Licence Committee - minutes

Centre 0341 (The Fertility & Gynaecology Academy)
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	Fieldfisher 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:

    - Executive Licensing Panel Minutes - 14 July 2017 - Executive Update
    - Executive Licensing Panel Minutes - 24 March 2017 - Renewal Inspection
    - Executive Licensing Panel Minutes - 29 July 2016 - Interim Inspection

1. Background

1.1. The Fertility & Gynaecology Academy, centre 0341 is located in central London. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since May 2015 and provides a full range of fertility services.

Licence

1.2. The centre's current licence was issued for a period of 4 years in March 2017 and is due to expire on 21 May 2021.

1.3. The Executive has submitted a report of the unannounced interim inspection for consideration by the Licence Committee.

2. Consideration of application

Unannounced Interim Inspection

2.1. The committee noted that an unannounced interim inspection was conducted at centre 0341 on 28 March 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 renewal inspection.

2.2. The inspection covered:

- Quality of care
- Patient safety
- Patient experience

2.3. The committee noted that the centre provided 140 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In relation to activity levels this is a small centre.

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

2.5. The committee noted that in 2018, the centre reported four cycles of partner insemination with one pregnancy, which was in line with 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 12%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period. The committee acknowledged that the centre has made progress in reducing its multiple birth rate.

2.7. The committee noted that at the time of the unannounced interim inspection in March 2019, there were two critical and four major areas of non-compliance identified.

Critical areas of non-compliance:

- The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.
- The PR should ensure the information about reproductive immunology treatments provided to patients is compliant with HFEA guidance.

Major areas of non-compliance:

- The PR should review the gas storage facilities and ensure they comply with regulatory requirements.
- The PR should ensure that personnel are available in sufficient number and be qualified and competent for the tasks they perform.
- The PR should identify the barriers that prevent the Code of Practice guidance from being fully implemented.
- The PR must ensure compliance with the requirements of clinical waste and infection control regulations.

2.8. The committee noted that since the inspection visit the PR has provided evidence that action has been taken to implement the recommendations to address the major non-compliance relating to gas storage facilities. The PR has committed, where required, to audit the effectiveness of those actions within the required timescales.

Management Review Meeting – 23 May 2019

2.9. 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.

2.10. The Executive found that the non-compliances seen on inspection were significant and reflected direct and indirect risks to patients, and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. The Executive was particularly concerned with the findings in relation to medicines management and prescription of intralipid 'off label', as these failures were also identified at the renewal inspection in 2017 and considered to be major areas of non-compliance.

2.11. The Executive agreed steps to monitor and support the PR to achieve and maintain compliance.

2.12. The PR has now assured the Executive of his commitment to fully implement the recommendations to address the areas of non-compliance and the centre has now appointed an infection control lead and Quality Manager.

2.13. The committee agreed that the centre should encourage its patients to leave feedback both at the centre and via the HFEA website using Choose a Fertility Clinic. The centre should also monitor and act on patient feedback and ensure that action taken is effective.

Recommendations

Licence

2.14. The committee noted that the Executive expects that compliance in the areas of concern, identified at the interim inspection, will be achieved within the required timescales and resolved by the next inspection. The Executive recommends the continuation of the centre's licence.

Inspection

2.15. Due to the nature and number of non-compliances at the interim inspection, some of which were noted at previous inspections, the Executive recommends that an unannounced inspection takes place within twelve months of the interim inspection on 28 March 2019, which will focus on the non-compliances identified in the interim report, to ensure compliance has been maintained and corrective action has been effective.

3. Decision

3.1. The committee had regard to its decision tree.

Medicines Management

3.2. The committee noted that medicines management was a non-compliance at the last inspection and recommendations have been made to address the issues in order to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.

3.3. The inspectorate reviewed the centre's processes for medicines management and the safe storage, disposal and administration of medicines. The centre was found to be partially compliant with guidance due to poor record keeping.

3.4. In one entry noted in the controlled drugs register, the dosage the patient was given was omitted. The PR was advised to investigate this further as an identified incident.

3.5. The committee noted that the PR has taken some action to address the issues. However, the Executive cannot reconcile the claims in the PR's response regarding the documentation of errors and explanation given in the controlled drugs register being compliant. This was discussed during the inspection, the evidence was presented, and best guidance was discussed.

3.6. The committee was deeply concerned about the issues raised in this area of medicines management and deliberated on the potential implications for patient safety. The committee would like to see the centre's independent review summary report with corrective action plan, which the Executive reported is already overdue, and the committee would also like to see the summary report after corrective actions at the Licence Committee meeting scheduled in November 2019.

Prescription of Intralipid ‘off label’

3.7. The committee noted that there were discrepancies between the information provided to patients and the centre’s SOP in relation to the administration of intralipid infusion. The patient information does not make it sufficiently clear about the lack of strong evidence for the use of these treatments in IVF, in order to enable patients to make an informed decision. Also, the centre’s SOP does not identify at what points in the patient’s treatment pathway intralipids are administered and it was confirmed that some intralipid therapies are provided on patient request, rather than based on clinical assessment. Staff were reluctant to engage in a conversation about this type of treatment and there are concerns that the processes and information given to patients surrounding intralipid therapy were insufficient. The Executive was concerned that relevant staff may not have the appropriate knowledge and skills to provide care to patients undergoing this treatment. Therefore, the committee recommended that the centre voluntarily suspend intralipid treatment for all patients until the Executive is satisfied that the centre is following HFEA guidance and has implemented the recommendations.

3.8. The committee noted that information provided on reproductive immunology treatment was identified as non-compliant at the last inspection and therefore escalated to a critical area of non-compliance. The committee was concerned that the PR had failed to acknowledge this non-compliance and attempted to minimise the significance of it. The committee also noted with concern that the Executive could not reconcile the PR’s response on a number of issues including reproductive immunology therapies. The committee acknowledged that extensive discussions had already taken place at the inspection and during a teleconference meeting with the PR.

Staff

3.9. The committee noted that the centre did not have a Quality Manager at the time of inspection and that staff members did not know who the centre’s infection control lead was and a number of audits were not conducted due to the shortage of nursing staff. Also, due to staff shortages, the routine daily checks were not undertaken. The committee was further concerned with the PR’s response.

3.10. The committee acknowledged that since the inspection the centre has appointed an infection control lead and Quality Manager.

3.11. The committee noted that the PR is now committed to addressing the issues and looks forward to considering the Executive’s update at the Licence Committee meeting in November 2019, and receiving assurance from the Executive that the processes in place will ensure that staffing levels are regularly reviewed and maintained and that there are arrangements in place for covering sickness and annual leave.

Quality Management

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

3.13. The centre is partially effective in implementing learning from its audits and guidance from the HFEA.

3.14. The committee noted the inspectorate's recommendations that the PR should identify the barriers that prevent the Code of Practice guidance from being fully implemented.

3.15. The PR should ensure that the centre has a robust and efficient quality management system 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.

3.16. The committee was pleased to hear that the PR is engaging with the Executive and requested an update at the Licence Committee meeting in November 2019

Infection Control

3.17. The committee noted the non-compliance relating to infection control and the recommendations for improvement in this area. The PR must ensure compliance with the requirements of clinical waste and infection control regulations.

3.18. The centre's infection control practices were found to be partially compliant with guidance. The clinical waste bins were not in a locked area and one of the bins remained open and the recovery area did not have sealed flooring.

3.19. The PR has started to address the issues identified on inspection. The committee noted that the recommendations are basic requirements and should be fully implemented as soon as possible.

Compliance with HFEA standard licence conditions

3.20. The committee noted the non-compliance relating to the safe storage and signage of cylinders and the recommendation that the PR should review the gas storage facilities and ensure they comply with regulatory requirements.

3.21. The committee noted that since the inspection visit, the PR has provided evidence that action has been taken to implement this recommendation. The committee noted that this was also a basic requirement and was satisfied that the centre is now compliant in this area.

Licence

3.22. The committee endorsed the inspectorate's recommendation for the continuation of the centre's licence.

Inspection

3.23. The committee endorsed the inspectorate's recommendation to carry out an unannounced interim inspection within twelve months of the interim inspection completed on 28 March 2019. This unannounced inspection will focus on the non-compliances identified in the interim inspection report, to ensure compliance has been maintained and corrective action has been effective. The committee acknowledged that the PR had requested the withdrawal of the unannounced interim inspection in light of the information provided, however the committee considered that due to the centre's history of non-compliance it was necessary and proportionate to endorse this recommendation.

3.24. The committee requested that the report of the unannounced inspection is submitted to the Licence Committee for consideration. The committee expects to see that patient information has been revised and is satisfactory and that staff have been trained and are competent to provide the relevant treatments available to patients. Failure to comply with the recommendations may result in 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

Interim Licensing Report

Centre name: The Fertility & Gynaecology Academy
Centre number: 0341
Date licence issued: 22 May 2017
Licence expiry date: 21 May 2021
Additional conditions applied to this licence: None
Date of inspection: 28 March 2019
Inspectors: Grace Lyndon (Lead) and Lesley Brown
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 foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Licensing Committee (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 LC is asked to note that this report makes recommendations for improvement in relation to two critical, four major areas of non compliance or poor practice as follows:

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

Major areas of non compliance:

- The PR should review the gas storage facilities and ensure they comply with regulatory requirements.

The PR has given a commitment to fully implementing the following recommendations:

Critical areas of non compliance:

- **The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.**
- **The PR should ensure the information about reproductive immunology treatments provided to patients is compliant with HFEA guidance.**

Major areas of non compliance:

- The PR should ensure that personnel are available in sufficient number and be qualified and competent for the tasks they perform.
- The PR should identify the barriers that prevent the Code of Practice guidance from being fully implemented.
- The PR must ensure compliance with the requirements of clinical waste and infection control regulations.

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 meeting on 23 May 2019 found that the non-compliances seen on inspection were significant and reflected direct and indirect risks to patients, and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. Of particular concern were the findings in relation to Medicines management and Prescription of intralipid 'off label'.

The management review meeting discussed the non-compliances mentioned within this report where the issues relating to medicines management and the prescription of intralipid 'off label' therapy, were of particular concern as the centre has a history of previous failures in these areas which were considered major non-compliances at the time of the renewal inspection in 2017.

The management review team agreed to implement the following actions to support the PR to achieve and maintain compliance;

- Within a week of receiving the report, a telephone conference (tele-conference) meeting will be held. The meeting will include the PR, the centre's inspector and the Chief inspector to ascertain the PR's commitment to fulfil the requirements of the non compliances identified in this report. If sufficient progress in the areas for improvement were made, it was agreed that weekly updates would not be necessary.
- The report is to be returned to the centre's inspector within the given timescale.
- If suitable assurances and appropriate plans are not provided in the PR's response to this report, the Executive will arrange a further management review meeting to consider the PR's responses, his ability to discharge his duties under section 17(1) of the Act and whether the recommendation made in this report should be modified. In addition, the quality of the PR's responses and proposed plans to address the non-compliances and ensure the centre operates in a compliant manner, will strongly influence the final recommendation made by the inspection team.
- The PR will update the centre's inspector with any actions and progress undertaken to close the non compliances.

Following the tele-conference meeting consideration was given to weekly updates with the PR, to support the centre to achieve compliance, to promote learning and support embedding good practices. The PR provided assurance to the Executive of his commitment to fully implementing the recommendations made in the report and therefore the decision to hold weekly updates was not considered proportionate. The centre has now appointed an infection control lead and Quality Manager and it is expected that compliance in these and the other areas of practice identified in this report, will be achieved within the required timeframes.

Recommendation to the Licencing Panel

The Executive recommends continuation of the centre's licence, but due to the nature and number of non-compliances at this inspection, some of which were noted at previous inspections. The Executive recommends an unannounced inspection takes place within twelve months of this inspection which will focus on the non-compliances identified in this report, to ensure that compliance has been maintained and corrective actions have been effective.

It is expected that all of the non-compliances identified in this report will be resolved by the next inspection.

Information about the centre

The Fertility & Gynaecology Academy is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since May 2015. This initial licence was granted for two years without additional conditions, which is the standard term for new centres. The centre's treatment (including embryo testing) and storage licence was renewed in March 2017 for four years with no additional conditions.

The centre provides a full range of fertility services.

The centre provided 140 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31December 2018. In relation to activity levels this is a small centre.

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.

In 2018, the centre reported four cycles of partner insemination with one pregnancy, which is in line with the national average.

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 rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

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 and to preserve their fertility prior to undergoing other medical treatment such as

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, 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 during the inspection appeared suitable for the activities being carried out that day. The atmosphere in the clinic appeared calm, the staff in the laboratory were able to carry out their activities without distraction and they were available to carry out witnessing activities when required.

However, there were concerns regarding the following;

- The centre does not currently have a quality manager.
- Staff members did not know who the centre's infection control lead was.
- A number of audits were not conducted due to the shortage of nursing staff.
- The routine daily checks were not undertaken on the emergency resuscitation equipment, or the controlled drugs register due to the lack of staff. This was evident in some of the March 2019 documentation logs and the latest audits.

During the inspection staff discussed workforce pressures during the summer and autumn months of 2018. At that time there was only one registered nurse working at the centre after one registered nurse had left the centre earlier that year. This raised concerns about patient care and the role of the registered nurse. It was unclear, if during that time the centre employed additional nursing support, as there were conflicting accounts regarding the presence of temporary nursing staff.
Recommendation 3.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

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

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

- Where non compliances were identified in the audits, corrective actions and the timeframe for their implementation were not recorded in all instances.
- The centre does not audit non controlled drugs.
- Many of the centres audits and SOP's were in draft form and not authorised for use.

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
- the use of the Single European Code
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- Clinic Focus articles

The centre is partially effective in implementing learning from their audits and guidance from the HFEA because:

A review of actions taken in response to the update of Standard Licence Conditions (SLC) T53 and the publishing of the 9th edition of the HFEA Code of Practice (CoP) showed that the centre had not fully updated or fully implemented into the centre's practices or documentation. The screening SOP to guide practice was due for review in March 2018 but remains under review. Patient information describing 'add-on' treatments was also unavailable to be reviewed on the day of inspection.
Recommendation 4.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because:

It was noted on the review of the controlled drugs (CD) register that:

- One entry noted in the CD register, the dosage the patient was given was omitted. The PR was advised to investigate this further as an identified incident.
- Two patient identifiers were not routinely recorded.
- Within the CD register, errors were not always marked as errors and explanations were not always provided in line with guidance and best practice.
- Some entries in the CD register were illegible
- The amount of controlled drug discarded was not always documented in the CD register; however, the entries had been signed by the responsible person and witness.

Medicines management was a non-compliance at the last inspection.
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 partially suitable for the reasons described below.

- Written information provided to patient's states that the intralipid infusion is administered over one hour but the centre's SOP states that the drip infusion is delivered over a period of approximately two hours.
- The patient information does not make it sufficiently clear about the lack of strong evidence for the use of these treatments in IVF to enable patients to make an informed decision.
- During the inspection, centre staff were reluctant to discuss questions asked regarding intralipid therapy such as the centre's process, who may be offered intralipids, infusion times before or throughout a treatment cycle for example. The inspection team were referred to the PR. This leads the inspection team to be concerned that relevant staff may not have the appropriate knowledge and skills to provide care to patients undergoing this treatment.
- The centre's intralipid SOP does not identify at what points in the patient's treatment pathway intralipids are administered.
- The PR informed the inspection team that some intralipid therapies are provided on patient request, rather than based on clinical assessment.

The inspection team were not assured that the processes and information given to patients surrounding intralipid therapy was sufficient.

The lack of clarity of the written information and the clear lack of strong evidence of the use immunology therapies were identified as non compliance at the last inspection. Recommendation 2.

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;

- The clinical waste bins are not in a locked area and one of the bins remained open.
- The recovery area does not have sealed flooring.

Recommendation 5.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and 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: media, media supplements, vitrification kits and sperm preparation kits and plastic wear. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' (CaFC) page enabling patients to provide feedback on their experience of their clinic. Only sixteen patients have provided feedback in the last 12 months, giving an average four star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work, it is important that every patient knows about the rating system.

The website also gives the ability for patients to comment on the cost of treatment. Four patients provided individual comments to the HFEA, two of which were complimentary about the care they had received, and the other comments were in relation a lack of support, costs of treatment and patients feeling they were bothering the clinic when seeking advice. These were discussed with the PR. He advised the inspectors that actions will be taken to address these matters. The inspection team urge the centre to monitor, take action on the patient feedback, ensure the actions taken are effective and encourage their patients to leave feedback both at the centre and on CaFC.

The centres own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

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

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

- provides a clean and well organised environment for patient treatment;

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 broadly compliant with HFEA requirements because;

- The cylinder store outside housed eight large full and one empty cylinder. These were not chained therefore were at risk of falling over.
- There was no safety signage on the cage to indicate there was a fire risk.

Recommendation 6.

Compliance with recommendations made at the time of the last inspection

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

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

In responding to the report immediately after the inspection, the PR had agreed to implement the recommendations. However, the non-compliance relating to medicines management and immunology therapies has reoccurred. See recommendations 3 and 4.

On-going monitoring of centre success rates

Since the last renewal inspection in December 2016, the centre has received four risk tool alerts related to performance, to which the PR has responded appropriately by providing evidence and confirmation that the issues have been resolved.

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.

Feedback received from the Registry team at the HFEA prior to this inspection reported that there are currently no significant data submission issues at this clinic.

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.

In October 2015, the HFEA's Chief Inspector asked all newly licensed centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided evidence that an audit had been conducted and submitted a report to the HFEA. The audit found that since undertaking donor treatment cycles, only three cycles of treatment had been completed; consent to legal parenthood was not required in each case.

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 the most recent legal parenthood consenting audit. This audit was undertaken in November 2017. Nine sets of records where treatment with donor sperm had recently been provided 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 It was noted on the review of the controlled drugs register that: • One entry noted in the CD register, the dosage the patient was given was omitted. The PR was	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should follow best practice for medicines	An audit of CD non-conformities (See attached: Non-conformity no: 2019/03) was carried out on 1/4/19. This showed that patient 7080-N did not have 2 patient identifiers and patient 6708-N did not have a complete record of the CD dispensed and wasted. The involved anaesthetist has been	The Executive notes the PR's response to this non-compliance and the work undertaken in response to the inspection report. However, the Executive cannot reconcile the claims in the PR's response

advised to investigate this further as an identified incident. • Two patient identifiers were not routinely recorded. • Within the CD register, errors were not always marked as errors and explanations were not always provided in line with guidance and best practice. • Some entries in the CD register were illegible. • Controlled drugs given to the patient were not always recorded, however, there were signatures present to say something had been supplied, administered and discarded by the responsible person and the witness. • The amount of controlled drug discarded was not always documented in the CD register; however, the entries had been signed by the responsible person	management both to protect patients and ensure that medicines are stored and used in the correct way. The PR should undertake an independent review medicines management practices in relation to the non-compliances identified in this report but not exclusively. This should include staff training requirements. A summary report of the review with corrective actions should be provided to the centre's inspector by 28 June 2019. Three months after this review the PR should audit medicines management practice to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 28 September 2019.	informed and he would take the necessary corrective action according to the guide limes. Preventative actions have been implemented and training has been updated as shown on the non-conformity record. Within the CD register, all errors were always marked as errors and explanations were always provided at the bottom at the pages in line with guidance and best practice. A Controlled Drugs and Medicines Management Audit was carried out on 24/1/19 (See attached) which identified that regular checks were not being completed. The resulting CAPA was a daily duties review to ensure that all regular checks are completed. Ongoing monitoring will continue. An audit of the CD register was carried out on 6/6/19 (see attached) with no errors identified. The CD NICE guideline NG46 (https://www.nice.org.uk/guidance/ng46) will also be used to ensure best practice in the management and use of CD. The "Controlled Drugs in Preoperative Care" (2018) document, quoted in the report, was not found after through search of	regarding the documentation of errors and explanation given in the controlled drugs register being compliant. This was discussed during the inspection, the evidence was presented, and best guidance was discussed. The Executive awaits the independent review summary report with corrective action plan which was not provided to the centre's inspector by 28 June 2019 and the summary report after corrective actions by 28 September 2019. The Controlled Drugs in Perioperative Care' (2018) is currently being ratified. Please refer to the 2006 version of this document until the 2018 becomes available. Further action required

and witness. Medicines management was a non-compliance at the last inspection. An incident found on this inspection has bought about an investigation from the PR and has therefore escalated the non compliance to a critical. SLC T2, 'Controlled Drugs in Perioperative Care' (2018), 'The Misuse of Drugs Regulations' 2001		the internet.	
2. Prescription of intralipid 'off label' It was noted that; • Written information provided to patient's states that the intralipid infusion is administered over one hour but the centre's SOP states that the drip infusion is delivered over a period of approximately two hours.	The PR should ensure the information about reproductive immunology treatments provided to patients is compliant with HFEA guidance. The PR should revise patient information describing 'add-on' treatments, and ensure it complies with the	The PR and the Team are reluctant to accept that there is a non-compliance re. intralipid, let alone a critical non-compliance. The PR and the Team are surprised and disappointed as the inspector misunderstood or misinterpreted the info she was told and given. Intralipid and other immune supportive therapies are not part of the assisted conception treatment but just a mere parallel medical intervention. It is given to patients with over-active	The Executive acknowledges the PR's commitment and passion for the use of immunology therapies. However, the Executive cannot reconcile the PR's response with the extensive discussions that took place at the inspection and the subsequent tele-conference meeting or acknowledge why the PR

• The patient information does not make it sufficiently clear about the lack of strong evidence for the use of these treatments in IVF to enable patients to make an informed decision. • During the inspection, centre staff were reluctant to discuss questions asked regarding intralipid therapy. This leads the inspection team to be concerned that relevant staff may not have the appropriate knowledge and skills to provide care to patients undergoing this treatment. • The centre's intralipid SOP does not identify at what points in the patient's treatment pathway intralipids are administered. • The PR informed the inspection team that some intralipid therapies are provided on patient request, rather than	requirements of HFEA guidance. Copies of the updated patient information should be provided to the centre's inspector when responding to this report. The PR should ensure that the version of the patient information sheet provided to the HFEA is the one that will be provided to patients undergoing this treatment. The PR should ensure that staff involved in the care of patients undergoing immunology treatments are fully trained and assessed to be competent in providing this care and treatment. The PR should inform the centre's inspector of the actions taken together with any timeframes for implementation. It is expected that the centre will be fully compliant with this	immune system imbalance and repeated reproductive failure whether they have IVF or try naturally. Having said that we were happy to explain to the HFEA inspector and answer her questions. Both the SOP and the patient info/consent sheet states that intralipid is given over an hour. The PR is not sure where the confusion has come from. The patient info sheet contains enough info about the intralip[id, its effect, risks involved and the provisional time it is given. It clearly says that the evidence is not conclusive. It also has a web page address for the HFEA view. This info sheet was accepted and approved by the inspection team in the last main inspection. We only have one version of the document whether it goes to the HFEA or the patients. These SOPs and info/consent documents are under continuous review and updating if necessary. The Intralipid SOP has been revised and updated to include details on the timing of Intralipid treatment, the same as clearly documented in the patient informed	states this area of practice was 'fine' during the last HFEA inspection where it was also noted as a non compliance. The PR claims the information that guides both patients and staff states that intralipid infusions are infused over an hour; however, the documents provided to the Executive by the PR post inspection gave different instructions for these infusions. Two documents ('Consent 27' and 'SOP13') directed infusions to last approximately one hour, and another ('Consent 28') states the infusion should last two hours. Therefore, the information provided, the consents for patients and the information to guide the centre staff are not consistent. The Executive is concerned

based on clinical assessment. The inspection team were not assured that the processes and information given to patients surrounding intralipid therapy was sufficient. The clarity of the written information and the clear lack of strong evidence of the use immunology therapies were identified as non compliance at the last inspection. This non-compliance has been cited at previous inspections and has therefore been escalated to a critical. SLC T58 RCOG 'The Role of Natural Killer Cells in Human Fertility' 2016	recommendation by 28 June 2019.	consent. Our staff have enough knowledge about the intralipid within the capacity of their jobs. There are enough info in the nurses SOP and patient info/consent sheet. Having said that a refreshing update session to all staff will be carried out by the PR on Monday 8 July 2019. The info/consent sheet clearly indicates when intralipid is given to the patients unless decided differently by the Doctor based on clinical assessment. The PR never informed the inspector that intralipid is sometimes given indiscriminately according to the patient request without clinical assessment. This is a misunderstanding. The PR about explained to the inspector that intralipid as an immune supportive therapy is given based on immune tests and not indiscriminately. She then asked if it was ever given to patients without the tests. The PR replied yes sometimes based on clinical assessment particularly for pregnant women with history of recurrent miscarriage when the blood test results are not available or not done.	by the PR's attempt to minimise the significance of this non-compliance by claiming that his use of these off-label therapies are 'parallel medical interventions' when he is using them as part of the treatment for patients undergoing assisted reproduction. The Executive remain concerned that the PR has failed to acknowledge this non-compliance and will be having further discussions with him. Further action required.

		On our website we clearly site a link to the HFEA and the RCOG view on intralipid for the patients to read and have their own autonomy. Intralipid is prescribed where the immune testing indicates that treatment may be of benefit to the patient. Patients understand that the technology is unproven and that Intralipid is being used in this context as an 'off label' therapy. All patients sign informed consent prior to treatment. HFEA and RCOG guidelines regarding Intralipid are regularly reviewed by the team at The Fertility & Gynaecology Academy. In view of the above we are reluctant to accept that intralipid is considered a non-compliance and we ask the inspector to kindly amend the report accordingly.	

‘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. Staff The following was noted during the inspection; • The centre does not currently have a quality manager. • Staff members did not know who the centre’s infection control lead was. • A number of audits were not conducted due to the shortage of nursing staff. • The routine daily checks were not undertaken on the emergency resuscitation equipment, or	The PR should ensure that personnel are available in sufficient number and be qualified and competent for the tasks they perform. The PR should ensure that staffing levels are regularly reviewed and appropriate for the level of activity conducted at the centre. There should be suitable arrangements in place to manage staff absence and annual leave. The PR should inform the centre’s inspector of the actions taken to implement	Professor Peter Hollands has been employed as Quality Manager on a part-time basis. Peter has extensive experience in both Quality Management and Clinical Embryology and has previously been PR at Chelsfield Park Hospital. The Infection Control Lead is the Senior Nurse “Jeana Alaba”. All the audits that are scheduled for 2019 were done according to the time table.	The Executive acknowledges the actions taken and the commitment to implement this recommendation. The Executive cannot reconcile the PR’s response stating the audits were completed. On inspection, it was noted a few audits stated ‘unable to complete due to staff shortages’. Extensive discussions took place during the inspection with both senior and junior staff members who also confirmed this.

the controlled drugs register due to the lack of staff. This was evident in some of the March 2019 documentation logs and the latest audits. SLC T12; CoP 23.3 (a)&(d)	this aspect of the recommendation by 28 September 2019 The centre should ensure that they appoint a suitably qualified quality manager to oversee the quality management system and undertake the required audits The PR should confirm to the centre's inspector that a quality manager has been appointed by 28 September 2019.	Training and competence documentation will be reviewed for all staff and any deficiencies corrected with additional training. Staffing levels will be reviewed and systems put in place to ensure that the clinic has sufficient staff in the event of illness or during annual leave.	The PR should provide the Executive with evidence of the process he has in place to ensure staffing levels are regularly reviewed and maintained and the arrangements in place for covering sickness and annual leave by 28 September 2019. Further action required
4. Quality Management A number of issues were identified at the inspection, which are described in the main body of the report. SLC T32, T36, T53	The PR should identify the barriers that prevent the CoP guidance from being fully implemented. The PR should inform the centre's inspector of the actions taken to address this recommendation when responding to this report. The PR should ensure that guidance received from the HFEA identified in this report (but not exclusively) is	A vertical audit of current clinic practice against the HFEA CoP will be carried out immediately to identify barriers to compliance. If barriers are identified CAPA's will be implemented. This is a large undertaking and the results are unlikely to be available before September 28th 2019. HFEA guidance will be incorporated into clinic practice where relevant. A bi-annual vertical audit of	The Executive acknowledges the receipt of the Infection control audit. The Executive notes the PR's comment that he will be unable to fulfil the requirements of the non-compliance by 28 June 2019. The Executive therefore grants an extension for completion of this non-compliance by 28 October 2019.

	implemented into practice. It is expected that all practice updates will be fully documented and implemented by 28 June 2019 and the PR should provide confirmation of this to the centre's inspector. The PR should ensure that the centre has a robust and efficient quality management system 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. The PR should ensure that all of the centres practices are audited at least every two years and that any corrective or preventative actions are documented and acted upon within specified timeframes. The PR should ensure that the audits are undertaken, but not exclusive to those mentioned	clinic practice against the HFEA CoP (in addition to the vertical audit planned immediately) will be carried out starting September 2021. Non-controlled drugs audit will be implemented The Infection Control Audit is already operational (see Section 5 below: Infection Control.	Further action required

	in the report. The non controlled drugs audit, the infection control audit and the immunology SOP should be forward to the centre's inspector by 28 June 2019.		
5. Infection Control • The clinical waste bins are not in a locked area and one of the bins remained open; • The recovery area did not have sealed flooring. SLC T2 HTM 07-01 Safe Management of Healthcare Waste. DH Health Building Note 00-09: 'Infection control in the built environment' 2013.	The PR must ensure compliance with the requirements of clinical waste and infection control regulations. The PR should ensure that clinical waste bins are locked at all times and not accessible to unauthorised personnel. The PR should ensure that the flooring in the recovery area is sealed in line with infection control regulatory requirements. The PR should provide confirmation to the centre's inspector when the floor has been appropriately sealed. It is expected that this will have been completed by 28 September 2019.	The clinical waste bin is kept in a cove under the pavement with access through a locked gate or the back door of the clinic only by authorised personnel. Clinical waste and infection control policies and procedures will be reviewed and revised where needed. Additional training will take place where needed. The cleaners have confirmed that the clinical waste bin will be locked all the time. This was added to daily check list by the clinic staff. The recovery room floor will be sealed in line with infection control requirements as soon as possible. Possible options at present are either sealing all the joints by a flooring professional, Resincoat	The Executive acknowledges the new implementations the PR's has already made and the commitment to replace the flooring in the clinical area. Further action required

	Three months after the implementation of any corrective actions, the PR must audit infection control practices including, but not exclusively, those areas of non-compliance identified in this report, to ensure that corrective actions taken have been effective in achieving and maintaining compliance with regulatory requirements. A summary report of this audit should be provided to the centre's inspector by 28 September 2019.	(https://www.resincoat.co.uk/) or Cobra Hard Floor Protector (https://www.trioplus.co.uk/hard-floor-surface-protection/) An infection control audit was carried out on 24/1/19 and 6/6/19 (see attached) which did not identify any issues despite the unsuitable flooring in recovery identified by the HFEA.	
6. Compliance with HFEA standard licence conditions • The cylinder store outside housed eight large and one empty cylinder but these were not chained therefore were at risk of falling over. • There was no safety signage on the cage to indicate there was a fire	The PR should review the gas storage facilities and ensure they comply with regulatory requirements. The PR should confirm to the centre's inspector when the actions taken to implement this non-compliance have been completed. It is expected that this will be by 28 September 2019.	All the cylinders, subject of the inspector report are small, actually very small. We have only one big cylinder of nitrogen as a backup for the nitrogen generator and it is well chained to the wall all the time. Gas storage has been reviewed and revised to comply with regulatory requirements. Chains and signage have been implemented as	The Executive cannot reconcile the PR's response with the extensive discussions that took place at the inspection and within the subsequent tele-conference. The Executive acknowledges the PR's commitment to implementing this recommendation and the implementations that have

risk. SLC T17 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).		requested.	already been undertaken. 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
None			

Additional information from the Person Responsible
In the light of the information provided in this response, and the very constructive discussions with the HFEA, we request that another Interim Inspection requirement is withdrawn. The inspection team note the PR's comment. A rationale for an unannounced interim inspection has been provided in the report for LC consideration.