Executive Licensing Panel - minutes

Centre 0105 (London Women's Clinic)

Interim Inspection Report

Tuesday, 9 April 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Richard Sydee Niamh Marren	Director of Strategy and Corporate Affairs Director of Finance and Resources Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Dina Halai Danielle Vincent	Licensing Manager Scientific Policy Manager Communications 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 London Women's Clinic (LWC) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing to self-funded patients. LWC is part of a nationwide group of centres and has several satellite and transport centres.

1.2. The panel noted that, in the 12 months to 30 November 2018, the centre had provided 2888 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that HFEA register data for the 12 months prior to October 2018, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.4. The panel noted that, in 2018, the centre reported 173 cycles of partner insemination with 14 pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that HFEA register data for the 12 months prior to October 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that following a grade 'A' incident in 2012, an additional condition was imposed on the centre's licence and remains in place. This condition suspended the centre (and other centres within the LWC group) using donor sperm procured, processed and stored at the centre prior to the introduction of the electronic witnessing system in May 2010.

1.7. The panel noted that a renewal inspection performed at the centre in October 2017 identified two critical, six major and five 'other' areas of non-compliance; this inspection report was considered by the Licence Committee on 8 March 2018. The committee granted a licence for three years and requested that an interim inspection be conducted within 12 months of the renewed licence coming into force on 29 March 2018.

1.8. The panel noted that the inspection took place on 29 January 2019.

1.9. The panel noted that at the time of inspection there were three major areas of non-compliance concerning the Quality Management System (QMS), medicines management and legal parenthood. Since the inspection, the Person Responsible (PR) has provided evidence that the recommendation concerning medicines management has been implemented and where required, by the date specified, will provide an update or summary of audits conducted to ensure the corrective actions taken are effective. The PR has given a commitment to also implement the recommendations regarding the QMS and legal parenthood.

1.10. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

2.1. The panel noted that the PR had made a significant impact on the centre's level of compliance since the renewal inspection, which was considered at the March 2018 Licence Committee.

2.2. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued and noted the additional conditions on the licence as outlined in paragraph 1.6 above.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

15 April 2019

Interim Licensing Report

Centre name: London Women's Clinic
Centre number: 0105
Date licence issued: 29 March 2018
Licence expiry date: 28 March 2021

Additional conditions applied to this licence: 'to suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.'

Date of inspection: 29 January 2019
Inspectors: Victoria Lamb (lead), Polly Todd (clinical), Sandrine Oakes (observer), Nicola Lawrence (observer)
Date of Executive Licence Panel: 9 April 2019

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 unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. 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 ELP is asked to note that this report makes recommendations for improvement in relation to three major areas of non-compliance or poor practice:

Since the inspection the PR has provided evidence that the following recommendation has been implemented. Where required and by the date specified, the PR will provide an up-date or summary of audits conducted to ensure the corrective actions taken are effective.

Major area of non-compliance:

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

The PR has given a commitment to fully implement the following recommendations.

Major areas of non-compliance:

- The PR should ensure that the quality management system is effective and fit for purpose.
- The PR should ensure that procedures for legal parenthood consents are robust and compliant with statutory requirements and regulatory guidance.

Information about the centre

The London Women's Clinic (LWC) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing to self-funded patients. LWC is part of a nationwide group of centres and has several satellite and transport centres.

The centre provided 2888 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 Nov 2018. In relation to activity levels this is a large centre.

Following a grade 'A' incident in 2012, an additional condition was imposed on the centre's licence and remains in place. This condition suspended the centre (and other centres within the LWC group) using donor sperm procured, processed and stored at the centre prior to the introduction of the electronic witnessing system in May 2010.

A renewal inspection performed at the centre in October 2017 identified two critical, six major and five 'other' areas of non-compliance. The report of that inspection was considered by Licence Committee on 8 March 2018. The committee granted a licence for three years and requested that an interim inspection be conducted within 12 months of the renewed licence coming into force on 29 March 2018. This is the report of that inspection.

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 12 months prior to October 2018 show the centre's success rates are in line with national averages.

In 2018, the centre reported 173 cycles of partner insemination with 14 pregnancies. This represents a clinical pregnancy rate of 8% which is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.
HFEA held register data for the 12 months prior to October 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is likely to be 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 activities were observed in the course of the inspection: egg collection and preparation for embryo

[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%.

transfer. All of the procedures observed were witnessed using a manual and electronic witnessing system 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, 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.

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

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

- In the general medicines audit, performed in September 2018, the date by which corrective actions were due to be completed was not recorded, and there was no record as to whether the corrective actions had been completed. This was a non-compliance at the renewal inspection in 2017.The date on which the controlled drugs audit had been conducted was not recorded.
- There was no infection control audit available to the inspection team.

The quality manager reported there were different versions of these audit reports on the system which would demonstrate compliance. The QM was unable to access these at the time of the inspection due to IT issues. Completed controlled drugs and infection control audtis were sent to the inspection team the next day.

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:

- information provision
- implications of treatment and consent
- consent
- surrogacy
- screening
- imports of gametes and embryos from outside the EU/EEA

The centre is broadly effective in implementing learning from guidance from the HFEA because:

- The centre has not incorporated the Department of Health and Social Care (DHSC) 2018 guidance on surrogacy for patients, intended parents and healthcare professionals into their surrogacy protocols and patient information which have been in force since February 2018.

See recommendation 1.

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:

- There were several entries in the controlled drugs register that were illegible.
- The carry-over of controlled drugs from one page to another is not recorded or witnessed.

These non-compliances had not been identified by the centre's own controlled drugs audits.

See recommendation 2.

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 a sample of reagents and plasticware was reviewed in the course of the inspection. 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. Only 26 patients have provided feedback in the last 12 months, giving an average four 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 is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The website also gives the ability for patients to comment on the cost of treatment. A third of patients who responded had stated that they paid more than they had expected to. This was discussed with the quality manager who confirmed that as a result of this feedback, the centre's price list had been amended to provide greater clarity to patients.

Patients are encouraged to provide feedback to the centre via an online system. The centre's survey for February 2018 was reviewed and it was noted that 8% of respondents had stated they had not been offered counselling. This was discussed with centre staff who confirmed that all patients receive an offer of counselling at the centre and in all correspondence sent to the patient. Feedback from CaFC and the centre's own survey included both positive and negative comments. Survey responses are reviewed and discussed regularly be centre staff and actions are taken to address issues identified.

No patients were available to speak to inspectors during this visit.

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.

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 exceptions noted elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to two critical, six major and five 'other' areas of non-compliances or poor practice.

In responding to the report immediately after the inspection, the PR agreed to implement the recommendations. All actions were completed within the required timeframe.

On-going monitoring of centre success rates

Since the renewal inspection in October 2017, the centre has received four risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issues have 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 renewal inspection in 2017 there were a total of three cases where anomalies with legal parenthood consent were identified. All patients involved have been supported by the centre to seek legal remedy. Following the inspection, the PR provided evidence to demonstrate that the centre's legal parenthood consenting processes had been reviewed.

To provide assurance of continued compliance and effectiveness of the centre's legal parenthood consenting procedures at this interim inspection, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits which did not find any anomalies.

Ten 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:

- The HFEA WP consent form (consent to begin the legal parent) requires the patient to sign and date a ‘page declaration’ section on page 2 In one electronic patient record reviewed, the month in which the WP consent form was signed was absent. Centre staff considered that this consent form could have been scanned onto their database before it had been completed by the patient (and prior to treatment). Patients are given the original copies of their consent forms for their records. Subsequently the PR was able to provide the inspection team with a further fully completed scanned copy of this consent form, that had been located elsewhere in the patient record.
- It appears that this anomaly was not picked up in the centre’s legal parenthood records audit and it appears that it wasn’t identified during the checks of consents performed before treatment is provided. On discussion at inspection with the PR and medical director, it was acknowledged that there had been failures in their systems and processes for legal parenthood consents. The PR confirmed that this treatment cycle did not result in a pregnancy.
- Additionally, in another set of records reviewed the offer of counselling had not been recorded.

The inspection team is concerned that the centre’s processes for obtaining and recording legal parenthood consents are not as robust as they should be and will be closely scrutinising the centre’s activity in this area of practice at the renewal inspection.

These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements.

See recommendation 3.

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			

‘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
1. Quality management system: In the general medicines audit the date by which corrective actions were due to be completed was not recorded, and there was no record as to whether the corrective actions had been completed. This was a non-compliance at the renewal inspection in 2017 so has been escalated to a major non-compliance. The date on which the controlled drugs audit was	The PR should ensure that the quality management system is effective and fit for purpose. The PR should review the quality management system and investigate why non-compliances at the last inspection have re-occurred. A summary report of this review with corrective actions taken to address the issues identified in this report and timescales for their completion, should be provided to the centre’s inspector by 29 April 2019.	The audit mentioned was not signed off since it had not completed the CAPA process which was to be finalised at the next nurses meeting department meeting. This has now happened and the audit has been closed. This audit has been submitted to Victoria Lamb/ Nicola Lawrence. As explained to all of the inspectors, there was an IT failure on the day of inspection which prevented access to many of the documents. Both of these audits mentioned	The inspection team acknowledges the PR’s response. The centre has provided a completed medicines management audit to the inspection team. We await the summary of the centre’s review of the quality management system due by 29 April 2019. Further action is required.

conducted was not recorded and there was no infection control audit available to the inspection team. The centre has not implemented practice guidance from the DHSC for surrogates, intended parents and healthcare professionals into their protocols and patient information which has been in force since February 2018. SLC T34, T36.	Details of when corrective actions noted in the centre's medicine management audit were due and completed should be provided when responding to this report. Three months after the review the PR should audit the QMS to ensure that corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this review should be forwarded to the centre's inspector by 29 July 2019. The PR should ensure all relevant guidance issued from the HFEA and other bodies is incorporated into centre practice. A revised copy of the centre's surrogacy protocols and patient information should be provided to the centre's inspector by 29 April 2019.	were submitted to Victoria Lamb on the day following the inspectionwhen the IT issue had been resolved. Even so an audit will be completed as requested by 29 April 2019, followed by a further review for submission on 29 July 2019. On the 15th March we will be launching the Audit module of Q-Pulse, which will ensure that the follow up of audits and any subsequent tracker is more easily tracked. The DHSC document has now been added to Q-Pulse Document Module and is therefore available for all staff at all locations. An email was immediately sent to all relevant staff within the JDH Group to make them aware of the addition of the document.	

		The document was also presented at the Clinical Governance Meeting which is attended by staff from all clinical departments. The PR and QM are also now signed up for monthly updates from the DH to ensure that such oversights do not occur in future.	
2. Medicines management On inspection the following issues were identified: • There were several entries in the controlled drugs register that were illegible. • The carry-over of controlled drugs from one page to another is not recorded or witnessed. SLC T2. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should review practices and procedures relating to medicines management, including, but not exclusively, the issues identified in this report. A summary report of this review, with corrective actions, including staff training, with timescales, should be provided to the centre's inspector by 29 April 2019.	The staff have been reminded of the importance of neatness within the CD book. The illegible writing was related to a signature of one particular staff member. We have requested that he is my concise in his writing style. The current CD book has been reviewed and all missing carry-over page numbers have been added. The audit will be completed as requested for submission on 29 April 2019.	The inspection team acknowledges the PR's response, review of processes and actions taken in implementing this recommendation. No further action is required beyond submission of the audit of medicines management practice and procedures due by 29 July 2019.

	Three months after the implementation of corrective actions the PR should audit medicines management practice and procedures to ensure that corrective actions implemented, have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 29 July 2019.		
3. Legal Parenthood In one patient record, the month on which the PP consent form (consent to being the legal parent) was completed was absent on one page of the consent form and the month in which it had been signed could only be assumed by the inspection team. A fully completed consent form was later provided to the executive. In another patient's record, the offer of counselling was not recorded.	The PR should ensure that procedures for legal parenthood consents are robust and compliant with statutory and regulatory guidance. The PR should conduct a root cause analysis (RCA) into the circumstances which led to the failings in the scanning and uploading of an incomplete legal parenthood consent in this case, including why the centre's own audit and processes failed to identify this anomaly.	The scanning equipment for the nursing team has been checked by the IT team and it was noted that one of the machines required cleaning. This may have led to a poor quality scan result. This machine has now been cleaned and a log added to the to ensure that the screens are cleaned daily. JDH is currently in the process of introducing an electronic consenting platform to reduce	The inspection team acknowledges the PR's response and await the summary of the centre's full RCA into this incident due by 29 April 2019. Further action is required.

The centre's audit had not identified these errors. Section 44(1) of Part 2 of the HF&E Act 2008. SLC T36.	A copy of the RCA should be provided to the centre's inspector by 29 April 2019.	the risk of poor scanning quality in the future.	

‘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
None			

Additional information from the Person Responsible