Executive Licensing Panel Minutes

Centre 0357 (Thames Valley Fertility)

Interim Inspection Report

Date:	23 March 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Anna Coundley	Director of Strategy and Corporate Affairs Communications Manager Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood India Hickey	Licensing Manager Research Officer (Induction)

Declarations of interest

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

The panel had before it:

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

1. Consideration of Application

1.1. The panel noted that 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.

1.2. The panel noted that Thames Valley Fertility is part of The Fertility Partnership (TFP) corporate group of HFEA licensed centres, which includes Boston Place (0327), Oxford Fertility (0035), GCRM Fertility (0250), NURTURE Fertility (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 TFP do not currently operate under common practices and procedures across all areas, this inspection was not undertaken using the HFEA's 'group approach' methodology.

1.3. The panel noted that, in the 12 months to 31 December 2020, the centre had provided 608 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that, HFEA register data, for the period October 2019 to September 2020, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.5. The panel noted that, in 2019, the centre reported eight cycles of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that, HFEA register data, between October 2019 and September 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is significantly lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.8. The panel noted that, following the centre's renewal inspection in February 2019, a focused inspection was scheduled to be undertaken in 2020; this was deferred due to the Covid-19 pandemic, restrictions and closures of the centre. However, following the Desk Based Assessment and Risk Based Approach (DBA/RBA), for this centre, it was concluded that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.9. The inspection report presented to the panel is of a routine interim inspection; previous non-compliances, where there were significant concerns, were also reviewed and lessons have been learnt.

1.10. The panel noted that the virtual inspection was conducted on 22 January 2021 and included videoconferencing with key members of centre staff. This process also took into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection and the on-going monitoring of the centre's performance.

1.11. The panel noted that at the time of the inspection, there was one 'other' area of non-compliance regarding medicines management. Since the inspection, the Person Responsible (PR) has fully implemented the recommendation and will provide an update or summary of audits conducted to ensure the corrective actions taken are effective where required and by the dates specified.

1.12. The panel noted the centre is well led and provides a good level of patient support.

1.13. The panel noted that the inspection team recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the low multiple pregnancy rate and improvements made since the last inspection.

2. Decision

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

3. Chairs signature

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

Signature

Clare Ettinghausen

Name

Date

29 March 2021

Interim Licensing Report

Centre name: Thames Valley Fertility
Centre number: 0357
Date licence issued: 11 July 2019
Licence expiry date: 10 July 2022
Additional conditions applied to this licence: None
Date of inspection: 22 January 2021
Inspectors: Grace Lyndon (lead), Sara Parlett and Karen Campbell (HFEA observer)
Date of Executive Licensing Panel: 23 March 2021

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.

Licensed centres usually receive a licence to operate 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 (SLC).

This is a report of an interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non-compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected on-site in February 2019 therefore an on-site inspection should usually be conducted by February 2021. An additional focused inspection was to be carried out in 2020, but due to the COVID-19 pandemic, restrictions and closures of centres, that inspection was deferred. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site

inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

The current foci for an interim inspection are:

- **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 – pre review of draft by PR

The inspection team recommends the continuation of the centre's licence. In particular we note the centre's low multiple pregnancy rate, improvements since the last inspection.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to one 'other' area of non compliance or poor practice.

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

'Other' area of practice that require improvement:

- The PR should ensure that all entries in the controlled drugs register are legible, accurate and in line with regulations.

Information about the centre

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's current licence has been varied to reflect a change of Person Responsible (PR) in February 2020.

The centre provided 608 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2020. In relation to activity levels this is a medium centre.

Thames Valley Fertility is part of The Fertility Partnership (TFP) corporate group of HFEA licensed centres, which includes Boston Place (0327), Oxford Fertility (0035), GCRM Fertility (0250), Nurture Fertility (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 TFP do not currently operate under common practices and procedures across all areas, this inspection was not undertaken using the HFEA's 'group approach' methodology.

Following the centre's renewal inspection February 2019, a focused inspection was scheduled to be undertaken in 2020. However, due to the COVID –19 pandemic, this inspection was not carried out. The inspection reported on here is a routine interim inspection, however previous non compliances where there were significant concerns were also reviewed and lessons have been learnt.

The centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

Details of Inspection findings

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 for the period October 2019 to September 2020 show the centre's success rates are in line with national averages.

In 2019 the centre reported eight cycles of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

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

Between October 2019 and September 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is significantly lower than the 10% multiple live birth rate target for this period.

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 activity was observed in the course of the inspection: preparation for embryo transfer. The inspection team also discussed witnessing with staff and reviewed the results of recent audits. These activities indicated that witnessing procedures are compliant 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, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. 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.

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, following assessment of information provided as part of the DBA and discussions with the PR during the virtual inspection. The PR regularly reviews

[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%.

staffing requirements in light of changes in working practices due to the Covid-19 pandemic.

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: medicines management; infection control; legal parenthood; witnessing and consent to storage.

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:

- extension of storage consent
- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- reopening of the clinic during the Covid-19 pandemic.

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 found to be broadly compliant with guidance because:

- There are entries in the controlled drugs register where the administration and discard amounts of a controlled drug looked like 200mg when it should have been 250mg.

See 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 centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. The inspection team noted that 106 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 complimenting the kind and friendly staff at the clinic.

On the basis of this feedback and observations made in the course of the virtual 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;
- treats patients with empathy and understanding.
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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 virtual inspection indicate that the centre is fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019, recommendations for improvement were made in relation to one critical, two major and three 'other' areas of non compliance.

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

During the inspection in 2019, there were a number of concerns in relation to competency of staff providing surrogacy treatments. This was discussed during this inspection and the PR confirmed that surrogacy treatments are not being carried out at this centre. Any patients requiring surrogacy treatment are considered by TFP on a case by case basis and would have their treatment at a specified centre within the group.

On-going monitoring of centre success rates

Since the last renewal inspection in February 2019 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.

There are currently no data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 03 February 2021.

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.

At the last inspection in 2019, legal parenthood consenting processes were found to be robust.

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.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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	Executive review
None identified			

‘Major’ areas 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	Executive review
None identified			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas 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	Executive review
1. Medicines Management There are entries in the controlled drugs register where the administration and discard amounts of a controlled drug looked like 200mg when it should have been 250mg. SLC T2. The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Good practice, a guide for departments of anaesthesia, critical care and pain management’ (2006), section 7 and 7.1. DH ‘Safer Management of Controlled Drugs; A guide to	The PR should ensure that all entries in the controlled drugs register are legible, accurate and in line with regulations. The PR should carry out a review of the centre’s processes for documenting the drugs administered and discarded. The PR should provide a timeline for completing this review when responding to the report. A copy of the findings of the review should be forwarded to the centre’s inspector upon completion. It is expected this will be completed by 22 April 2021.	Immediate communication has been shared with both the anaesthetic team and the medical/nursing team who witness the controlled drugs register, reminding all parties that upon signing and witnessing for the entries they have checked and ensured the legibility and accuracy of these. The CD audit is now performed monthly to ensure we can consistently meet the above requirements on legibility and accuracy. Both actions have already been implemented. Any subsequent findings will be shared with the centre’s	The Executive acknowledges the PR’s implementation of this recommendation. No further action required beyond submission of the audit due 22 April 2021.

good practice in secondary care (England)' (2007)		inspector before the 22 April 2021.	

Additional information from the Person Responsible
Thank you for your feedback and compliments regarding our clinic at Thames Valley Fertility. We are delighted that our efforts to improve our services and performance have been successful. During these times, having to adjust to conduct a virtual inspection, we are pleased that the process went very smoothly and still felt personable, whilst not in person. The Executive thanks the Centre for their support in this new process of inspecting and the hard work the centre has undertaken over the past years.