Executive Licensing Panel - minutes

Centre 0357 (Thames Valley Fertility)

Interim Inspection Report

Wednesday, 10 October 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Laura Riley Howard Ryan	Director of Strategy and Corporate Affairs Head of Regulatory Policy Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel noted that Thames Valley Fertility is located in Maidenhead, Berkshire and has held a licence with the HFEA since July 2017. This initial licence was granted for two years (as standard for new centres) without additional conditions. The centre provides a full range of fertility services, including embryo testing.

1.2. The panel noted that, from the time of opening to 31 May 2018, the centre provided 224 cycles of treatment (excluding partner intrauterine insemination). In relation to activity level this is a small sized centre. The centre is gradually increasing patient numbers and has also been awarded contracts to treat NHS patients.

1.3. The panel noted that 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 the local conditions. Audit findings, QI monitoring data, SOPs and centre forms and other documents are exchanged between the centres, as is experience via cross over and sharing of experienced staff.

1.4. The panel noted that an application to change the Person Responsible (PR) has recently been received and this has been submitted for consideration at the same time as the interim report.

1.5. The panel noted that, between July 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 31%. Although high, because of the small number of patients treated so far, this still represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that, during the inspection, centre staff provided evidence that they are closely monitoring their multiple pregnancy rate. Changes to their multiple births minimisation strategy have been made and appears to have been effective. The centre's own data demonstrates a 7% multiple pregnancy rate for March to May 2018, which is encouraging. The HFEA verifies clinics' information prior to publishing performance on their outcomes. The verification process for the reporting period the clinic cites will take place in 2019. Progress with meeting the multiple pregnancy rate target will continue to be monitored and will be reviewed at the renewal inspection due to occur in January 2019.

1.7. The panel noted that in 2017, the centre reported 6 cycles of partner insemination with one pregnancy, which is likely to be in line with the national average.

1.8. The panel noted that, from July 2017 to February 2018, HFEA held register data showed that the centre's success rates for IVF and ICSI are in line with national averages.

1.9. The panel noted that the inspection took place on 21st August 2018.

1.10. The panel noted that at the time of the inspection, one 'other' area of non-compliance was identified concerning medicines management. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendation made in the report and has committed to audit the effectiveness of those actions within the required timescale

1.11. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the positive comments made by patients and the centre's use of an on-line 'patient portal' to enhance communication between clinic staff and patients. Additionally, the centre's reduction in its multiple pregnancy rate demonstrates that its processes for monitoring key outcomes are effective.

2. Decision

2.1. The panel particularly noted the PR's timely response in addressing the one non-compliance, regarding medicines management, identified at the inspection, acknowledging that a re-audit would be conducted in November 2018. The effectiveness of the implementation of this recommendation will be reviewed at the centre's renewal inspection in January 2019.

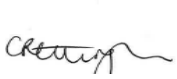
2.2. The panel congratulated the centre on it's positive patient feedback through the Choose a Fertility Clinic mechanism, available on the HFEA's website. The panel also commended the centre on their use of an on-line patient portal.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

17 October 2018

Interim Licensing Report

Centre name: Thames Valley Fertility
Centre number: 0357
Date licence issued: 11 July 2017
Licence expiry date: 10 July 2019
Additional conditions applied to this licence: None
Date of inspection: 21 August 2018
Inspectors: Sara Parlett, Janet Kirkland and Morounke Akingbola (observer)
Date of Executive Licensing Panel: 10 October 2018

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Newly licensed centres usually receive a licence to operate for two years and are subjected to an unannounced interim inspection after one year, to assess whether they are operating in a compliant manner. If the licence is renewed, it can be awarded for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. The focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients and the centre's use of an on-line 'patient portal' to enhance communication between clinic staff and patients. Additionally, the centre's reduction in its multiple pregnancy rate demonstrates that its processes for monitoring key outcomes are effective.

The ELP is asked to note that this report makes a recommendation for improvement in relation to one 'other' area of non compliance.

The PR has provided evidence that actions have been taken to implement the following recommendation and has committed to audit the effectiveness of those actions within the required timescale:

'Other' areas of practice that require improvement

- The PR should ensure that signatures in the controlled drugs register are legible.

Information about the centre

Thames Valley Fertility is located in Maidenhead, Berkshire and has held a licence with the HFEA since July 2017. This initial licence was granted for two years (as standard for new centres) without additional conditions.

The centre provides a full range of fertility services, including embryo testing.

The centre provided 224 cycles of treatment (excluding partner intrauterine insemination) from the time of opening to 31 May 2018. In relation to activity levels this is a small centre. The centre is gradually increasing patient numbers and has also been awarded contracts to treat NHS patients.

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 the local conditions. Audit findings, QI monitoring data, SOPs and centre forms and other documents are exchanged between the centres, as is experience via cross over and sharing of experienced staff.

An application to change the Person Responsible (PR) has recently been received. The application has been submitted to the ELP for consideration at the same time as this report.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data from July 2017 to February 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported six cycles of partner insemination with one pregnancy, which is likely to be in line with the national average.

Multiple births[2]

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

Between July 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 31%. Although high, because of the small number of patients treated so far, this still represents performance that is not likely to be statistically different from the 10% multiple live birth rate target. On inspection, centre staff

[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%.

provided evidence that they are closely monitoring their multiple pregnancy rate. Changes to their multiple births minimisation strategy have been made and appear to have been effective. The centre's own data demonstrates a 7% multiple pregnancy rate for March – May 2018, which is encouraging. The HFEA verifies clinics' information prior to publishing performance on their outcomes. The verification process for the reporting period the clinic cites will take place in 2019. Progress with meeting the multiple pregnancy rate target will continue to be monitored and will be reviewed at the renewal inspection due to take place in January 2019.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: embryo biopsy, vitrification of embryos and disposal of embryos. All of the procedures observed were witnessed using an electronic witnessing system, with additional manual witnessing steps where relevant, in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, the centre's storage records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective. A group wide review of processes for the management of stored material is planned in the next two months.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: traceability, infection control, medicines management, legal parenthood and an egg collection process audit.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices;
- the content of the centre's website;
- HFEA Clinic Focus articles regarding: screening requirements and knowledge of new legal requirements on the importation and coding of gametes and embryos;
- action taken following a recent alert relating to mixed gas cylinders.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be broadly compliant because:

- the signature of the anaesthetist administering drugs is not always legible in the controlled drugs register, therefore the identity of the anaesthetist cannot be easily established. A separate staff signature list is held, however in some instances a match to the signature in the register could not be made (recommendation 1).

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.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture medium, vitrification and thawing medium, culture dishes and other plasticware used to culture and manipulate gametes and embryos. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Thirty seven patients have provided feedback in the last 12 months, giving an average five 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, giving positive feedback about the clinic. Patients were especially complimentary of the centre's 'patient portal'. This is a system allowing patients to manage their treatment online, for example providing access to test results, medical history and a treatment calendar. It also has an integrated messaging system.

The centre's own patient survey process was reviewed on inspection and also demonstrates a theme of positive feedback. Where negative comments are received, these are acted upon.

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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- has staff that treats patients with empathy and understanding.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements, with the one exception noted elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the initial inspection in 2017, no recommendations for improvement needed to be made.

On-going monitoring of centre success rates

Since the initial inspection in 2017 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

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

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 the centre's legal parenthood consenting audit. Three 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.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas 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 child who may be born as a result of treatment services. A critical 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	Inspection team's response to the PR's statement
None noted.			

‘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 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;
- which can comprise 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	Inspection team’s response to the PR’s statement
None noted.			

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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	Inspection team’s response to the PR’s statement
1. **Medicines management** The signature of the anaesthetist administering drugs is not always legible in the controlled drugs register, therefore the identity of the anaesthetist cannot be easily established. A separate staff signature list is held, however in some instances a match to the signature in the register could not be made. SLC T2. NMC (2015) ‘Standards for medicines management’.	The PR should ensure that the controlled drugs register is completed in line with regulatory and best practice requirements. The PR should ensure that the centre holds an accurate, up to date and legible staff signature list and that signatures in the controlled drug register are legible. The PR should review the centre’s processes for record keeping in the controlled drugs register. A summary of the findings of the review including corrective actions and the timescale for implementation should be provided to the lead inspector when responding to this report.	An email was immediately sent to the Lead Consultant Anaethetist to advise her that this had been recognised during our inspection. She was in clinic the following day and was shown the particular page that demonstrated the signature. She immediately took a photo of a page where the anaethetist had written his surname in capitals after the first signature and emailed it to all of the anaethetists asking them to follow this example in future.They were also asked to confirm that they had signed the sample signatures list.I will look at the signatures in the CD book on a monthly basis for compliance and reaudit in November 2018.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The effectiveness of the implementation of this recommendation will be reviewed at the centre’s renewal inspection in January 2019.

	Within three months, the centre should carry out an audit to ensure that the proposed corrective actions have been effective in ensuring compliance. This audit will be reviewed at the centre's renewal inspection due January 2019.		

Additional information from the Person Responsible
Thank you for your feedback and compliments regarding our clinic at Thames Valley Fertility. We work very hard as a cohesive team to ensure the patient journey is a positive one even if the outcome is not. It was lovely to hear that the patients free text comments on the HFEA website were also very positive.