Executive Licensing Panel Minutes

Centre 0094 (Barts Health Centre for Reproductive Medicine)

Interim Inspection Report

Date:	6 October 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Yvonne Akinmodun Joanne Anton	Director of Strategy and Corporate Affairs Head of Human Resources Head of Regulatory Policy (Job-share)
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 Barts Health Centre for Reproductive Medicine is located in central London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services, including storage of gametes and embryos.

1.2. The panel noted that at the centre's renewal inspection, in May 2018, a number of areas of practice were identified that required improvement, including one critical, five major and four 'other' areas of non-compliance. Following the inspection, the centre had a grade A incident (an incorrect gas cylinder was attached to a laboratory incubator); therefore, the report of the renewal inspection was presented alongside the report of the incident to a Licence Committee (LC) in September 2018.

1.3. The panel noted that LC endorsed the inspectorate's recommendation for the renewal of the centre's licence for a period of four years, without additional conditions, subject to a targeted inspection that took place in July 2019. The inspection team noted one major non-compliance and one 'other' area of concern during the targeted inspection; this report was considered by the Executive Licensing Panel (ELP) in February 2020. The panel commented on the swift action of the PR in relation to these non-compliances, alongside the ongoing support from the Trust. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

1.4. The panel noted that, in the 12 months to 28 February 2021, the centre had provided 562 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will likely have had an impact on treatment numbers.

1.5. The panel noted that, HFEA register data, for the period April 2020 to March 2021, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.6. The panel noted that, in 2020, the centre reported six cycles of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.7. The panel noted that, HFEA register data, between April 2020 and March 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be statistically different to the 10% multiple live birth rate target for this period.

1.8. The panel noted that, 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.

1.9. The panel noted that 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.

1.10. The panel noted that, following the initial DBA/RBA conducted for the centre's interim inspection, some potential areas of concern were identified. The assessors considered these were associated with significant enough risk to merit further review during an onsite inspection. Therefore, a shorter than normal on-site visit to the centre, with one inspector, was undertaken, reducing the risks of travel and close contact during the pandemic. This on-site inspection allowed for potential non compliances to be appropriately reviewed.

1.11. The panel noted that an on-site inspection was conducted on 30 June 2021. This was followed by an additional virtual inspection, carried out on 27 July 2021, which included videoconferencing with key members of staff, covering areas not addressed during the on-site visit. The centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection and on-going monitoring of the centre's performance, were also considered.

1.12. The panel noted that at the time of the inspection, there was one major area of non-compliance identified concerning medicines management. There was also one 'other' area of non-compliance regarding legal parenthood. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations concerning medicines management and legal parenthood, and has committed, where required, to audit the effectiveness of those actions.

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

1.14. The panel noted that the inspection team recommends the continuation of the centre's treatment and storage licence.

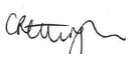
2. Decision

2.1. The panel was satisfied the centre was fit to have its treatment 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

11 October 2021

Interim Licensing Report

Centre name: Barts Health Centre for Reproductive Medicine
Centre number: 0094
Date licence issued: 1 October 2018
Licence expiry date: 30 September 2022
Additional conditions applied to this licence: None
Date of inspection: 30 June 2021 (on site) and 27 July 2021 (virtual inspection)
Inspectors: Sara Parlett, Julie Katsaros and Karen Campbell (observing)
Date of Executive Licensing Panel: 6 October 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).

This is a report of a standard interim inspection, carried out as required two years following the previous inspection.

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.

For this centre, the DBA/RBA process identified some potential areas of concern which the assessors considered were associated with significant enough risk, to merit further review during an onsite inspection. Therefore a shorter than normal on-site visit to the centre, with one inspector, was undertaken, thereby reducing the risks of travel and close contact during the pandemic. This on-site inspection allowed for potential non compliances to be appropriately reviewed. It was combined with an additional virtual inspection, which included videoconferencing with key members of centre staff, to cover areas not addressed during the on site visit.

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 major and one 'other' area of non compliance or poor practice.

Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions:

Major areas of non compliance:

- PR should ensure compliance with medicines management regulatory requirements and professional body guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that any woman being treated with donor sperm, and her partner, are given appropriate information about legal parenthood which is relevant to their marital status and are not asked for consent that is not applicable in their situation.

Information about the centre

Barts Health Centre for Reproductive Medicine is located in central London and has held a licence with the HFEA since 1992.

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

The centre provided 562 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2021. In relation to activity levels this is a medium sized centre**.** The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will likely have had an impact on treatment numbers.

The centre had a renewal inspection in May 2018 which identified a number of areas of practice that required improvement, including one critical, five major and four 'other' areas of non compliance. Following the inspection, the centre had a grade A incident (an incorrect gas cylinder was attached to a laboratory incubator) and therefore the report of the renewal inspection was presented alongside the report of the incident to a Licence Committee in September 2018.

The committee endorsed the inspectorate's recommendation for the renewal of the centre's licence for a period of four years, without additional conditions, subject to a targeted inspection that took place in July 2019. The inspection team noted one major non compliance and one 'other' area of concern during the targeted inspection. The panel commented on the swift action of the PR in relation to these non compliances, alongside the ongoing support from the Trust. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

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

- 4 March 2021 - all centres: Variation of all licences without application (European Union (EU) Exit requirements)

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 for the period April 2020 to March 2021 show the centre's success rates are in line with national averages.

In 2020, the centre reported six cycles of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

[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 $p \leq 0.002$.

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

Between April 2020 and March 2021, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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 did not observe laboratory activities during the inspection but was able to discuss witnessing with staff and review the centre's own audit of witnessing. 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.

During the DBA and virtual inspection process, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent 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, with the exceptions noted below.

Following a non compliance noted at the centre's last renewal inspection in 2018, a full audit of all cases where gametes or embryos had been in storage for more than 10 years was completed at the end of 2019. The audit found that three sets of embryos and one set of eggs are currently in storage where it is not clear if effective consent is in place because of gaps in completion of the medical practitioner statement (MPS). Legal advice has been provided, and further patient record reviews are currently being performed. Additional legal advice will be sought following this review. This is an ongoing non compliance from the previous inspection at the clinic and therefore it is not referenced as a new non compliance in this report. It is expected that this non compliance will be fully resolved by the time of the centre's renewal inspection in early 2022.

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 were suitable for the activities being carried out, following assessment of information provided as part of the DBA, observations on site 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 pandemic.

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[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%.

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:

- coronavirus storage regulations
- introduction of the new HFEA consent form for women providing eggs or embryos created with their eggs for use in their partner's treatment
- the content of the centre's website
- the use of CE marked medical devices

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 partially compliant with guidance because:

- the centre's controlled drugs (CD) register does not always contain records of signatures and times for the discard of drugs.
- in one of ten patient records reviewed, the amount of controlled drug recorded as being given to the patient on the anaesthetic chart did not match the amount recorded in the CD register.

This is a re-occurrence of a non compliance seen at the centre's last inspection in 2019.

Following the on-site visit where these non compliances were noted, the PR took several actions, including:

- a full audit of 100 patient records was performed and the findings shared with the lead anaesthetist and the multi-disciplinary team during the clinic's monthly fertility audit session.

- changes have been made to the theatre checklist that is completed on the day of the egg collection. This now includes a sign out step to ensure the anaesthetist or operating department practitioner (ODP) confirms that the CD book has been fully completed and signed.
- the scrub nurse, ODP and clinic lead nurse will also check the CD log daily.
- the CD register will be audited weekly.

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'.

As part of the DBA, the inspection team reviewed the centre's list of CE marked equipment and materials used. We found the centre to be 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. Only 12 patients have provided feedback in the last 12 months, giving an average three star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system.

The PR explained that this will be encouraged by introducing computer tablets into waiting areas so that patients can provide feedback whilst waiting for appointments. The success of this in increasing patient feedback will be followed up at the next inspection.

The centre's own most recent patient survey responses were reviewed. Out of 473 patients, 82% said they were extremely likely or likely to recommend the clinic to friends and family. The majority of feedback provided was positive, although there were some negative comments regarding communication and these were discussed with the PR. She advised the inspectors that actions have already been taken to address this matter. The inspection team urges the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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 DBA and observations and discussions during the inspection, indicate that the centre is fully compliant with HFEA requirements, with the exceptions noted elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the focussed interim inspection in 2019, recommendations for improvement were made in relation to one major and one 'other' area of non compliance.

The PR subsequently provided information and evidence that both recommendations were fully implemented. However, the non compliance related to medicines management has re-occurred at this inspection.

On-going monitoring of centre success rates

The centre has received one risk tool alert related to performance since the last inspection, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed.

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the last renewal inspection in 2018, 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. Four 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 broadly compliant with HFEA requirements.

Due to historic legal parenthood issues, the clinic takes a very cautious approach to consenting patients by requiring couples that are married or in a civil partnership to complete legal parenthood consent forms which are only required by unmarried couples. The inspection team considers that asking patients to complete consent forms that are not relevant to them could be confusing. The PR has acknowledged this and has confirmed that they will change their practice. See recommendation 2.

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

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
1. **Medicines management** • The centre’s CD register does not always contain records of signatures and times for the discard of drugs. • In one of ten patient records reviewed, the amount of controlled drug recorded as being given to the patient on the anaesthetic chart did not match the amount recorded in the CD register. SLC T2. Controlled Drugs in	The PR should ensure compliance with medicines management regulatory requirements and professional body guidance. Corrective action has already been taken by the PR following the inspection, as described in the body of the report. The PR should audit medicines management practice to ensure that the corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this review	We will continue to audit our medicines management practice on a weekly basis during this period.	The executive acknowledges the PR’s response and the corrective actions implemented immediately following the on site inspection. No further action beyond the submission of the summary report of the audit of medicines management practice by 27 October 2021.

Perioperative Care' (2019) Rec 5). Misuse of Drugs (safe Custody) Regulations (2001)(Reg 19,19a,27 (3)). NICE Guideline [NG46] 'Controlled drugs: safe use and management' (2016)(1.7.4). DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007)(4.11.1.2 & 4.11.1.3). Clinic Focus (February 2020).	should be provided to the centre's inspector by 27 October 2021.		

‘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
2. **Legal parenthood** Due to historic legal parenthood issues, the clinic takes a very cautious approach to consenting patients, by requiring couples that are married or in a civil partnership to complete legal parenthood consent forms which are only required by unmarried couples. The inspection team considers that asking patients to complete consent forms that are not relevant to them could be confusing. The PR has acknowledged this and has confirmed that they will change their practice. CoP Guidance 6.11.	The PR should ensure that any woman being treated with donated sperm, and her partner, are given appropriate information about legal parenthood which is relevant to their marital status and are not asked for a consent that is not applicable in their situation. The PR should review the centre’s processes and supply a copy of their revised procedures by 27 October 2021, along with confirmation that all relevant staff have been provided with appropriate training in the revised procedure. The PR should conduct an audit three months after	We will continue to audit all cycles where donor sperm has been used on a monthly basis, following the April 2021 Clinic Focus guidance. The provision of information and our consenting process is currently under review. This will include; a review of all protocols and checklists, a change to how we check and document marital status, and training of relevant staff on the revised procedure.	The executive acknowledges the PR’s response. Further action is required.

	implementing any corrective actions, to confirm that the revisions to the processes have been followed through in practice. A summary of the audit should be provided to the centre's inspector by 27 January 2022.		

Additional information from the Person Responsible