Executive Licensing Panel Minutes

Centre 0258 (The Fertility Centre at Whittington Health)

Interim Inspection Report

Date:	6 April 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Helen Crutcher Dan Howard	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Chief Information Officer
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood	Licensing 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:

- 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 The Fertility Centre at Whittington Health is located in London and has held a licence with the HFEA since 2007. Initially, the centre was issued a treatment (partner insemination) licence; this was varied in 2016 to a treatment (insemination using partner/donor sperm) and storage licence. The centre provides basic fertility services.

1.2. The panel noted that, in the 12 months to 31 October 2020, the centre had provided 27 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a very small sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

1.3. The panel noted that, for the year ending 31 December 2020, the centre reported 18 cycles of partner insemination, with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.4. The panel noted that, in the 12 months to 31 December 2020, the centre did not report any multiple pregnancies following partner insemination treatment.

1.5. The panel noted that 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.

1.6. The panel noted that the centre was last inspected in January 2019 and an interim inspection should have been conducted by January 2021. However, due to the Covid-19 pandemic a Desk Based Assessment and Risk Based Approach (DBA/RBA) was taken for the interim inspection. It was concluded that items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology rather than an on-site visit. This process 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.

1.7. The panel noted that a DBA and virtual inspection, including a videoconference with key members of the centre's staff, was conducted on 2 February 2021. The inspector also took into account the centre's own assessment of its service, progress made in implementing the actions identified at the last inspection and the on-going monitoring of the centre's performance.

1.8. The panel noted that at the time of the virtual inspection, one 'other' area of non-compliance was identified regarding equipment and materials. The Person Responsible (PR) has given a commitment to fully implement the recommendation made in the report.

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

1.10. The panel noted that the inspection team recommends the continuation of the centre's treatment (insemination using partner/donor sperm) and storage licence.

2. Decision

2.1. The panel was satisfied the centre was fit to have its treatment (insemination using partner/donor sperm) and storage licence continued.

3. Chairs signature

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

Signature

Name

Clare Ettinghausen

Date

12 April 2021

Interim Licensing Report

Centre name: The Fertility Centre at Whittington Health
Centre number: 0258
Date licence issued: 1 July 2019
Licence expiry date: 30 June 2023
Additional conditions applied to this licence: None
Date of inspection: 2 February 2021
Inspectors: Nicola Lawrence (lead), Louise Winstone (scientific) and Bernadette O'Leary (observer)
Date of Executive Licensing Panel: 6 April 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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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).

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 in January 2019; therefore an on-site inspection should usually be conducted by January 2021. 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 desk based assessment 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

The inspection team recommends the continuation of the centre's licence.

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.

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

'Other' areas of practice that require improvement:

- The PR should ensure that appropriately CE marked medical devices are used where possible.

Information about the centre

The Fertility Centre at Whittington Health is located in London and has held a licence with the HFEA since 2007.

This initially was a Treatment (Partner Insemination) Licence but was varied in 2016 to a Treatment (insemination using partner/donor sperm) and Storage licence. The centre provides basic fertility services.

The centre provided 27 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2020. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers. In relation to activity levels this is a very small centre.

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 the year ending 31 December 2020, the centre reported 18 cycles of partner insemination with 2 clinical pregnancies which is in line with the national average.

[1,2] 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 $p \leq 0.002$.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy
The centre did not report any multiple pregnancies following partner insemination treatment in the 12 months to 31 December 2020.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review 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 of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed. Documentation provided as part of the DBA and discussions with staff during the virtual inspection 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 staffing requirements in light of changes in working practices due to the Covid19 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: 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:

- leadership
- patient support
- extension of storage consent
- the use of CE marked medical devices
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding screening requirements and safeguarding practices.

The centre has been effective in ensuring compliance with guidance issued by the HFEA with the exception noted below in the section 'Equipment and Materials'.

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 DBA and virtual inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

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

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.

Documentation provided as part of the DBA and discussions during the virtual inspection indicate that the clinic's infection control practices are 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 all medical devices was reviewed in the course of the inspection. We found the centre to be broadly compliant with HFEA requirements to use CE marked

medical devices wherever possible because the sample pots used for the collection of sperm prior to treatment are not CE marked at the appropriate level.

See recommendation 1.

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. Eleven patients have provided feedback in the last 12 months, giving an average five-star rating to the clinic. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

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.

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 January 2019, recommendations for improvement were made in relation to two major and four 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in January 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.

Legal parenthood

Where a couple to be treated with donated gametes 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 2014, this centre has only been providing treatment using donor sperm since 2016. The centre's proposed legal parenthood consenting practices were considered compliant at the time their licence was varied.

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.

Annex 1

Areas of practice that require the attention of the Person Responsible

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, 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			

‘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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None			

‘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. Equipment and materials The sample pots used for the collection of sperm prior to treatment are not CE marked at the appropriate level. SLC T30.	The PR should ensure that appropriately CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment; however, the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre’s inspector when responding to this report and should include the timescales by which the product identified in this report will either be replaced with a suitably CE marked alternative	We have already ordered replacement specimen pots made by Birr, and these will be put into use as soon as the old ones are finished.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has confirmed that appropriately CE marked devices will be used by the centre. The PR should inform the centre’s inspector when appropriately CE marked specimen pots are in use, no later than 2 August 2021. Further action required.

	or will obtain CE mark certification. The plan should be fully implemented by 2 August 2021.		

Additional information from the Person Responsible