Executive Licensing Panel - minutes

Centre 0006 (The Lister Fertility Centre)

Interim Inspection Report

Variation of Licenced Premises

Tuesday, 28 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dina Halai Laura Riley	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Bernadette O'Leary	Licensing Manager Clinical Inspector (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 The Lister Fertility Clinic has held a licence with the HFEA since 1992, providing a full range of fertility services. Licensed activities at the centre include storage of gametes and embryos and embryo testing.

1.2. The panel noted that, in the 12 months to 30 September 2019, the centre had provided 2848 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, for IVF and ICSI, HFEA register data, for the period October 2018 to September 2019, show the centre's success rates are in line with the national averages with the following exception;

- The clinical pregnancy rate following FET in women aged under 38 years is higher than average at a statistically significant level.

1.4. The panel noted that, in 2018, the centre reported 318 cycles of partner insemination, with thirty-one pregnancies. This represents a clinical pregnancy rate of 9% which is in line with the national average.

1.5. The panel noted that, HFEA register data, for the period between August 2018 and September 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is significantly lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 30 October 2019.

1.7. The panel noted that at the time of inspection there were five major areas of non-compliance concerning medicines management, infection control, compliance with HFEA standard licence conditions, suitable premises and legal parenthood. There was also one 'other' non-compliance regarding equipment and materials. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement all the recommendations made in the report and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the centre's low multiple pregnancy rate.

2. Decision

2.1. The panel congratulated the centre on its low multiple birth rate.

2.2. The panel noted that only seventeen patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

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

3. Variation of Premises

3.1. The panel noted that the centre's PR had also submitted an application to change the centre's premises on the 11 November 2019.

3.2. The panel noted that, in November 2017, an application was made by the PR to extend the cryostore facilities by utilising a consultation room next to the existing cryostore. The PR subsequently postponed this application and it was not considered by the Executive Licensing Panel (ELP). During the interim inspection on 30 October 2019, the new cryostorage room, placed on hold two years previously, was seen to have been constructed and to be in full working order, with cryostorage dewars containing stored sperm. No new application to vary the licence to reflect this change to the licensed premises had been received or approved; an application was required given the change in function of the consultation room to cryostorage. The PR was advised of this and submitted an application, on 11 November 2019, to vary the centre's licence to reflect the change to the licensed premises seen on inspection.

3.3. The panel acknowledged that the non-compliances identified at the 30 October 2019 interim inspection are being addressed by the PR, with one being relevant to the cryostorage processes, due to the lack of licensing of part of the cryostore premises.

3.4. The panel noted as the new cryostore room was inspected during the interim inspection, it was not deemed necessary to undertake an additional on-site inspection for this variation application. A desk-based assessment of the application and associated documentation, supported by the interim inspection notes, was undertaken on 20 November 2019.

3.5. The panel noted that the inspector considered that sufficient information had been drawn from the documentation submitted by the centre and from the interim inspection to conclude that:

- The new cryostorage room is suitable for storing gametes and embryos;
- The practices used for storing gametes and embryos are suitable;
- The centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licensed premises.

3.6. The panel noted that there are no areas of practice that require improvement.

4. Consideration of Application

4.1. The panel considered the papers, which included an application form and licensing minutes for the past four years.

4.2. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

4.3. The panel noted that the inspectorate recommended that the application to vary the licence to reflect a change of existing premises to incorporate the creation of the additional cryostore is approved.

4.4. The panel noted that, should the application be approved, the new cryostore will provide additional space to future proof the storage facilities at the centre. Sufficient storage space will be available for some years to satisfy patients' requests to freeze and store their gametes and/or embryos.

5. Decision

5.1. The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

5.2. The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.

5.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

5.4. The panel endorsed the Executive's recommendation to approve this application to change the function of a consultation room to cryostorage.

6. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

4 February 2020

Interim Licensing Report

Centre name: The Lister Fertility Clinic
Centre number: 0006
Date licence issued: 1 March 2018
Licence expiry date: 28 February 2022
Date of inspection: 30 October 2019
Inspectors: Grace Lyndon (lead) and Louise Winstone
Date of Executive Licensing Panel: 28 January 2020

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. In particular we note the centre's low multiple pregnancy rate of 8%.

The centre provides a good level of patient support.

Since the inspection visit, the 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 within the required timescales:

Major areas of non compliance:

- The PR should ensure that staff prescribing and administering controlled drugs are aware of the record keeping requirements for controlled drugs and maintain full compliance with controlled drugs regulations and practice guidance.
- The PR should ensure that sharps bins are used in line with best practice guidance and waste management regulation.
- The PR should ensure that applications to the HFEA to vary the centre's licence are approved before any changes to licensed premises take place.
- The PR should take immediate action to ensure that the premises are safe for staff and patients and medical gases are stored appropriately.
- The PR should ensure that the centre's audits are robust.

'Other' areas of practice that require improvement:

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

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Information about the centre

The Lister Fertility Clinic has held a licence with the HFEA since 1992, providing a full range of fertility services. Licensed activities at the centre include storage of gametes and embryos and embryo testing.

The centre provided 2848 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2019. In relation to activity levels, this is a large centre.

The centre's licence was varied in March 2018 to reflect a change of PR.

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 October 2018 to September 2019 show the centre's success rates are in line with national averages with the following exception:

- The clinical pregnancy rate following FET in women aged under 38 years is higher than average at a statistically significant level.

In 2018, the centre reported 318 cycles of partner insemination with 31 pregnancies. This represents a clinical pregnancy rate of 9%, which is in line with the national average.

Multiple births[2]

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

Between August 2018 and September 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is significantly lower than 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 following laboratory activity was observed in the course of the inspection: egg collection. The procedure observed was witnessed using an 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

[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%.

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 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 and consent to storage.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the following exception. See Legal parenthood section and recommendation 5.

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
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding screening requirements

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:

- During observations in theatre, it was noted that the controlled drugs register was completed at the end of the theatre list and not at the end of each procedure and the discard of left-over drugs for four patients was not witnessed.
- In the controlled drugs register, the following issues were noted:
    - There is no log of anesthetists' signatures within the department and staff members were unsure whose signature or initials were used.
    - Unused portions of controlled drugs are discarded into sharps bins that do not have the appropriate labelling for incineration, which is not in line with waste management regulations.
    - A connector on the 'resuscitation airway trolley' was out of date (April 2019), this was not picked up on the routine weekly trolley checks.

The centre has full use of a main hospital theatre for services of the fertility patients. Theatre is manned by hospital staff, however, the centre still have the responsibility to ensure that safe practices are followed.

See recommendation 1.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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 partially compliant with guidance because:

- Temporary closures were not in use on two sharp bins, one in the theatre prep room and one in the consultation room.
- The self-closing mechanism was not in use on the clinical waste bin in the theatre prep room, which presented a risk of infection control.
- Sharps bins were filled beyond capacity in the theatre prep room and a clinical room.

See recommendation 2.

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 for use in treatment are not CE marked at the appropriate level.

See recommendation 6.

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 seventeen 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. The majority of patients (12) confirmed that they had paid what they

expected to, and five patients commented it was either more expensive (3) or way above the estimate (2).

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

On this inspection, the centre's own most recent patient survey responses were reviewed from 1 July 2019 and 30 September 2019. The feedback the centre received was extremely positive.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- 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 visit to the centre, indicate that the centre is not compliant with the following HFEA requirements:

- The centre submitted an application on 14 November 2017 to vary its licensed premises to extend their current cryostore. This application was put on hold by the centre in February 2018. On inspection, it was noted that this work had been completed and the new cryostore is in use. A room that was previously used as a consultation room has been refurbished and is now used as a cryostore housing the frozen sperm samples. The original cryostore is now used to store the frozen embryo samples. The application to vary the licence to change the licensed premises to reflect this was not completed. The inspection team reviewed the changed premises and considered that they are suitable for use as a cryostore. This does not however mitigate that the PR failed to ensure that the application to vary the licence had been approved.

See recommendation 3.

- There were numerous items of theatre equipment stored in a corridor, leading from theatre to the emergency fire exit. The inspection team considered this to be a safety risk to patients and staff.
- Medical gases are stored in three different locations within the centre and the following issues were noted:
    - In the 'plant room', although chains were in place on the gas canisters, they were not secured to a wall. More than four cylinders were not secure and were at risk of falling over.

- Gases are also stored behind a metal fenced area outside the building. None of the cylinders were chained in accordance with guidance and were at risk of falling over.
- There is no safety signage on the outside of the area and the area appeared crowded.
- In another storage area a number of large cylinders were not secured sufficiently and were at risk of falling over.

See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in July 2017, recommendations for improvement were made in relation to one 'other' area of non compliance.

The PR subsequently provided information and evidence that the recommendation was fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in 2017, the centre has received six risk tool alerts related to performances, which have not been responded to within the prescribed timescales. This was discussed with the PR during the inspection and he explained that it had been an oversight in the understanding of what was required. The PR has committed to ensure that risk tool alerts are now appropriately responded to. This will be monitored by the centre's inspector.

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 complaint with requirements to submit information to the HFEA, however the clinic currently have a number of missing outcome and donor registration forms. The PR is urged to ensure that this is rectified as soon as possible and this will be reviewed at the next inspection.

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 its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies. At the interim inspection in September 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to legal parenthood, in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

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. The centre's most recent audit had not been performed according to the method specified by the HFEA . 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 partially compliant with HFEA requirements.

The centre's own legal parenthood audit was not robust for the following reasons:

- There was no check that counselling was offered prior to obtaining consent to legal parenthood.
- There was no check that the consent forms had been completed before the treatment date.

See recommendation 5.

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	Inspection team's response to the PR's statement
None identified.			

‘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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Medicines management Several issues were noted as detailed in the main body of the report. DH (2007) ‘Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)’. The Controlled Drugs (Supervision of Management and Use) Regulations 2013.	The PR should ensure that staff prescribing and administering controlled drugs are aware of the record keeping requirements for controlled drugs and maintain full compliance with controlled drugs regulations and practice guidance. The PR should review practices and procedures relating to medicines management, including, but not exclusively to the issues identified in this report. A summary report of this	CD audits are being carried out and pharmacy team are monitoring compliance with a clear action plan. In addition to the regular audits an obervational audit has been added to monitor practice and compliance. This will be carried out by the pharmacy team or theatre manager, unannnounced, and will be carried out monthly. The log has been updated to include anaesthetists, to kept in Theatres & Pharmacy Theatre staff have been educated regarding best	The Executive notes the PR’s response to this non-compliance and the work undertaken in response to the inspection report. No further action required beyond submission of an audit of medicines management practice due by 30 April 2020.

	review, including any corrective actions, staff training, with timescales for implementation, should be provided to the centre's inspector by 30 January 2020. 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 30 April 2020.	practice for CD documentation and this is being monitored continiously. Theatre induction materials will also be reviewed and updated to ensure new starters and temporary/agency staff are aware of practice and expecation. A report of the audit will be provided in April 2020	
2. Infection control • Temporary closures were not in use on two sharp bins one in the theatre prep room and one in the consultation room. • The self-closing mechanism was not in use on the clinical waste bin in the theatre prep room which presented a risk of	The PR should ensure that sharps bins are used in line with regulatory requirements. The PR should provide a summary of actions taken to address this recommendation when responding to this report. Three months after implementation, the PR should	Stick on labels have been added to all sharps bins to remind staff to use temporary closures. In addition to the regular quarterly infection control audits, an unannounced audit will be carried out by the infection control lead (ad-hoc) to monitor practice. Infection control lead will	The Executive acknowledges the new implementations the PR's has already made and the commitment to be compliant. No further action beyond submission of audit due by 30 April 2020.

infection control. • Sharps bins were filled beyond capacity in the theatre prep room and in a clinical room. DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance.	conduct an audit of infection control practices, to ensure the effectiveness of the new process and staff training are embedded. The audit should be submitted to the centre's inspector by 30 April 2020.	create a 'waste management at a glance' guide for staff. tThe above actions will be monitored and a report will be submitted ibn April 2020.	
3. Compliance with HFEA standard licence conditions The centre submitted an application on 14 November 2017 to vary its licensed premises to extend their current cryostore. This application was put on hold by the centre in February 2018. On inspection, it was noted that this work had been completed and the new cryostore is in use. A room that was previously used as a consultation room has been refurbished and is now used as a cryostore housing the frozen sperm samples. The original cryostore is now used to store the frozen embryo samples. The application to	The PR should ensure that applications to the HFEA to vary the centre's licence are approved before any changes to licensed premises are undertaken. When responding to this report, the PR should submit an application to vary the licence (change of premises) and all the required associated documentation so that this application can be considered by a committee together with this inspection report. The PR should investigate why the change to the premises was made without adhering to the requirements of General	Application completed well in advance of work start or completion but incorrectly not submitted in portal when internal planning complete. It is not clear as to how and why the application was not resumed after being put on hold in February 2018. To mitigate this happening again, HFEA licensing requirements and portal review will be a regular agenda item on our quality management meeting and unit management agenda to ensure PR has complete oversight.	The Executive acknowledges the PR's commitment to implementing this recommendation and the implementations that have already been undertaken. The application to vary the centres premises will be considered by the committee together with this inspection report. No further action required

vary the licence to change the licensed premises to reflect this was not completed. The inspection team reviewed the changed premises and considered that they are suitable for use as a cryostore. This does not however mitigate that the PR failed to ensure that the application to vary the licence had been approved. General Direction 0008.	Direction 0008. This review should include suitable and appropriate corrective and preventative actions, with timescales for implementation, and should be provided to the centre's inspector when responding to this report. On balance, the inspection team do not consider there to be benefit in requiring the centre to suspend the use of the new cryostore until the licence is formally varied, because of the disruption this may cause to patient treatment and because the inspection team consider the revised premises are appropriate for licensed activities.		
4. Suitable premises There were numerous items of theatre equipment stored in a corridor, leading from theatre to the emergency fire exit. The inspection team considered this to be a fire hazard and safety risk to patients and staff. The regulatory Reform (Fire	The PR should take immediate action to ensure that the premises are safe for staff and patients and medical gases are stored appropriately. The PR should undertake a review to identify the factors that have led to this non-compliance. A summary of the findings of the review including	The equipment stored in corridors (blocking emergency fire exit) has been moved immediately. Theatre porters have been tasked with checking exits throughout the day to ensure they remain clear at all times. Medical gas training has been provided to new/bank porters on 27.11.19 to ensure they are	The Executive acknowledges the actions taken and the commitment to implement this recommendation. No further action required

Safety) Order 2005 14b (but not exclusive to). Medical gases were not stored securely in three separate locations and the outside storage area was crowded with no safety signage. SLC T2 and T17. British Compressed Gases Association (BCGA) 2016 Code of Practice 44, The Storage of gas cylinders 6 (6.2). DH (2006) Medical gases Health Technical Memorandum 02-01: Medical Gas Pipeline Systems, Part B.	corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. The PR should ensure that all medical gases are kept secure at all times. When responding to the report, the PR should provide an update on immediate actions that have been taken to address this issue identified by the inspection team. It is expected that compliant medical gas storage arrangements are in place by 30 April 2020.	compliant with regulatory requirements. The estates team will do ad-hoc checks on the medical gasses storage.	
5. Legal Parenthood The centre's own legal parenthood audit was not robust for the following reasons: • There was no check that counselling was offered prior to obtaining consent to legal parenthood; • There was no check that the consent forms had	The PR should ensure that the centre's audits are robust. The PR must ensure that staff have the appropriate training and competence to undertake effective audits of practice and procedure. The PR should provide detail of this review, including staff training requirements and timescales	The PR acknowledges that the audit did not show that counselling had been offered prior to consent. The audit template was incomplete and this has been rectified. An updated audit has been submitted to the HFEA which shows that not only was counselling offered prior to	The Executive acknowledges the PR's commitment to implementing this recommendation and the implementations that have already been undertaken and acknowledges the receipt of the legal parenthood changes. No further action required.

been completed before the treatment date. SLC T36.	for implementation of the actions to be taken to rectify the shortcomings of the audit process, to the centre's inspector by 30 January 2020.	treatment, as is our routine practice, but that counselling was provided prior to consent in all cases. The clinic ensures that counselling is also provided free of charge to all patients. A competency assessment relevant to the area of practice being audited will be undertaken by any auditor prior to auditing of that process. The Audit template submitted will be used forward	

‘Other’ areas of practice that requires improvement

Other 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
6. Equipment and materials The sample pots used for the collection of sperm for use in 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 by 30 January 2020 and should include the timescales by which the product identified in this report will either be replaced with a suitably CE	This was an oversight by the centre. A full audit has been completed to ensure all consumable items are CE marked in accordance with regulations.	The Executive has received confirmation that the CE marked sample pots are now in use at the centre. No further action required

	marked alternative or will obtain CE mark certification. The plan should be fully implemented by 30 April 2020.		

Additional information from the Person Responsible
None beyond my thanks for your time and contsructive comments.

Licence Variation Application Report

Inspectors: Grace Lyndon
Date of inspection: 20 November 2019
Date of Executive Licensing Panel: 28 January 2020
Purpose of report: Assessment of the centre's application to vary its licence to add another room to the licensed premises for use as a cryostore.

Centre details

Centre name	The Lister Fertility Clinic
Centre number	0006
Licence number	L/0006/16/b
Centre address	The Lister Hospital, Chelsea Bridge Road, London, SW1W 8RH, United Kingdom
Person Responsible (PR)	Mr James Nicopoullos
Licence Holder (LH)	Mrs Safira Batha
Date licence issued	27 February 2018
Licence expiry date	28 February 2022
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Lister Fertility Clinic is located in the Chelsea area of London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services to patients, including embryo testing.

The centre provided 2,848 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2019. In relation to activity levels, this is a large centre.

The centre was last inspected on 30 October 2019 when an interim inspection was performed. Recommendations were made to address five major and one other non-compliances. These are being addressed by the PR and are not relevant to cryostorage processes, but one is relevant to the lack of licensing of part of the cryostore premises, as discussed below.

In November 2017, an application was made by the PR to extend the cryostore facilities by utilising a consultation room next to the existing cryostore. The PR subsequently postponed this application and it was not considered by the ELP. Whilst undertaking the interim inspection on 30 October 2019, the new cryostorage room, placed on hold two years previously, was seen to have been constructed and to be in full working order, with cryostorage dewars containing stored sperm. No new application to vary the licence to reflect this change to the licensed premises had been received or approved, but an application was required given the change in function of the consultation room to cryostorage. The PR was advised of this and submitted an application, on 11 November 2019, to vary the centre's licence to reflect the change to the licensed premises seen on inspection.

The new cryostore room was inspected during the interim inspection so it was not deemed necessary to undertake an additional on-site inspection of this variation application; rather, a desk-based assessment of the application and associated documentation, supported by the interim inspection notes, has been performed.

The centre's licence was varied in March 2018 to reflect a change of PR.

Summary for licensing decision

In considering overall compliance, the inspector considers that they have sufficient information drawn from documentation submitted by the centre and observations from the interim inspection on 30 October 2019, to conclude that:

- the new cryostorage room is suitable for storing gametes and embryos;
- the practices used for storing gametes and embryos are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licensed premises.

The ELP is asked to note that there are no areas of practice that require improvement.

Recommendation to the Executive Licensing Panel

The Executive recommends that the application to vary the licence to reflect a change of existing premises to incorporate the creation of the additional cryostore is approved.

If the ELP approves this variation to the centre's existing premises, the new cryostore will provide additional space to future proof the storage facilities at the centre. Sufficient storage space will be available for some years to satisfy patients' requests to freeze and store their gametes and/or embryos.

Details of assessment findings

The licence variation application

An application was submitted by the PR at centre 0006 on 11 November 2019 to vary the centre's licence to reflect a change of premises, specifically the conversion of a consultation room into a room used for storing gametes and embryos.

The new cryostore room is needed because many of the centre's patients are opting to store their gametes and/or embryos and the centre wishes to continue to offer this service. The centre has reviewed their current cryostore space and decided to implement the new cryostore to future proof cryostorage capacity. This additional space was achieved by converting a consultation room into an additional cryostore with access independent from the current cryostore.

The applicant has complied with all the requirements of General Direction 0008 H (14) in submitting at the time of application or on request thereafter:

- an application form;
- a floor plan showing the new cryostore;
- evidence that the equipment used to provide gamete and embryo storage in the room has been validated.

Details of the inspection findings

1. Key documents were provided by the centre in support of the change of premises application, to provide assurance that the premises and equipment in the proposed new facilities are suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)). The new cryostore was also reviewed at the interim inspection on 30 October 2019.

2. On the basis of the submitted application and supporting information, and the inspection findings, it was concluded that the new cryostore is compliant with requirements because:
    - The room is within the existing premises authorised by the centre's licence. A floor plan has been provided detailing the room's location.
    - The room is under the control of the PR, is secure and access to it is limited to specific members of the laboratory team authorised by the PR.
    - The room has been refurbished to meet the requirements of the relevant health technical memoranda and health building notes.
    - The room has been fitted with appropriate safety signage.
    - The room has been equipped with an appropriate and validated oxygen monitoring system, with displays and alarms inside and outside the room, and a boosted extraction system to clear any nitrogen spillages.
    - Dewars and a dewar temperature monitoring system, all validated, are present in the new cryostore room.
    - The centre's critical processes related to cryopreservation are not affected by the introduction of this new cryostore to the licensed premises, and were considered appropriate at the interim inspection on 30 October 2019.
    - The PR has advised that standard operating procedures have been reviewed and updated where necessary.

- Staff using the new cryostore room have had appropriate induction and training to allow them to use the room safely.

3. In summary, based on the inspector's assessment of the application and observations from inspection on the 30 October 2019 and as detailed above, the inspector concludes that the centre's new cryostore is suitable for the conduct of licensed activities, specifically gamete and embryo storage.

4. No areas of practice required improvement.

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 carried out.

Critical area 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 to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

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 to a 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;
- 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

Additional information from the Person Responsible