Licence Committee - minutes

Centre 0333 (Harley Street Fertility Clinic)
Targeted Unannounced Interim Inspection

Thursday, 5 September 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Anita Bharucha (Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Debbie Okutubo - Observer	Committee Secretary Governance Manager
Legal Adviser	Tom Rider	Field Fisher 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:

- Inspection report
- Previous licensing minutes for the last three years:
    - Licence Committee Minutes - 10 January 2019 - Executive update – Interim Inspection
    - Executive Licensing Panel Minutes - 16 August 2018 –- Interim Inspection
    - Executive Licensing Panel Minutes - 6 October 2017 - Inspection to Investigate Whistle Blower Concerns
    - Executive Licensing Panel Minutes - 20 May 2016 - Renewal Inspection
    - Executive Licensing Panel Minutes - 29 January 2016 - Progress Report

1. Background

1.1. The Harley Street Fertility Clinic, centre 0333 is located in central London. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014 and provides a full range of fertility services. This is a relatively new centre.

Current Licence

1.2. The centre's current licence was issued for a period of 4 years in July 2016 and is due to expire on 22 July 2020.

Executive Licensing Panel – Decision – August 2018 (Interim Inspection Report)

1.3. An interim inspection was carried out in April 2018. Recommendations for improvement were made in relation to four critical, four major and two 'other' areas of non-compliance. The centre was guided and supported by the inspectorate and the Person Responsible (PR) provided evidence to confirm that most of the recommendations had been fully implemented. The PR made a commitment to audit the effectiveness of action taken within the set timescale.

1.4. The Executive recommended the continuation of the centre's licence and a further unannounced inspection within twelve months of the last inspection, due to the number and severity of non-compliances, some of which were noted at previous inspections. This recommendation was made to ensure that compliance has been maintained and corrective action has been effective and embedded into the centres current practices.

1.5. On 16 August 2018, the Executive Licensing Panel (ELP) considered the centre's interim inspection report. The panel considered the centre's history of non-implementation of HFEA recommendations.

1.6. The panel was particularly concerned with the lack of awareness and action in relation to multiple clinical pregnancies. The centre's multiple clinical pregnancy rate had been at 26% since October 2014 and increased to 28% in 2018, meaning that the maximum multiple live birth target of 10% was exceeded and continued to increase.

1.7. The panel did not feel it had sufficient evidence to suggest that the centre would be able to implement recommendations without considerable long-term support from the Executive. Despite the PR's history of engagement with the inspectorate, non-compliances which had been identified on earlier inspections remained and additional non-compliances had appeared.

1.8. The panel was not confident in the PR's ability to ensure regulatory compliance in a timely manner and decided to adjourn its decision and refer the matter to the Licence Committee for consideration with the relevant updates.

1.9. The Licence Committee considered the centre's interim inspection report at its meeting on 10 January 2019. The committee shared the Executive Licensing Panel's concerns about the history of non-compliance outlined in the report.

1.10. The committee noted that the PR was engaging with the Executive and making progress with significant support. The committee endorsed the Executive's recommendation for the continuation of the centre's licence and agreed that, due to the nature and number of non-compliances identified at the interim inspection in April 2018, and the recurrence of non-compliances noted at previous inspections, a further unannounced inspection should take place within 12 months of the previous inspection, to ensure that compliance has been maintained.

1.11. The committee agreed that the report of the targeted unannounced interim inspection should be submitted to the Licence Committee for consideration.

2. Consideration of application

Targeted Unannounced Interim Inspection – April 2019

2.1. The committee noted that a targeted unannounced interim inspection was conducted at centre 0333 on 17 April 2019. The inspection report covers the findings from this inspection, together with an assessment of the centre's performance based on information received, including the centre's self- assessment of its service and progress made implementing the recommendations identified at the last inspection.

2.2. The inspection covered:

- Quality of care
- Patient safety
- Patient experience

2.3. The committee noted that in the 12 months to 28 February 2019, the centre provided 245 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period January 2018 to December 2018 showed the centre's success rates were in line with national averages.

2.5. The centre failed to submit annual IUI data for 2018 within the required time frame. The IUI data was submitted after it was requested during the interim inspection. In 2018, the centre reported 68 cycles of partner insemination with nine clinical pregnancies. This represented a clinical pregnancy rate of 6% which was below the national average.

2.6. The committee noted that between January 2018 and December 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 17%. This represents performance that is not likely to be statistically different from the maximum 10% multiple live birth rate target for this period.

2.7. The committee noted that a targeted unannounced interim inspection took place on 17 April 2019. At the time of the inspection there were two critical, three major and one other area of non-compliance identified.

Critical areas of non-compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements.
- The PR should ensure that all compressed gas cylinders are stored in accordance with compressed gas safe handling and storage requirements.

Major areas of non-compliance:

- The PR should ensure that the quality management system is effective and fit for purpose.
- The PR should ensure that infection control guidance is adhered to.
- The PR should ensure that only CE marked medical devices are used wherever possible.

Other areas of non-compliance or poor practice:

- The PR should ensure that the centre's data is submitted within the allotted timescales.

2.8. There were a number of concerns regarding patient, staff and public safety, found during this inspection, which had been noted previously. The inspectorate was particularly concerned about the critical area of non-compliance relating to the storage of compressed gas cylinders as they are accessible to members of the public and pose a significant risk. The PR has fully implemented most of the recommendations made by the HFEA following this unannounced inspection and, where required, will provide an update or summary of audits conducted to ensure that corrective action taken is effective, within the set timescales. The PR has also committed to fully implementing the outstanding recommendation to address the critical area of non-compliance relating to the storage of compressed gas cylinders.

2.9. Since the inspection in 2018, the Executive has given the PR significant support, including weekly teleconference meetings, to implement the recommendations and achieve compliance. The inspectorate remains concerned about the level of progress made by the centre and noted that the centre is not proactive in taking action or learning.

2.10. The committee noted that significant improvement is required in order for the centre to reflect suitable practices.

2.11. The centre has a Quality Management System (QMS) and the PR is encouraged to continue to use it to monitor and improve the centre's success rates and the quality of the service offered to patients.

Management Review Meeting – 23 May 2019

2.12. Due to the serious nature of the critical areas of non-compliance identified, a management review meeting was held on 23 May 2019, in accordance with section 3.1 of the HFEA Compliance and Enforcement Policy, to evaluate the findings of the interim inspection and consider a proportionate course of action.

2.13. A report was sent to the PR, and shortly after, a conference meeting was held with the PR, Centre Manager, the HFEA lead Inspector and Chief Inspector. The PR provided updates on action taken and progress to date and made a commitment to work closely with the Executive to achieve compliance within the set timescales.

Recommendations

Licence

2.14. The committee noted that, the Executive recommends continuation of the centre's licence.

Inspection

2.15. The committee also noted that centre 0333 is due to have a renewal inspection later this year, subject to an application being submitted by the PR to renew the licence. This scheduled renewal inspection will focus on the non-compliances in inspection reports. Failure to achieve and maintain compliance, may result in a recommendation to Licence Committee for more formal regulatory action.

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Medicines Management

3.2. The committee noted that recommendations were made to address issues relating to medicines management and the safe storage, disposal and administration of medicines as the centre was not compliant. Issues were found with witnessing, staff not following standard operating procedures and the Misuse of Drugs Regulations. There were also issues with record keeping and monitoring expiry dates. Despite the centre having had an independent review of medicines management, practice in this area continues to fall short of expected standards.

3.3. The PR has investigated why non-compliances identified in this report have not been addressed from previous inspections.

3.4. The committee noted that the PR had investigated the issues and taken action as a result. This report was submitted to the Executive who confirmed receipt and no further action is required.

Compliance with HFEA standard licence conditions, gas cylinder storage

3.5. The committee noted that the cylinders were not secured in accordance with gas cylinder storage regulations as six large and one medium compressed gas cylinder were secured by one chain outside, in an area accessible to the public. This non-compliance poses a significant risk to the public and has been identified at each inspection since 2017, therefore it has been upgraded to a critical non-compliance.

3.6. The committee noted that planning permission was refused and awaits an update on the outcome of the independent review of the centre's gas storage facilities.

Quality Management System (QMS)

3.7. The committee noted that the effectiveness of the centre's Quality Management System was assessed by reviewing the reports of audits for medicines management, infection control, legal parenthood, witnessing and consent to storage.

3.8. The centre's procedures for auditing and acting on the findings of audits were not compliant with requirements. The centre's documentation was incomplete and there were no audits in place for infection control, and no Standard Operating Procedure (SOP) for safeguarding. The controlled drugs SOP was not robust and there was no clear evidence that the centre responds to patient feedback.

3.9. The inspectorate recommended that the PR reviews practices and procedures relating to the quality management system, including, but not exclusively, the issues identified in this report.

3.10. The committee noted that timeframes for implementation or indication of any action undertaken to complete the recommendations were also issues identified at the last inspection.

3.11. The Executive confirmed receipt of the QMS review, information on action taken, and documents provided to demonstrate evidence of compliance with this recommendation.

3.12. No further action is required beyond submission of the audit due by 16 November 2019.

Infection Control

3.13. This was an area of non-compliance identified at the last inspection.

3.14. The committee noted that the centre's infection control practices were reviewed and found to be partially compliant. There were issues with the quality and condition of furnishing and flooring, uncleansed areas and accessibility of clinical waste to the public. The inspectorate could not reconcile the PR's claim that the clinical waste bins were locked on the day of inspection as this was not what was observed or reported on the day of inspection.

3.15. The inspectorate recommended that the PR should provide an action plan with timeframes for implementation to address the infection control issues identified in this report. A summary report, including any corrective actions, with timescales, should be provided to the inspectorate.

3.16. The committee noted that the timescale set for completion of corrective action is 16 October 2019.

3.17. The centre has submitted the infection control review and revised policy.

CE Marked Medical Devices

3.18. This was an area of non-compliance identified at the last inspection.

3.19. The committee noted that 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 a 'CE mark'.

3.20. The committee noted that the centre's medical devices were reviewed in the course of the inspection and the centre was found to be partially compliant with HFEA requirements as some medical devices were not CE marked.

3.21. The centre has submitted a plan to ensure CE marked medical devices are used where possible. The Executive confirmed receipt of the plan and no further action is required.

Data Submission

3.22. The committee noted that the centre had failed to submit annual IUI data for 2018 within the required time frame.

3.23. The centre has completed a review of procedures used to submit licensed treatment data. The Executive confirmed receipt of the review and no further action is required.

Licence

3.24. The committee endorsed the Executive's recommendation for the continuation of the centre's licence.

3.25. The committee noted that this is a relatively new centre and that the PR has received significant support from the Executive. The committee agreed that the PR should be more proactive and take ownership of her responsibility to ensure that the centre is compliant and maintains compliance. The committee was disappointed to see reoccurring non-compliances and suggested that the PR considers seeking support from her peers at other established compliant centres.

Inspection

3.26. The centre is due a renewal inspection later this year, subject to an application being submitted by the PR, which will focus on the non-compliances in current and past inspection reports. The committee requested that the centre's renewal inspection report is considered by the Licence Committee which expects to see continuous improvement. The committee also expects to see that the PR has been proactive in leading the centre and embedding learning, demonstrating a notable shift in culture to learning, improving and maintaining good practice. Failure to achieve and maintain compliance, may result in a recommendation to the Licence Committee for more formal regulatory action.

4. Chair's signature

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

Signature

Name

Anita Bharucha

Date

4 October 2019

Targeted Interim Licensing Report

Centre name: Harley Street Fertility Clinic
Centre number: 0333
Date licence issued: 23 July 2016
Licence expiry date: 22 July 2020
Additional conditions applied to this licence: None
Date of inspection: 17 April 2019
Inspectors: Grace Lyndon (lead) and David Gibbon
Date of Executive Licensing Panel: 5 September 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current focus 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 requested additional inspection unannounced inspection to review the centre's performance based on information given above and to include review of practices outlined in the centres last minutes from Licensing committee (LC). The aim is to provide the LC with information on which to make a decision about the continuation of the licence.

Summary for the Licence Committee

Summary for licensing decision

The centre has two critical and three major and one other areas of concern.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The LC is asked to note that this report makes recommendations for improvement in relation to two critical, three major and one 'other' area of non compliance or poor practice. The PR has fully implemented the following recommendations. Where required and by the dates specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective:

Critical areas of non compliance:

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

Major areas of non compliance

- The PR should ensure that the quality management system is effective and fit for purpose.
- The PR should ensure that infection control guidance is adhered to.
- The PR should ensure that only CE marked medical devices are used wherever possible.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre's data is submitted within the allotted timescales.

The PR has made a commitment to fully implement the following recommendation:

Critical area of non compliance

- **The PR should ensure that all compressed gas cylinders are stored in accordance with compressed gas safe handling and storage requirements.**

The inspection team continue to be concerned with the level of progress made by this centre in their short licencing history. The centre is relatively new in its licence history and we are not seeing evidence that the centre is being proactive in their actions or their learning. There were a number of concerns found during this inspection regarding patient, staff and public safety which had been noted previously.

The PR has already received a significant level of support since the last inspection in 2018. This included weekly teleconference meetings to support the PR to achieve compliance with inspection recommendations.

One non-compliance identified in 2017 was still outstanding at the inspection in 2018, this related to the safe storage of compressed gas cylinders. In 2017, the centre informed the inspectors that they had applied for planning permission, and were awaiting the outcome of that application, to install a compliant storage facility for the gas cylinders. To date, the centre still does not have a compliant storage area for these cylinders and has been unable to provide the inspection team with any documented evidence of declined planning permission. These gases are accessible to members of the public and pose a significant risk.

Due to the serious nature of the critical non-compliances identified in this report, and in accordance with section 3.1 of the HFEA's Compliance and enforcement policy, a management review meeting was held on 23 May 2019, to evaluate the findings of this interim inspection report and consider a proportionate course of action.

The management review considered the non compliances noted in this report.

Within a week of the PR receiving the report, a conference meeting was held to discuss the non compliances identified. The meeting attendees included the PR, the Centre Manager, the centre's inspector and the Chief Inspector. The PR provided updates on the actions and progress undertaken to date and made a commitment to work closely with the Executive and make the required improvements to achieve compliance within the specified timeframes.

Recommendation to the Licencing Panel

The Executive recommends continuation of the centre's licence.

Subject to an application being submitted by the PR, the centre will be due to have a renewal inspection later this year. The scheduled renewal inspection will focus on the non compliances in this and past inspection reports. If the Executive remains concerned that the PR has failed to achieve and maintain compliance, it will consider more formal regulatory action and submit the report to Licence Committee (LC) for consideration.

Information about the centre

The Harley Street Fertility Clinic is located in central London and has held a Treatment (including embryo testing) and Storage licence with the HFEA since July 2014.

The centre provides a full range of fertility services and is registered with the Care Quality Commission (CQC).

The centre provided 245 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2019. In relation to activity levels this is a small centre**.**

The centre's last interim inspection was in April 2018. The report made recommendations for improvement in relation to four critical, four major and two 'other' areas of non-compliance or poor practice.

Following the inspection visit, teleconference calls were undertaken to support and guide the centre through the completion of the non compliances. The PR provided evidence that the outstanding actions had been fully implemented and had made the commitment to audit the effectiveness of the actions within a given timescale.

The Executive recommended the continuation of the centre's licence, but due to the number and severity of non-compliances, some of which were noted at previous inspections, the recommendation for a further unannounced inspection was requested to take place within twelve months of last inspection (2018), to ensure that compliance had been maintained and corrective actions had been effective and embedded into the centres current practices.

An Executive Licencing Panel (ELP) on 16 August 2018, considered the long history of non-implementation of recommendations and in particular, the lack of action in the area of multiple clinical pregnancies. The centre's multiple clinical pregnancy rate had been at 26% since October 2014 and increased to 28% in 2018, meaning that the multiple live birth target of 10% was exceeded and continued to increase. The panel was concerned with the apparent lack of awareness from the PR with respect to this matter at the time.

The panel did not feel they had sufficient evidence that the centre would be able to implement the recommendations without considerable long-term support from the Executive. Despite reports of historic engagement between the inspectorate and the PR, non-compliances which had been identified on earlier inspections remained and additional non-compliances appeared. However, the ELP did not feel confident in the PR's ability to ensure regulatory compliance in a timely manner and decided to adjourn its decision on the interim inspection report, referring it to the Licence Committee (LC) to consider with the relevant updates.

On the 10 January 2019, the LC shared the concerns of the Executive Licensing Panel. The committee noted that the Person Responsible was making progress and engaging with the Executive and that had been achieved with much support.

The committee endorsed the Executive's recommendation for the continuation of the centre's licence and agreed that, due to the nature and number of non-compliances at the inspection on the 17 April 2018 and the recurrence of non-compliances noted at previous

inspections, a further unannounced inspection should take place within 12 months of the previous inspection to ensure that compliance has been maintained.

The committee agreed that the report of the targeted interim inspection should be submitted to the Licence Committee for consideration.

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 January 2018 to December 2018 show the centre's success rates are in line with national averages.

The centre failed to submit their annual IUI data for 2018 within the required time frame. On 4 April, the IUI data was submitted after being requested during the interim inspection. In 2018, the centre reported 68 cycles of partner insemination with 9 clinical pregnancies. This represents a clinical pregnancy rate of 6%. This is below the national average.

See recommendation 6

Multiple births[2]

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

Between January 2018 and December 2018 the centre's multiple pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 17%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. Egg collection activities were observed in the course of the inspection. The procedures observed were witnessed using (a manual system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

---

[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%.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out. The atmosphere in the clinic appeared to be calm; 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 (SOP) and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage.

The centre's procedures for auditing and acting on the findings of audits are not compliant with requirements because;

- The timeframe for the implementation of corrective actions was not always documented on the audits.
- There was no indication on the audits as to whether corrective actions had been implemented or completed.
- The centre does not have an infection control audit.
- The centre does not have a SOP for safeguarding.
- The controlled drugs SOP is not robust as fails to review areas such as the drug disposal and errors in the controlled drugs register for example.
- There is no clear evidence of action or preventative measures undertaken in response to patient feedback.

The timeframe for implementation of corrective actions, and confirmation that corrective actions completed were issues identified in the last report as a major non compliance and also identified during this inspection.
Recommendation 3

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

- leadership
- patient support
- extension of storage consent
- consent
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood

The centre is effective in implementing learning from their audits and or guidance from 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 not compliant with guidance because;

- Witness signatures were missing to document the supply (S), Administration (A) and discard (D), and the time was not always added when the medication was SAD within the controlled drugs register.
- Errors made in the controlled drugs register did not follow the centres own SOP and the Misuse of Drugs Regulations.
- The source of where additional stocks of controlled drugs were received from was not recorded in the controlled drugs register.
- The carry over of drugs from one page to another was not signed or witnessed. This was a non-compliance at the last inspection.
- The responsible person and the witness signatures were not easily identified by the comparison of signatures in the front of the register.
- Documentation within the patient records and the controlled drugs register was illegible. This was a non-compliance at the last inspection.
- There were 10ml syringes located in the phlebotomy drawer that had expired.
- There was a number of green top blood bottles located in the phlebotomy trolley that had expired.
- There were two bottles of sodium bicarbonate on the emergency resuscitation trolley that had expired. This was not identified during the weekly routine checks of the emergency trolley.

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 was 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:

- There was dust on the skirting boards, particularly in the phlebotomy rooms.
- Some clinical areas did not have sealed flooring.
- The fabric on two chairs in the phlebotomy room was torn.
- A chair in the recovery area was made of porous material and did not have a wipe clean surface.
- There was blood noted on cupboard drawers and on the wall in the phlebotomy room.
- The clinical waste bin was not locked and was accessible to the public. This was a non compliance during the last inspection.

Recommendation 4

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 the following medical devices was reviewed in the course of the inspection: Vitrification media, 5ml tubes, Oosafe 4 well dishes and round disks. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not CE marked;

- Kitazato repro plates.
- Oosafe 60 x 15 mm dishes - CE marked but only for IVD.
- Pipette tips - No CE mark.

The use of the Oosafe dishes was cited as a non-compliance at the last inspection.
Recommendation 5

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 'Only eight patients have provided feedback in the last 12 months, giving an average three star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR 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. One patient commented on the high price of the medicines prescribed as the patient sourced one of the medicines for half the price elsewhere.

There were also several negative comments. The centre's own patient feedback was reviewed and was similar to the negative comments received on the HFEA website. These were discussed with the centre manager. It was unclear to the inspection team what actions had been taken by the centre in response to this feedback. The centre manager assured the inspectors that actions will be taken to address these matters.
See recommendation 3.

There were no patients were available to speak to inspectors during this visit.

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:

- Six large and one medium compressed gas cylinders stored in an outside area accessible to the public were secured by one chain. The cylinders were not secured in accordance with gas cylinder storage regulations. This has been identified at each inspection since 2017. The centre informed the inspection team that they had applied for planning permission and it was expected shortly. At this inspection, the centre informed inspectors that their planning permission application had been refused but were unable to provide confirmation of this to the inspection team. The current arrangement for the storage of compressed gases poses a significant risk to the public and has therefore been graded as a critical non-compliance.

See recommendation 2

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2016, recommendations for improvement were made in relation to four critical, four major and two 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales. However non-compliances relating to the following areas of practice have reoccurred;

- The QMS
- Medicines management
- Clinical waste storage
- Compressed gas storage
- The use of non CE marked products

On-going monitoring of centre success rates

Since the last interim inspection in April 2018, 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. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 25 March 2019.

Legal parenthood

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in April 2018, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Three records one 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.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Medicines Management • Witness signatures were missing to document the supply (S), Administration (A) and discard (D), and the time was not always added when the medication was SAD within the controlled drugs register. • Errors made in the controlled drugs register did not follow	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should investigate why non-compliances identified in this report have not been addressed from previous inspections.	The PR will ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR has investigated why non-compliances identified in this report have not been addressed from previous inspections.	The Executive notes the PR's response. Considering the non-compliances noted in this and previous reports, the Executive is concerned that despite the centre having had an independent review of their medicines management, practice in this area continues to

the centre's own SOP and the Misuse of Drugs Regulations. • The source of where additional stocks of controlled drugs were received from was not recorded in the controlled drugs register. • The carry- over of drugs from one page to another was not signed or witnessed. This was a non-compliance at the last inspection. • The responsible person and the witness signatures were not easily identified by the comparison of signatures in the front of the register. • Documentation within the patient records and the controlled drugs register was illegible. This was a non-compliance at the last inspection. • There were 10ml syringes located in the phlebotomy drawer that had expired. • There was a number of green top blood bottles located on the phlebotomy trolley that had expired.	The PR should commission an independent review of the centre's medicines management practices including, but not exclusively, the issues identified in this report. A summary report of this review, including staff training requirements and corrective actions taken, should be provided to the centre's inspector by 16 August 2019.	Following the last inspection, The PR had commissioned an independent review of the centre's medicines management practices. A summary report, as requested, will be provided to the centre's insepctor by 16th August.	fall short of expected standards. The Executive acknowledges receipt of the PR's investigation into the medicines management non-compliances and the actions taken as a result. No further action required.

• There were two bottles of sodium bicarbonate on the emergency resuscitation trolley that had expired. This was not identified during the weekly routine checks of the emergency trolley. Due to the similar non compliances being identified in the last inspection and the potential risk to patients, this non compliance has been escalated to a critical. SLC T2 DH: Controlled Drugs (Supervision of management and use) Regulation 2013. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. Misuse of Drugs (safe Custody) Regulations 2001. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use			

and management'.			
2. Compliance with HFEA standard licence conditions, Gas cylinder storage Six large and one medium compressed gas cylinders stored in an outside area accessible to the public were secured by one chain. The cylinders were not secured in accordance with gas cylinder storage regulations. This has been identified at each inspection since 2017. The current arrangement for the storage of compressed gases poses a significant risk to the public and has therefore been graded as a critical non-compliance. SLC T2, Health Technical Memorandum 02-01: Medical gas pipeline systems, Part B: Operational management section 8.	The PR must ensure that all compressed gas cylinders are stored in accordance with compressed gas safe handling and storage requirements. The PR must provide the centre's inspector with evidence to confirm that applied for planning permission has been rejected and inform the inspector of the actions she intends to take to ensure compliance with the gas storage regulations. If the PR is not able to provide such information, she must apply for planning permission to provide a compliant gas cylinder storage facility at the centre and provide evidence of this application to the centre's inspector by 16 July 2019. If the PR is able to provide confirmation that planning consent has been declined for a suitable gas cylinder storage area she must commission an	The PR will ensure that all compressed gas cylinders are stored in accordance with compressed gas handling and storage requirements. Planning permission rejection is sent separately to the centre's inspector with this response. As planning consent for a suitable gas cylinder has been declined, the PR has coimmissioned an independent review of the current cylinder	The Executive acknowledges the PR's response, commitment to implementing this recommendation and confirmation of planning application refusal. The Executive awaits the outcome of the independent review of the centre's gas storage facilities. Further action required

	independent review of the current cylinder storage arrangements. This review must be undertaken by a suitably qualified individual who is conversant with the regulatory requirements of the storage of gases. It is expected that this review will have been commissioned and completed by 16 October 2019 and any required actions implemented before the next HFEA inspection.	storage arrangements. This review is being undertaken by a qualified individual who is conversant with regulatory requirements of storage of gases. This review work has commenced and we fully expect it to be completed by 16 October 2019. The PR confirms that required actions will be implemented before the next HFEA renewal inspection.	

‘Major’ area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
3. Quality Management System • The timeframe for the implementation of corrective actions was not always documented on the audits. • There was no indication on the audits as to whether corrective actions had been implemented or completed. • The centre does not have an infection control audit. • The centre does not have a SOP for safeguarding. • The controlled drugs SOP	The PR should ensure that the quality management system is effective and fit for purpose. The PR should review practices and procedures relating to the quality management system, including, but not exclusively, the issues identified in this report. The PR should ensure that the quality management system is used effectively to improve the quality and effectiveness of the services provided.	The PR will ensure that the quality management system is effective and fit for purpose. The PR will review practices and procedures relating to the quality management system, including, but not exclusively, the issues identified in the report. The PR will ensure that the quality management system is used effectively to improve the quality and effectiveness of the services provided.	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. The Executive confirms receipt of the QMS review, actions taken, and documents provided to demonstrate evidence of compliance with this recommendation. No further action required beyond submission of the audit due by 16 November 2019.

is not robust as fails to review areas such as the drug disposal and errors in the controlled drugs register for example. • There is no clear evidence of action or preventative measures undertaken in response to patient feedback. Issues identified in the last inspection report were also identified during this inspection such as timeframes for implementation or indications of any action undertaken to complete non compliance. SLC T33 and T36	The PR should review the centre's auditing practices and ensure they are robust in ensuring that all non-compliances are acted upon; corrective and preventative actions are recorded and implemented and effective in achieving improvements in quality standards. The PR should provide a summary report of this review, including corrective actions taken to address this non-compliance, to the centre's inspector by 16 August 2019. Three months after the implementation of corrective actions, the PR should audit practice to ensure that the actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 16 November 2019.	The PR will review the centre's auditing practices and ensure they are robust in ensuring that all non-compliances are acted upon; corrective and preventative actions are recorded and implemented and effective in achieving improvements in quality standards. The PR will provide a summary report of this review, including corrective actions taken to address this non-compliance, to the centre's inspector by 16 August 2019. Three months after implementation of corrective actions, the PR will audit practice to ensure that the actions implemented have been effective in achieving compliance. A summary report of this audit will be provided to thje centre's inspector by 16 November 2019.	
4. Infection Control	The PR should ensure	The PR will ensure	The inspection team cannot

• There was dust on the skirting boards, particularly in the phlebotomy rooms. • Some clinical areas did not have sealed flooring. • The fabric on two chairs in the phlebotomy room was torn. • A chair in the recovery area was made of porous material and did not have a wipe clean surface. • There was blood noted on cupboard drawers and on the wall in the phlebotomy room. • The clinical waste bin was not locked and was accessible to the public. This was a non compliance during the last inspection. SLC T2 Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste (2013)	compliance with infection control regulations. The PR should provide an action plan with timeframes for implementation to address the infection control issues identified in this report. A summary report of this review, including any corrective actions, with timescales, should be provided to the centre's inspector by 16 July 2019. It is expected that corrective actions have been completed by 16 October 2019. The PR should ensure that if the clinical waste bin is unable to close a suitable replacement should be sort.	compliance with infection control regulations. The PR has provided an action plan with timeframes for implementation to address the infection control issues identified in this report. A summary report of this review, including any corrective actions, with timescales, will be provided to the centre's inspector by 16 July 2019. The PR confirms that the corrective actions will have been completed by 16 October 2019. The clinical waste bins were locked on the day of inspection as the lead nurse recalls checking them herself that morning. Further, the clinical waste bins are behind a locked gate and not accessible to the public. The PR will ensure that if a clinical bin lock is broken or cannot be closed, a suitable replacement is sought.	reconcile the PR's claim that the clinical waste bins were locked on the day of inspection as this is not what was observed or reported on the day of inspection. The Executive confirms receipt of the infection control review and revised policy. No further action beyond confirmation of completion of corrective actions due by 16 October 2019.

5. Equipment and Materials The following items were not CE marked for Class II medical use: • Kitazato repro plates. • Oosafe 60 x 15 mm dishes CE marked but only for IVD. • Pipette tips - No CE mark. The use of non-CE marked equipment was a non-compliance at the last inspection. SLC T30	The PR should ensure that only CE marked medical devices are used wherever 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 CE marked medical devices are used. This plan should be provided to the centre's inspector by 16 July 2019 and should include the timescales by which products identified in this report will either be replaced with a suitably CE marked alternative, or will obtain CE mark certification.	The PR will ensure that only CE marked medical devises are used wherever possible. The PR will ensure that a plan is developed and implemented so that CE marked devises are used. The plan will be provided to the centre's inspector by 16 October 2019 and will include the timescales by which products identified in this report will either be replaced with a suitably CE marked alternative, or will obtain CE mark certification.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The Executive confirms receipt of the plan to ensure CE marked medical devises are used where possible. No further action required.

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
6. Submission of data to the HFEA The centre has failed to submit their annual IUI data for 2018 within the required time frame. General Direction 0005	The PR should ensure that all licenced treatment activity is reported to the Authority. The procedures used to submit licenced treatment data should be reviewed to identify and address the reasons for non and late reporting. A report of this review, including corrective actions with timescales for implementation should be provided to the centre’s inspector by 16 July 2019.	The PR will ensure that all licenced treatment activity is reported to the Authority. The procedures used to submit licensed treatment data will be reviewed to identify and address the reasons for non and late reporting. A report of this review, including corretive actions with timelines for implementation will be provided to the centre's inspector by 16 July 2019.	The Executive acknowledges the PR’s commitment to implementing this recommendation and confirms receipt of the data submission review received 16 July 2019. No further action required.

Additional information from the Person Responsible