non controlled drugs. This review, including proposed actions to address non compliances identified	We accept the points highlighted by the inspection in relation to the medicines management practices. The Controlled Drugs (CD) register was immediately archived and a new register was placed in the procedure room on the second day of the inspection (28.2.19). Since the inspection, we have revised the Controlled Drugs SoP and revised the CD audit checklist. All	The Executive acknowledges the PR response to this critical non compliance. No further action beyond submission of the medicines management audit report due by 28 August 2019.

requirements of The Misuse of Drugs Regulations, 2001 and professional body guidance. SLC T2; T15(a) CoP 25.21; 25.23.	including the provision of appropriate training, should be forwarded to the centre's inspector when responding to this report. The PR should review the requirements of the CDAO role and ensure that the person undertaking this role fully satisfies these requirements. This should include, but is not exclusive to, having the necessary competence, knowledge and authority to undertake the role. Three months after the implementation of corrective actions, the PR should audit medicines management practices, to ensure that the actions taken have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 28 August 2019.	Anaesthetists were required to read and acknolwegde via email the revised CD SoP. A thorough CD Audit was carried out and the actions from this audit have been completed with regular updates submitted to our inspector. The CDAO role has been reallocated. This will be undertaken by the PR to ensure independence in relation to the safe administration and handling of CDs. CDAO training will be completed.The HFEA register will be updated to reflect this as soon as the application has been approved. A weekly CD audit was carried out for 8 weeks to ensure processes are being followed as per the revised SoP. All audits showed 100% compliance and will now be undertaken on a standard monthly basis. However, should any future non-compliances be identified we will revert to weekly audits.	

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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. QMS A number of issues concerning the QMS were identified, as detailed in the main body of the inspection report. SLCs T32, T33, T34, T35 and T36.	The PR should ensure that the centre has an effective and robust QMS, compliant with CoP requirements and guidance, to improve the quality and effectiveness of the service. The PR should complete a comprehensive review and revision of the QMS to ensure its compliance. This includes, but is not exclusive to: • Review all SOPs to ensure they are compliant with regulatory and statutory requirements and document	The QMS is an ever evolving system and under regular review as the clinic grows. The clinic has an audit plan with regular audits completed since opening. We are still within the first 2 year period of operating and have undertaken audits in many areas of practice and would anticipate completion of the comprehensive first cycle as per 2 year requirement. Many areas will have undergone multiple audits within this period. An audit schedule to show areas of practice and related	The Executive acknowledges the PR's response and is in agreement with the process of Quality Management being a continuously evolving critical area of practice and should reflect the guidance of the Code of Practice and the Law, however, this was not evident in all cases during the inspection as discussed within the body of the report. The PR should ensure that a sample of SOP's, audits and QI's for the critical activities and processes, are sent to the

	procedures for all activities authorised by the licence; • Ensure QIs are in place for all key activities and processes; • Ensure robust audits of all areas of practice are performed, that review the compliance of SOPs and practices with CoP and other requirements. • The PR must address all QMS issues detailed in this report. The PR must ensure that staff have the appropriate training and competence to undertake robust audits of practice and procedure. The PR should provide a copy of this QMS review, including details of the actions to be taken with timescales for implementation, to the centre's inspector when responding to this report. It is expected that the centre will have a fully compliant and effective QMS in place by 28	policy or SoP was provided to demonstrate this activity at inspection. The QMS includes the requirement for a minimum of annual document review. This process is managed via Q Pulse and this was demonstrated at inspection. An integral part of the review process for any SOP is to ensure that it reflects current practice and that this practice is compliant with relevant regulatory and statutory requirements. A summary of Quality Indicators (QIs) was provided at the initial inspection and also at the renewal inspection with no comment. As part of our evolving QMS, our QIs and audit plan have been developed further. Many robust audits were provided during the inspection. Historically, the staff undertaking the audits have significant experience of	centres inspector with a summary detailing compliance with regulatory requirements by 28 August 2019. Further action required.

	August 2019.	working in HFEA licensed settings and undertaking audits which are pertinent to the CoP and regulatory requirements.To ensure future audit reliability all staff undertaking audits will undergo audit training. An effective QMS by its nature is ever evolving and as such there is no end date to completion. An updated QI table has been distributed to the team and the audit schedule, including controlled document review, continues to be actioned and monitored. We consider this to be an ongoing process with no additional action required.	
3. Staff On inspection it was noted that: • The competence of staff to undertake treatments involving surrogacy arrangements, to perform WoC assessments and to guide patients providing consent to disclosure,	The PR should ensure that all staff members receive training and that their competence to undertake their designated tasks is assessed. The PR should review staff training and competence assessment to ensure it is compliant with requirements. A	Competency assessment with respect to Surrogacy has not been undertaken as we are not currently offering this treatment. Surrogacy is addressed in section 6. All staff undergo a comprehensive orientation and induction programme with	The Executive notes the PR's response, however, the inspection team found that practice did not align with centre procedures or best practice. The Executive cannot reconcile the relevance of the 'Zone' area as there was not a

has not been assessed; • The quality manager could not provide evidence of an assessment of their competence to perform the role; • As discussed above in 'Medicines Management', a qualified and competent nurse is not available in theatre during oocyte retrieval, to witness the administration and disposal of controlled drugs SLC T12, T14 and T15.	copy of the review, including the actions to be taken to rectify shortcomings, with timescales for implementation, should be provided to the centre's inspector when responding to this report. The PR should ensure that all staffing concerns noted in this report are addressed by 28 August 2019, and centre's inspector is advised.	some generic elements as well as department and role specific elements. Records of orientation and training are held for each member of the team. This log also includes records of training courses and professional activities as well as competency sign offs for specific activities. Staff training and competence is regularly reviewed by line managers and also at Group level and includes individual performance reviews as part of the appraisal process. Generic training plans for each role are being developed and implemented to ensure training consistency and support across all clinics. A selection of staff training logs were provided to the inspection team and we were delighted with to the complimentary feedback received during the inspection. The clinic has adequate numbers of appropriately	registered practitioner in theatre to witness the administration and the discard of controlled drugs and the attendance of the recovery nurse going into theatre to review the controlled drugs would then leave recovering patients without a trained practitioner. Good and appropriate placement of staff is essential for the safety of patients, staff and service users. The PR should ensure a comprehensive summary of the actions taken to comply with this non compliance are sent to the centres inspector by 28 August 2019. Further action required.

		trained staff in all teams. Our procedure room and recovery area are part of the same treatment zone. There is always a registered nurse present in this zone during procedures or whilst patients are recovering post procedure. I can assure you that our patients are appropriately and safely cared for.	

Other areas of practice that requires improvement

Other 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
4. Preoperative care The pre operative vital signs are not consistently documented in the patient's notes or using the pre operative assessment pathway record sheet, before theatre procedures. SLC T2	The PR should ensure that all patients have their baseline vital signs assessed and documented pre-operatively. The PR should review record keeping practices and take appropriate actions to ensure that all patients have their baseline vital signs assessed and documented pre-operatively. Three months after implementing actions, the PR should audit their effectiveness. The PR should provide the centre's inspector with a summary report of the review of record keeping practices	Following a review of our operative record sheet at the time of inspection, we accept it was not always clear to see where the vital signs was documented. The operative record sheet has been revised to include a section on the first page to clearly document vital signs. This was implemented on 22/03/2019. There is also a table of drugs on page 3 to be signed by the anaesthetist and registered member of staff when drugs are prescribed and administered. An audit has been completed to review all March, April and May operative record sheets to check that documentation is complete for vital signs and	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of audit report due by 28 August 2019.

	and the by 28 August 2019.	any drugs prescribed or administered. The results of these audits will be reported by 5th of July as part of our Controlled Drugs audit action plan.	
5. Third Party Agreements A review of a selection of the centre's third party agreements showed that their content did not meet HFEA requirements. SLC T113.	The PR should review the centre's third party agreements to ensure that they meet CoP requirements by 28 August 2019. A copy of the review findings, including corrective actions with timescales for implementation, should be provided to the centre's inspector by 28 May 2019. A selection of the third party agreements will be requested by the executive on 28 August 2019 for review to ensure compliance.	TPAs are reviewed annually. Provision of services and goods is ensured via a dual process of completing TPAs as well as SLAs and contracts in certain instances. I can confirm that we have TPAs in place with all suppliers and are 100% compliant. The inspection report only specifies our TPA with TDL. I can confirm that an SLA between TDL and TFP is in place and that it specifies turnaround time and format for secure reporting of test results. As stated at the time of inspection, this and other contracts are held centrally due to commercial sensitivity. A redacted version is available upon request. As PR I am satisifed that we have compliant agreements in place	The Executive notes the PR's response and confirms that more than one TPA was found to be non-compliant with HFEA requirements during the inspection and TDL was used as an example. However, the Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of a selection of third party agreements by 28 August 2019.

		as a clinic and also under the umbrella of agreements and contracts held at Group level.	
6. Obligations and reporting requirements 4% (4/112) of the IVF treatments reviewed had not been reported to the HFEA. The Donor Insemination data provided for post inspection review was found to be incomplete. The centres data confirmed 14 DI cycles, however, the HFEA data confirmed 21. 94% (102/112) of the IVF and 93% (13/14) of the DI treatments reviewed had been reported to the HFEA within the period required. General Direction 0005; SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority as required by General Direction 0005. A complete record of DI treatment data undertaken between the 1 December 2017 and 30 November 2018 should be re-submitted to the HFEA by the time this report is returned to the centre's inspector. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non- and late reporting. A report of this review, including corrective actions with timescales for implementation, should be provided to the centre's inspector by 28 May 2019 The PR should conduct an	As PR and as a clinic we appreciate the importance of fulfilling our obligation to submit the required data relating to licensed treatments and patients within the specified reporting periods. Since becoming PR I have instigated regular audit of the data we submit. This is primarily driven by reports obtained from our clinic database and EDI interface (IDEAS) which detail any: -Missing data -Treatment using unregistered donors -Late data submission -Data submitted with validation errors. The most recent audit was submitted to the inspection team prior to our inspection visit (please refer to email sent by PR dated 25.01.2019). This audit demonstrated a drastic improvement in compliance	The Executives notes the PR's response. The Executive acknowledges the PR's actions implementing this recommendation. No further action beyond submission of the audit by 28 August 2019.

	audit three months after implementing corrective actions, to confirm that the actions have been effective. A report of the audit should be provided to the centre's inspector by 28 August 2019.	and the reduction in errors and omissions since the new Nurse Manager and myself have targeted this area. Some apparent errors and omissions are generated due to peculiarities of the EDI-HFEA server relationship and can be eliminated by calling the HFEA Register Team. The remainder are corrected and submitted by the clinic. I am pleased to report that the most recent audit shows no missing register data (100% compliance). I think there has been some confusion regarding Donor Insemination data. A review of our clinic data confirms that 14 D-IUI treatments were undertaken and reported in the period of 1st December 2017 and 30th November 2018. We have addressed the timeliness of data submission and our actions to improve this. The HFEA data submission SoP has been	

		reviewed to highlight responsibilities and reporting times. Regular audit is used to monitor compliance with feedback to both nursing and laboratory teams if actions are required. This includes email alerts and departmental meetings.	

Responses from the Person Responsible to this inspection report

We welcome any form of constructive feedback and accept feedback as an essential part of the process of continuous improvement. Self-analysis as well as external feedback from both patients and professional bodies is crucial if we are to maintain the best service to our patients and achieve good results.

However, I would like to note the following points:

Pg10 bullet point5 states that a 'registered and trained member of staff' is not present in theatre. I can assure you that that our patients are not appropriately and safely cared for. Our procedure room and recovery area are part of the same zone. There is always a registered nurse present in this zone during procedures or whilst patients are recovering post procedure.

pg11, QMS notes that 'Regulatory requirements are not audited against'. We have undertaken multiple audits against areas of regulatory requirement. Although we have not yet completed audit of all areas, we are within the first 2 year cycle of obtaining our initial license and have the remaining audits planned.

Our WoC audit did include content as well as presence of the form in patient records. We have also completed audits in the areas highlighted on pg12:

- Provision of information
- Donor recruitment
- Record keeping
- Submission of data to the HFEA

Pg16 Surrogacy treatment has been paused at this clinic rather than within The Fertility Partnership. In the one couple who have undergone surrogacy at this clinic, I am satisfied that the intended parents (gamete providers) underwent all appropriate screening prior to commencing treatment.

Executive response:

Paragraph two:

I acknowledge that you have documented that you are assured that your patients are not appropriately and safely cared for when your intention may have been that the patients are appropriately cared for.

As discussed during and subsequently after the inspection, there is a registered nurse in the ‘zone’. This ‘zone’ covers theatre and the recovery area. However, there is a health care assistant in theatre who assists with the egg retrieval contrary to your centres own SOP. As a healthcare assistant, they are unable to witness the supply, administration and destruction of controlled drugs and therefore document as such. Your centres own SOP confirms the presence of a trained nurse in theatre for these purposes. Similarly, a trained nurse is required to recover patients after sedation, therefore there will be a period of time that patients in either theatre or recovery will not have a trained member of the nursing team to either witness or be recovered by.

Paragraph three:
Thank you for your comment. Audits are undertaken on a maximum of a two year cycle, however, your initial licence to practice was granted on 11 July 2017 which is almost at the two year bench mark.

Paragraph four:
As per feedback to your centre during the inspection, the inspection team will only comment on the quality of the audits and content on the documents provided both prior and during the inspection processes.

Paragraph five:
It has been confirmed that the Fertility Partnership as a whole have put surrogacy on hold with the exception of those already in treatment, to review their practices.