Licence Committee - minutes

Centre 0321 (NewLife Fertility Centre)
Unannounced Targeted Interim Inspection

Thursday, 7 May 2020

Teleconference

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Karen Conyers (Observing)	Committee Secretary Inspector
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Interim Inspection Report
- Licensing minutes from the past three years:
  - 2019-09-05 Licence Committee Minutes - Renewal Inspection
  - 2019-07-09 Executive Licensing Panel Minutes - Renewal Inspection / Variation of Person Responsible (PR) and Licence Holder (LH)
  - 2018-10-01 Licensing Officer Record of Consideration - Variation of Licence Holder (LH)
  - 2017-10-06 Executive Licensing Panel Minutes - Targeted Interim Inspection

1. Background

1.1. NewLife Fertility Centre, centre 0321 is located in Epsom, Surrey. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2011 and provides a full range of fertility services.

1.2. A licence renewal inspection was carried out at the centre on 5 and 6 March 2019.

Executive Licensing Panel (ELP) Decision - 9 July 2019 - Renewal

1.3. The Executive Licensing Panel (ELP) considered the centre's renewal inspection report on 9 July 2019, alongside applications for a change of Person Responsible (PR) and a change of Licence Holder (LH).

1.4. The panel noted that recommendations were made to address one critical, two major and three other areas of non-compliance.

1.5. The panel also noted that the centre's previous licence had been issued for three years, rather than the usual four, due to concerns about compliance.

1.6. The panel had major concerns regarding the range of non-compliances identified at the renewal inspection, in particular the critical non-compliance relating to legal parenthood, and decided to adjourn its decision to renew the centre's licence and Importing Tissue Establishment (ITE) certificate, making a referral to the Licence Committee for consideration, requesting that the Executive provides further updates on legal parenthood, medicines management, witnessing, quality management and record keeping.

1.7. The centre's licence was soon to expire on 2 August 2019, therefore the panel also issued Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended) to permit the continuation of licensed activity upon expiry of the centre's licence, to allow time for the renewal to be considered by the Licence Committee.

1.8. The panel agreed to vary the centre's existing licence to reflect a change of PR and LH with immediate effect.

Licence Committee Decision – 5 September 2019 - Renewal

1.9. The Licence Committee considered the centre's renewal inspection and renewal of its ITE certificate on 5 September 2019. Carefully weighing all factors in the balance, the Licence Committee agreed that a three year licence, rather than the usual four years, without additional conditions was appropriate, subject to the Executive's recommendations being implemented within the prescribed timescales.

1.10. The committee noted that since the renewal inspection, the Executive considered that the new PR had fully engaged with the HFEA and has demonstrated a commitment to ensure that the centre achieves full compliance. The committee urged the PR to continue along this improved path. The committee noted that action had been taken to address all of the non-compliances within the set timescales, however further information was required to fully implement the recommendations. The PR provided information in a timely manner. The Executive planned to complete a final assessment of the centre's compliance with all of the recommendations in due course.

1.11. The committee endorsed the Executive's recommendation to complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance, including leadership. The committee decided that this inspection should be unannounced. The committee expected the PR to continue to engage with the Executive and gain full knowledge and understanding of her role and responsibilities, and of the staff working within the team, and to have developed systems through which she is able to lead the centre in a compliant manner, by the time of the interim inspection.

1.12. The committee requested that the report of the unannounced targeted interim inspection is considered by the Licence Committee which expect all of the recommendations to be fully implemented within the timescales with a shift in culture to learning, improving and maintaining good practice.

1.13. An unannounced targeted interim inspection was completed on 17 February 2020 and a report of this inspection has been submitted for consideration by the Licence Committee.

Whistle Blower Investigation – November 2019

1.14. On 18 November 2019 the HFEA received information from a 'Whistle Blower' raising concerns regarding a number of areas of practice at the centre. The Executive had regards to the HFEA Whistle Blowing Policy and the HFEA Compliance and Enforcement Policy and a management review meeting was held on 22 November 2019 to consider the allegations. The PR was given notice of a visit which was conducted on 29 November 2019.

1.15. The Whistle Blower's allegations were numerous and the subjective nature of some meant that assessment by the Executive was difficult. However, the Executive went to considerable lengths to ensure that the allegations made were investigated and relevant documentation was reviewed. The Executive concluded that they had no immediate concerns about practices at the centre.

1.16. The Executive did identify a number of areas of practice that required improvement at the visit. A further management review meeting was held on 5 December 2019 to review the findings of the investigation. The Executive considered that these areas were being addressed and agreed that there were no immediate concerns regarding safe practices at the centre and that the PR had engaged positively with the HFEA. No formal action was required. Consideration was given to the fact that the Executive had planned an unannounced targeted interim inspection early in 2020.

2. Consideration of application

Application

Unannounced Targeted Interim Inspection

2.1. The committee noted that an unannounced targeted interim inspection took place on 17 February 2020.

Inspection Process

2.2. The committee noted that for IVF and ICSI, HFEA-held register data for the year ending 30 November 2019, showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages.

2.3. The committee noted that in the 12 months to 31 January 2020, the centre provided 218 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that for the year 2019, the centre reported 44 cycles of partner insemination with five clinical pregnancies, which was comparable to the national average.

2.5. The committee noted that between December 2018 and November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.6. The committee noted that the unannounced targeted interim inspection focused on reviewing all actions taken by the centre in response to the findings of the licence renewal inspection in March 2019.

2.7. The Licence Committee noted that at the time of the inspection there were a number of areas of practice that required improvement, including two major and four 'other' areas of non-compliance.

2.8. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement most of the 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 medicines management practices are compliant with regulations.
- The PR should ensure that the centre's premises and facilities are suitable for patients and staff.

Other areas of non-compliance:

The PR should ensure that there is a robust process for disseminating and acting on information and guidance provided by the HFEA and other sources.
The PR should ensure that the risks of Ebola infection are considered prior to patients being treated.
The PR should ensure compliance with infection prevention and control regulations.
The PR should ensure compliance with sedation practice professional guidance.

2.9. The PR has committed to implementing the outstanding recommendation relating to sedation practice.

Recommendations

Licence

2.10. The committee noted that the Executive recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

2.11. The Executive reported that the centre is well led and leadership at the centre has improved. Centre staff have worked hard to raise the level of compliance since the last inspection and the centre provides a good level of patient support.

3. Decision

3.1. The committee had regard to the HFEA Whistle Blowing Policy and HFEA Compliance and Enforcement Policy.

Licence

3.2. The committee deliberated on the non-compliances and the PR's response to the unannounced targeted interim inspection report.

3.3. The committee acknowledged that the PR has been in post for less than a year and the Executive considers that the PR is fully engaged with the team and the centre is well led. The committee agreed that good leadership improves patient care and is encouraged by the HFEA.

3.4. The committee endorsed the Executive's recommendation for the continuation of the centre's treatment (including embryo testing) and storage licence.

3.5. The report of the next inspection should be submitted to the Licence Committee for consideration, by which time all recommendations should be fully implemented and improvements maintained.

Timescales

3.6. In accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic, centres were required to suspend fertility treatments in March 2020. Therefore, the Executive will liaise with the PR to consider appropriate timescales to fully implement outstanding recommendations.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

1 June 2020

Targeted interim inspection report

Centre name: NewLife Fertility Centre
Centre number: 0321
Date licence issued: 3 August 2019
Licence expiry date: 2 August 2022
Additional conditions applied to this licence: None
Date of inspection: 17 February 2020
Inspectors: Louise Winstone and Sandrine Oakes
Date of Licensing Committee: 7 May 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).

The HFEA conducted a licence renewal inspection of this centre in March 2019. The report of that inspection was considered by the Licence Committee in September 2019, the committee's decision was to renew the centre's licence for three years, rather than the usual four, and required that a targeted interim inspection be performed within one year.

This is a report of the targeted interim inspection which was unannounced. The inspection was focused on reviewing all actions taken by the centre in response to the findings of the licence renewal inspection in March 2019.

The aim of this report is to provide the Licence Committee with information on the centre's progress with actions taken in response to findings so it can decide about the continuation of the centre's licence.

Summary for the Licence Committee

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 inspection team considers that leadership at the centre has improved and that clinic staff have worked hard to raise their level of compliance since the last inspection.

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major and four 'other' areas of non-compliance.

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 within the required timescales:

Major areas of non-compliance:

- The PR should ensure that medicines management practices are compliant with regulations.
- The PR should ensure that the centre's premises and facilities are suitable for patients and staff.

'Other' areas of non-compliance:

- The PR should ensure that there is a robust process for disseminating and acting on information and guidance provided by the HFEA and other sources.
- The PR should ensure that the risks of Ebola infection are considered prior to patients being treated.
- The PR should ensure compliance with infection prevention and control regulations.

The PR has committed to implementing the following recommendation:

'Other' areas of non-compliance:

- The PR should ensure compliance with sedation practice professional guidance.

Information about the centre

NewLife Fertility Centre has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2011 and provides a full range of fertility services.

The centre provided 218 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2020. In relation to activity levels this is a small centre.

The centre's licence was varied in July 2019 to reflect the following: change of PR and change of Licence Holder (LH).

The centre's licence renewal inspection on 5 and 6 March 2019 reported one critical, two major and three 'other' areas of non-compliance or poor practice. Given the nature and number of critical and major non-compliances identified during this inspection, the executive held a management review meeting in accordance with the HFEA's Compliance and Enforcement Policy on 23 June 2019. The purpose of this meeting being to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application.

The report of that inspection was considered by the Executive Licensing Panel (ELP) on 9 July 2019. The panel expressed major concerns regarding the range of non-compliances identified at the licence renewal inspection, particularly noting the critical non-compliance concerning consent to legal parenthood. The panel also noted that the previous licence had been issued for three years (rather than the usual four) because of concerns about the level of compliance at that stage. The panel decided to adjourn any decision regarding renewal of the centre's licence requesting the matter to be referred to the Authority's Licence Committee for consideration.

The Licence Committee considered the licence renewal inspection report on 5 September 2019. The committee granted a three-year licence rather than the usual four. The committee endorsed the executive's recommendation to conduct a targeted interim inspection within one year to assess the implementation of the recommendations made and the centre's general level of compliance, including leadership. The committee decided that this inspection should also be unannounced.

On 18 November 2019 the HFEA received information from a 'whistle-blower' raising concerns regarding a number of areas of practice at the centre. The HFEA's whistle blowing policy was followed and, in accordance with the HFEA Compliance and Enforcement Policy, a management review meeting was held on 22 November 2019 to consider the allegations made. The allegations were deemed serious, if founded, and of a type that the executive was unable to give a fair consideration to without visiting the centre. It was decided that an announced visit to the centre was appropriate. The PR was given notice of the visit which was conducted on 29 November 2019 by two members of the inspection team.

The whistle blower's allegations were numerous and the subjective nature of some meant that assessment by the executive was difficult. The inspection team went to considerable lengths to ensure that the allegations made were investigated and relevant documentation was reviewed. The allegations were discussed in full with the PR and with individual members of staff. The inspection team concluded that they had no immediate concerns

about practices at the centre. During the course of the visit the inspection team did however identify a number of areas of practice that required improvement, the details of which were provided to the PR for action. The PR fully engaged with the HFEA and was responsive to the inspector's recommendations.

A further management review meeting was held on 5 December 2019 to review the findings of the investigative visit. The executive agreed that there were no immediate concerns regarding safe practices at the centre and that the PR had engaged positively with the HFEA. The areas of practice identified as requiring some improvement at that visit were being addressed. Consideration was also given to the fact that the centre was to have a targeted (unannounced) interim inspection early in 2020. It was concluded that no formal action was required.

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 year ending 30 November 2019, show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2019, the centre reported 44 cycles of partner insemination with five clinical pregnancies, which is comparable to the national average.

Multiple births[2]

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

Between December 2018 and November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. 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 was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review witnessing in patient records. 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

[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%.

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 described that they 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.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- Leadership
- Consent
- Screening
- Imports of gametes and embryos from outside the EU/EEA
- Data submission to the HFEA
- The use of CE marked medical devices
- The content of the centre's website
- The centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding screening requirements and safe sedation practice

The centre is broadly effective in implementing learning from guidance (see recommendation 3) because the centre has not ensured compliance with guidance regarding safe sedation practice issued in September 2019 (see recommendation 4) and screening for Ebola issued in February 2017 and April 2017 (see recommendation 5).

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. The inspectors noted that there has been an improvement in the centre's practices since the last inspection; however the following further issues were identified on this inspection:

- The keys to the controlled drugs (CD) cupboard are kept in a locked 'master' key box with all other duplicate keys for the clinic. The inspection team acknowledges that nursing staff are the only staff accessing the 'master key box' and the key to this box is kept in another box in the nurses' room, which is locked overnight. However, the inspection team was concerned that the key to the 'master' key box was not sufficiently secure and may be accessible by other clinic staff during the day, if they needed to access a duplicate key located in the 'master' key box.
- In the CD register:
    - One entry for a drug administered had been recorded as '10 mcg' instead of '100 mcg'.
    - One correction was not adequately marked by an asterix and a footnote.

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 to be 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 broadly compliant with guidance because:

- In theatre, two face masks were connected to two manual resuscitators (ambu bags). Whilst the ambu bags were in a plastic bag, the face masks original packaging had been removed before the point of use, which poses an infection control risk.
- Several boxes in the nursing/embryology storage room were on the floor, which did not allow free access to floors for cleaning.

See recommendation 6.

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

Record keeping

Good medical records are essential for the continuity of the patient’s care. At the renewal inspection in March 2019, it was noted by the inspection team that there was no record of how, and by whom a patient, partner or donor was identified. Following the inspection, the PR reviewed this area of practice and implemented corrective actions. At this inspection, no further issues were identified.

Donor assessment and screening

It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. At the renewal inspection in March 2019, it was identified that a donor had not been screened in accordance with professional body guidelines; the donor had not had a physical genital examination. At this inspection, the centre’s donor screening SOP was reviewed and had been updated to be compliant with professional body requirements. The centre has not recruited any further donors since the last inspection, so no records were available to view.

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. Twelve patients have provided feedback in the last 12 months, giving an average 3.5-star rating to the clinic. This feedback was discussed with the PR during this inspection and the PR made a commitment to continue to act on patients' suggestions. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

No patients were available to speak to the inspectors during the inspection.

The centre's own most recent patient survey responses were reviewed. This questionnaire uses the same questions as those on the HFEA's 'Choose a Fertility Clinic'. Thirteen patients had provided feedback since January 2020 and feedback was mostly positive.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is non-compliant with the following HFEA requirements:

- One spare oxygen cylinder was stored unsecured in an unlocked storage cupboard, this cupboard had no medical gas safety signage and was not exclusively storing medical gas cylinders (see recommendation 2).

- There was no medical gas safety signage on the laboratory doors leading to the cryostorage room (see recommendation 2).
- One of the two outdoor clinical waste bins was not locked and there was a risk it may be accessible by the public (see recommendation 2).
- The centre is not using the recommended continuous waveform capnography during conscious sedation (see recommendation 4).
- The centre does not consider the need for additional screening tests which may be required because of patients travel and/or exposure history, with regards to Ebola (see recommendation 5).

Compliance with recommendations made at the time of the last inspection

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

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

On-going monitoring of centre success rates

Since the last licence renewal inspection in March 2019, the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

At the renewal inspection in March 2019, issues were identified in relation to legal parenthood consenting processes for a case involving surrogacy. The inspectors were assured that staff have since received training and all surrogacy documents have been reviewed by a legal team and updated. The centre has not performed any further surrogacy cases since the last inspection.

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 compliant with HFEA requirements.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

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

The centre's PR has been in post since July 2019 following a change of both PR and LH at that time. During the visit to the centre in November and again at this inspection the inspection team considers that the PR is fully engaged with her team and that the centre is well led.

Annex 1

Areas of practice that require the attention of the Person Responsible

This section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be made.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None 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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines Management The following issues were identified: • The keys to the CD cupboard are kept in a locked ‘master’ key box with all other duplicate keys for the clinic. The inspection team acknowledges that nursing staff are the only staff accessing the ‘master key box’ and the key to this box is kept in another box in the nurses’ room, which is locked overnight. However, the	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should review the practices regarding the safe custody and access to the controlled drugs cupboard to ensure compliance with regulatory requirements and best practice guidance. Details of the corrective actions taken should be provided to the centre’s	All CD keys are stored in a key safe inside a locked room that is only accessible by nurses The key to the master key box is now stored in a key safe that is also only accessible by nurses	The executive acknowledges the PR’s response and implementation of this recommendation. No further action required beyond submission of the audit due by 17 August 2020.

inspection team was concerned that the key to the 'master' key box was not sufficiently locked away and may be accessible by other clinic staff during the day, if they needed to access a duplicate key located in the 'master' key box. • In the CD register: o One entry for a drug administered had been recorded as '10 mcg' instead of '100 mcg'. o One correction was not adequately marked by an Asterix and a footnote SLC T2. Section 19(a) and 20(c) Misuse of Drugs (safe Custody) Regulations (2001).	inspector when responding to this report. The PR should ensure that all relevant staff are aware of the correct procedures for recording and making corrections in the CD register in accordance with Misuse of Drugs regulations. Details of the actions taken to ensure staff are informed should be provided to the centre's inspector when responding to this report. Three months after the review the PR should conduct an audit of controlled drug register entries to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 August 2020.	Staff have been given training and updates on the clinics SOP in line with recording and making corrections in the CD register and in accordance with the Misuse of Drugs Regulations. An audit will be conducted prior to 17th August 2020 and the report shared with the HFEA	

Sections 4.5.2 and 4.5.4 Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007). Recommendations 2 and 5 of The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' (2019). Section 20(c) Misuse of Drugs (safe Custody) Regulations (2001).			
2. Premises and facilities The following issues were identified: • One spare oxygen cylinder was stored unsecured in an unlocked storage cupboard and with no safety signage. • There was no safety gas signage on the laboratory doors. • One of the two outdoor clinical waste bins was	The PR should ensure that the centre's premises and facilities are suitable for patients and staff. The PR should ensure that systems are in place for the safe storage and signage of medical gases at all times. A plan of actions with timescale for implementation of this recommendation	The spare oxygen bottle was excess to requirement, it has been returned to supply and will not be replaced. Therefore no safety signage is required for this.	The executive acknowledges the PR's response and implementation of this recommendation. No further action is required.

not locked and there was a risk it may be accessible by the public. SLC T17. Sections 8.20, 8.27, 8.29 and 8.31 Department of Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006). Section 3.163 Department of Health Building Note 00-09: 'Infection control in the built environment' (2013).	should be provided by the PR when responding to the report. The PR should ensure that clinical waste awaiting collection is kept in a locked bin at all times. A plan of actions with timescale for implementation of this recommendation should be provided by the PR when responding to the report.	The safety gas signs have been placed on the laboratory doors The lock on the external clinical waste bin has been repaired and can now be easily locked / unlocked. The two external clinical waste bins are locked at all times and monitored by CCTV.	

‘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
3. Quality management system The clinic’s processes for learning are not effective in relation to implementing HFEA Clinic Focus guidance regarding safe sedation practices (the centre is not using the recommended continuous waveform capnography) and screening for patients with relevant travel history. SLC T32. Page 19; Safe sedation practice for healthcare procedures - standards and guidance (2013). Clinic Focus February 2017, April 2017 and September 2019.	The PR should ensure that there is a robust process for disseminating and acting on information and guidance provided by the HFEA and other sources. The PR should review the process in place for disseminating and acting on information and guidance provided by the HFEA to ensure robustness and allow learning. The PR should provide a summary report of the review, with corrective actions, to the centre’s inspector by 17 May 2020.	There is a process in place to distribute and act on information. This involves email distribution and assigning actions to members of staff. A review of the process has been conducted and provided with this report.	The executive acknowledges the PR’s response and implementation of this recommendation. The PR has provided a review of the processes in place to disseminate information. No further action is required.

	Three months after the implementation of corrective actions the PR should review the process for disseminating information to the team to ensure that actions implemented have been effective. The PR should provide a summary report of this review to the centre's inspector by 17 August 2020.	An audit will be conducted in three months' time and the report shared with the HFEA	
4. Sedation practice The centre is not using the recommended continuous waveform capnography during conscious sedation. SLC T2. Page 19; Safe sedation practice for healthcare procedures - standards and guidance (2013).	The PR should ensure compliance with conscious sedation practice professional guidance. A plan of actions with timescale for implementation of this recommendation should be provided by the PR when responding to the report.	We are in the process of purchasing capnography which is compatible with the available capnography masks	The executive acknowledges the PR's commitment to fully implementing this recommendation. The PR is asked to confirm when the appropriate capnography is in use. Further action is required.
5. Screening The centre does not consider the need for additional screening tests which may be required because of patients	The PR should ensure that the risks of Ebola infection are considered prior to patients being treated.		The executive acknowledges the PR's response and implementation of this recommendation.

travel and/or exposure history, with regards to Ebola. SLC 50(d).	The PR should ensure that the centre's procedures for screening patients, clearly document the requirement for consideration of additional screening, including (but not exclusively) Ebola. The PR should provide a copy of the revised procedure to the centre's inspector by 17 May 2020. Three months after implementing the revised procedure, the PR should audit patient history and screening procedures to ensure that corrective actions implemented have been effective. A summary report of the audit should be provided to the centre's inspector by 17 August 2020.	The need to consider exposure has been added to the initial consultation procedure/ form. -Screening Tests Info The doctors have incorporated this into their Initial consultation process alongside the Zika virus Patient information about Ebola is now displayed in the patient waiting area An audit will be conducted in three months' time and the report shared with the HFEA	No further action required beyond submission of the audit due by 17 August 2020.
6. Infection control The following issues were identified: • In theatre, two face masks were connected to	The PR should ensure compliance with infection prevention and control regulations.		The executive acknowledges the PR's commitment to fully implementing this recommendation.

two manual resuscitators (ambu bags). Whilst the ambu bags were in a plastic bag, the face masks original packaging had been removed before the point of use, which poses an infection control risk. • Several boxes in the nursing/embryology storage room were on the floor, which did not allow free access to floors for cleaning. SLC T2. Section 4, The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Safety Guideline, Infection Control in Anaesthesia' (2008). Section 3.105 DH Health Building Note 00-09: 'Infection control in the built environment' (2013).	A plan of actions with timescale for implementation of this recommendation should be provided by the PR when responding to the report.	The unpackaged masks have been discarded. New face masks have been ordered and will remain in sealed packaging. The stockroom is being reorganised to prevent floor storage. This may include additional shelving as required.	No further action is required.

Additional information from the Person Responsible