Licence Committee - minutes

Centre 0341 (The Fertility & Gynaecology Academy)
Additional Focused Unannounced Interim Inspection

Thursday, 9 July 2020

Teleconference

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Alistair Robertson	DAC Beachcroft LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Focused Inspection Report
- Licensing minutes from the past three years:
    - 2019-11-07 - Licence Committee Minutes - Executive update
    - 2019-09-05 - Licence Committee Minutes - Interim Inspection
    - 2017-07-14 - Executive Licensing Panel Minutes - Executive update
    - 2017-03-24 - Executive Licensing Panel Minutes - Renewal 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.

Renewal Inspection - December 2016

1.2. A licence renewal inspection was carried out at the centre in December 2016. The centre's licence was renewed and issued in May 2017 for a period of four years with no additional conditions. The centre's licence is due to expire in May 2021.

Interim inspection (Unannounced) - 28 March 2019

1.3. An interim inspection was carried out at the centre on 28 March 2019 and six major non-compliances were identified, two of which were upgraded to critical.

Critical areas of non-compliance

1.4. Two of the major non-compliances were also identified at the renewal inspection and therefore upgraded to critical. These non-compliances related to the following:

- 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

1.5. The remaining four major non-compliances included the following:

- 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 are 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.

1.6. The centre did not have a Quality Manager at the time of this inspection and 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. However, since the interim inspection, the centre has appointed an infection control lead and Quality Manager.

Licence Committee Decision – September 2019 (Interim Inspection Report)

1.7. The report of the centre's interim inspection carried out in March 2019 was considered by the Licence Committee at its meeting in September 2019.

1.8. The committee noted that since the inspection visit the PR had provided evidence that action had been taken to address the major non-compliance relating to gas storage facilities. The PR had committed to fully implementing all of the other recommendations to address the critical and major areas of non-compliance.

1.9. The committee noted that the Executive had a number of concerns regarding intralipid therapy, including patient information, staff competency and processes. The committee recommended that the centre voluntarily suspended intralipid treatment for all patients until the Executive was satisfied that the centre was following HFEA guidance and implements the recommendations.

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

1.11. The committee agreed that the Executive should complete an unannounced interim inspection within twelve months of the interim inspection which was carried out on 28 March 2019. This inspection would focus on the non-compliances identified in the interim inspection report and ensure compliance had been maintained and corrective action was effective.

1.12. The committee also agreed that the report of the unannounced interim inspection should be considered by the Licence Committee to oversee that patient information was revised and satisfactory and that staff had been trained and are competent to provide the relevant treatments available to patients.

Licence Committee Decision - Executive Update - 7 November 2019

1.13. The Licence Committee considered the Executive's update on the centre's progress with implementation of the recommendations at its meeting on 7 November 2019.

1.14. The PR had implemented the recommendations to address the two critical and four major areas of non-compliance detailed in the unannounced interim inspection report. One action remained to be completed to close the major non-compliance relating to staffing, i.e. the submission of formal contingency agreements with other licensed centres.

1.15. The committee noted that the Executive provided the PR with further guidance in the area of intralipid infusion, reiterating the fact that intralipid therapy provided during licensed fertility treatment is considered an 'add on' to fertility treatment, and as such, it is subject to HFEA regulation. Information about reproductive immunology treatments provided to patients should be compliant with HFEA guidance.

1.16. The committee was satisfied that the Executive had plans to monitor the centre's compliance in a number of areas of practice and complete a further unannounced interim inspection.

Additional Focused Unannounced Interim Inspection – 11 February 2020

1.17. The Executive carried out an additional focused unannounced interim inspection on 11 February 2020 to focus on the non-compliances identified in the interim inspection report and ensure compliance had been maintained and corrective action was effective. The Executive has submitted the centre's report for consideration by the Licence Committee.

2. Consideration of application

Application

Additional Focused Unannounced Interim Inspection

2.1. The committee noted that an additional focused unannounced interim inspection took place on 11 February 2020.

Inspection Process

2.2. The committee noted that in the 12 months to November 2019 the centre provided 108 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a small centre.

2.3. The committee noted that for IVF and ICSI, HFEA-held register data for the period 1 December 2018 to 30 November 2019 showed the centre's success rates were in line with national averages.

2.4. The committee noted that in 2018, the centre reported four cycles of partner insemination with one pregnancy. This represented a clinical pregnancy rate, which was in line with the national average. However, the centre had failed to submit its partner insemination data for 2019.

2.5. The committee noted that between 1 December 2018 and 30 November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 26%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.6. The committee noted that at the time of inspection, one major and two other areas of non-compliance were identified:

Major areas of non-compliance:

- The Person Responsible (PR) should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.

Other areas of non-compliance:

- The PR should review the compressed gas storage facilities and ensure they comply with regulatory requirements.
- The PR should ensure that IUI annual returns are submitted to the HFEA within the required timescales.

2.7. Since the inspection visit, the PR has provided evidence that action has been taken to implement the recommendations. The PR has committed, where required, to audit the effectiveness of action taken within the required timescales.

Recommendations

Licence

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

3. Decision

3.1. The committee had regard to its Decision Tree.

Medicines Management

3.2. The committee noted that the centre'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.

3.3. The management of controlled drugs was compromised in some cases by the practices of removing the closure flaps from boxes in which the drugs are provided and cutting tablets off the blister packs from either end when dispensing to patients for ease of access. Drug batch numbers and expiry dates are printed on the closure flaps and at the ends of blister packs, therefore removing them causes issues with traceability and an increased risk of using drugs which have passed their expiry date.

3.4. The committee noted that implementation of the recommendations has already been undertaken and the PR has shown commitment to achieving compliance.

3.5. The committee noted that no further action is required.

Reproductive Immunology Treatments – 'off label' use of Intralipid Therapy

3.6. The committee noted that Intralipid is not licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. When prescribing a medicine off-label, a healthcare professional's responsibilities may be greater than when prescribing a medicine for use within the terms of its licence.

3.7. The committee noted that the processes for administering and monitoring patients during intralipid infusion were reviewed at the additional focused unannounced interim inspection and were considered to be suitable. The committee also noted that written information provided to patients for intralipid therapy was considered compliant with the guidance.

3.8. As an aside, the committee notes that British Fertility Society (BFS)/Association of Reproductive and Clinical Scientists (ARCS) guidelines state that the use of immunosuppressive treatments should be avoided during the Covid-19 pandemic and anticipates that the centre is applying these guidelines.

Storage of gas cylinders

3.9. The committee noted that a group of eight cylinders had been chained together to the wall to stop them from falling over. Each cylinder should be independently supported and secured to comply with the compressed gas storage regulations.

3.10. The committee noted that the Executive is satisfied that the centre has addressed the non-compliance and that no further action is required.

Staffing

3.11. The committee noted that staffing has been an area of concern. The PR should ensure that staff are available in sufficient numbers, have access to appropriate training and development, are competent, and can contribute to discussions and decisions about patient care.

3.12. This area was reviewed at the additional focused unannounced interim inspection. The committee noted the Executive's observations that staffing levels at the centre were suitable for the activities being carried out, the centre has in place a contingency plan to cover staff absence, patients attending for consultations were seen promptly on arrival and the atmosphere in the centre appeared calm at all times. Staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

3.13. The Executive is satisfied that the issues have been addressed.

Quality Management System (QMS)

3.14. The committee noted that the auditing of the centre's processes was not effective and the centre was not efficient in responding to regulatory change communicated by the HFEA.

3.15. The committee noted that the deadline for implementation of this recommendation had been extended by the Executive to 31 March 2020. This extension had been provided partly in recognition that the centre has had two changes of Quality Manager, which has disrupted progress with the implementation of the recommendation, and the solution proposed by the centre, to provide a full vertical audit of their processes, will take a considerable amount of time.

Infection Control

3.16. The committee noted that at the interim inspection in March 2019 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.

3.17. During this additional focused unannounced interim inspection, the Executive reviewed infection control practices and found them to be compliant with the guidance.

Submission of data to the HFEA

3.18. The committee noted that the centre had failed to submit IUI data for 2018 within the required period (General Direction 0005).

3.19. The PR has implemented this recommendation to ensure that the data is submitted within the set timeframe.

3.20. The committee noted that no further action is required.

Multiple Births

3.21. The committee noted that the centre's performance, in relation to multiple births, shows that it is not likely to be statistically different from the 10% maximum multiple live birth rate target for that period. However, the committee also noted that the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 26%, which does appear to be high. Therefore, the committee has requested that the centre's most recent actual multiple live birth rate is included in the report of the centre's forthcoming licence renewal inspection.

Licence

3.22. The committee noted the progress the centre has made over the last year to address concerns regarding the level of compliance.

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

Monitoring

3.24. The committee requested that the report of the renewal inspection is submitted to the Licence Committee for consideration.

Timescales

3.25. In accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic, centres were required to suspend fertility treatments for a short period of time. Fertility centres can now apply to reopen.

3.26. Therefore, the Executive will liaise with the PR to consider appropriate timescales to fully implement outstanding recommendations.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

22 July 2020

Focused Inspection 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: 11 February 2020
Inspectors: Grace Lyndon and Andy Leonard
Date of Licencing Committee: 9 July 2020

Purpose of the report

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

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

This is a report of a focused additional, unannounced inspection performed at the request of the HFEA Licence Committee (LC) in response to the findings of a mid-licence interim inspection at the centre.

We also take into account our assessment of the centre's performance based on other information and 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 aim of this report is to provide the Authority's Licence Committee with information on the centre's progress with actions taken in response to findings so it can decide about the continuation of the centre's licence.

Summary for the Licence Committee

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular, we note the progress the centre has made over the last year to address concerns regarding the centre's level of compliance.

The LC is asked to note that this report makes recommendations for improvement in relation to one major and two 'other' areas of non-compliance or poor practice.

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 area of non-compliance:

- The Person Responsible (PR) should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.

'Other' area of practice that require improvement:

- The PR should review the compressed gas storage facilities and ensure they comply with regulatory requirements.
- The PR should ensure that IUI annual returns are submitted to the HFEA within the required timescales.

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.

The centre provides a full range of fertility services.

The centre provided 108 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to November 2019. In relation to activity levels, this is a small centre**.**

The centre's licence was renewed in March 2017 for a period of four years with no additional conditions. An interim licence inspection of the centre on 28 March 2019, found six major non-compliances, two of which had recurred after having been noted at the licence renewal inspection in December 2016.

In line with the HFEA Compliance Assessment Framework, the two recurring major non-compliances were upgraded to critical non-compliances. Thus, two critical non-compliances were noted regarding: Medicines management and Patient information about the 'off label' use of intralipid therapy.

Four major non-compliances were noted concerning: Staffing, Infection prevention and control, Quality Management System (implementation of HFEA guidance) and Suitable Premises (gas cylinder storage).

Subsequently the Chief Inspector met with the PR to discuss the centre's progress since licensing and the HFEA's concerns regarding the centre's level of non-compliance. The PR committed to address the inspection report's concerns.

A report of the interim inspection was considered by LC in September 2019 and requested an update, which was considered in November 2019. The LC subsequently required that an additional focused inspection be carried out within a year to review the progress made in addressing non compliance at the centre and that a report of the inspection be provided to the LC. The report below describes the findings of the additional focused inspection.

Details of Inspection findings

Quality of Service

Each 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 1 December 2018 to 30 November 2019 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. This represents a clinical pregnancy rate, which is in line with the national average. However, the centre has failed to submit their partner insemination data for 2019, see recommendation 3.

Multiple births[2]

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

Between 1 December 2018 and 30 November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: egg collection. All of the procedures observed were witnessed using an electronic witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as 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, the storage records and records of consent were reviewed. Audits of all stored gametes and embryos and of the accuracy of storage logs, and the 'bring-forward' system were also 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.

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[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 interim inspection in March 2019 noted a major non compliance regarding 'Staffing'. At this focused inspection, the inspection team observed that this concern has been addressed: the centre has put into place a contingency plan for use in the event of staff absence. The inspection team considered that staffing levels in the clinic were suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

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

The interim inspection in March 2019 noted a major non-compliance in the QMS, related to its lack of effectiveness in auditing the centre's processes and in responding to regulatory change communicated by the HFEA. This matter was discussed at this focused inspection. The PR advised that the centre has had a second change of Quality Manager and that a full vertical process audit is being undertaken which will be completed by the revised deadline agreed with the executive of 31 March 2020. This audit was submitted subsequent to the inspection discussed in this report and was considered by the executive to provide good evidence of compliance and implementation of the recommendation. The PR and the new Laboratory Manager also discussed with the inspection team recent Clinic Focus articles and the centre's responses to them.

We assessed the current effectiveness of the centre's QMS by reviewing the reports of the following audits: medicines management; infection control and legal parenthood. The centre's procedures for auditing and acting on the findings of audits were considered appropriate. The centre's inspector will be provided with the vertical audit of all centre processes by 31 March 2020, which should provide further evidence to contribute to our assessment of the compliance of the centre's QMS.

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 the HFEA or other bodies issue guidance. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- data submission to the HFEA
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood

The centre has been effective in ensuring compliance with guidance issued by the HFEA:

Medicines management

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

The interim inspection in March 2019 noted a critical non-compliance related to medicines management.

During this focused 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.

This was because controlled drug traceability and expiry date control was compromised in some cases, by the practices of removing a closure flaps from boxes in which the drug is provided (for ease of access) and cutting tablets off the blister packs from either end when dispensing to patients, once again for ease of access.

Drug batch numbers and expiry dates are printed on the closure flaps and at the ends of blister packs. By removing these, there is a risk that the drugs are stored without traceability and expiry date references. The inspection team notes that this major non-compliance is not related to previous non-compliances in medicines management practices at this centre. Therefore, the inspection team chose not to elevate this non-compliance to a critical grading.

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 interim inspection in March 2019 noted a critical non-compliance regarding the provision of information to patients about the 'off label' use of intralipid.

The processes for administering to and monitoring patients during intralipid infusion were reviewed at this focussed inspection and were considered to be suitable.

Written information provided to patients offered intralipid therapy was also considered 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.

The interim inspection in March 2019 noted a major non compliance regarding infection control practices.

During this focussed inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The issue of a 'CE mark' denotes the approval of such products.

The CE mark status of the following medical devices was reviewed in the course of the inspection: all media and consumables in use in the laboratory. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff, is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 24 patients have provided feedback in the last 12 months, giving an average five-star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were 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:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- treats patients with empathy and understanding.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

The interim inspection in March 2019 noted a major non-compliance regarding the storage of compressed gas cylinders. At this focussed inspection, it was seen that the PR has taken action to address this non-compliance; however, these actions are not completely effective. Specifically, a group of eight cylinders had been chained together to the wall to stop them from falling over. While this arrangement was stable, the removal of one or two cylinders from the group could destabilise the remaining cylinders, if the chains are not tightened as cylinders are removed. This possibility is exacerbated by the fact that four cylinders were round bottomed. The situation was discussed with the PR who considered that staff would tighten chains as cylinders are removed to ensure the remaining cylinders are held securely. While the inspection team recognise the efforts made by the PR to address the non-compliance, the situation was considered to still present a risk to staff. Each cylinder should be independently supported and secured to comply with the compressed gas storage regulations. The PR committed to consider the situation further immediately after the inspection.

The safe storage of compressed gases was a major non compliance at the interim inspection in March 2019. The inspection team acknowledges the actions taken by the centre since that inspection to address the non-compliance. Any associated risk has been significantly reduced and the centre's on-going engagement on this matter is noted. This non-compliance was graded as an 'other' non-compliance to reflect this.

Recommendation 2.

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

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in March 2019, recommendations for improvement were made in relation to two critical and four major areas of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations had been or would be implemented within the required timescales.

The PR is still implementing recommendations to address areas of non-compliance in the QMS, as discussed elsewhere in this report.

The deadline for implementation of this recommendation has been extended by the executive to 31 March 2020. This extension has been provided in partly, in recognition that the centre has had two changes of Quality Manager, which has disrupted progress with the implementation of the recommendation. The executive also recognised that the solution proposed by the centre in providing a full vertical audit of their processes will take some considerable time. The inspection team note that the PR has maintained contact with the executive regarding progress and the extension.

On-going monitoring of centre success rates

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

Provision of information to the HFEA

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

The clinic is broadly compliant with requirements to submit information to the HFEA because the centre has not submitted the annual return for partner inseminations for 2019 within the required period.

Recommendation 3.

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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 on 11 September 2019. The inspection team also audited one set of records where treatment with donor sperm had recently been provided. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

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

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	Executive review
None noted.			

‘Major’ areas of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines Management This was because controlled drug traceability and expiry date control was compromised in some cases, by the practices of removing a closure flaps from boxes in which the drug is provided (for ease of access) and cutting tablets off the blister packs from either end when dispensing to patients, once again for ease of access. Drug batch numbers and expiry dates are printed on the closure flaps and at the ends of blister packs. By removing	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should undertake a review of the storage and dispensing of medicines procedures and the processes used, to ensure compliance with requirements for traceability and expiry date control. A summary of the review and findings should be submitted to the centres inspector with confirmation of discard of medicines, when	The PR acknowledges the mistake of the nurses by cutting tablets off the blister pack from both ends and hence loosing the expiry date. Having said that we only had one box of the drug referred to, the expiry date of which was logged in the drugs book. The drug reffered to was Dihydrocodein which is a prescription and not controlled drug. Staff training has taken place to avoid this happening again.	The Executive acknowledges the PR’s commitment to implementing this recommendation and the implementations that have already been undertaken. No further action.

these, there is a risk that the drugs are stored without traceability and expiry date references. The inspection team notes that this major non-compliance is not related to previous non-compliances in medicines management practices at this centre. Therefore, the inspection team chose not to elevate this non-compliance to a critical grading. Royal Pharmaceutical Society 'Professional Guidance on the Administration of Medicines in Healthcare Settings' (2019) Section 11 and 15.6	responding to this report. The PR should ensure that drugs without traceability or evidence of their expiry dates are discarded appropriately in line with guidance and best practice.	The drug without clear expiry date on the strip was discarded in line with guidance and best practice.	

‘Other’ areas of practice that require improvement

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
2. Premises and Facilities A group of eight cylinders have been chained together to the wall to stop them from falling over. This arrangement was stable but the inspection team considers that cylinder storage still presents some risks to staff, notably when cylinders are moved into and out of the store, for reasons discussed in the main body of the report. Cylinder storage was a major non-compliance at the interim inspection in March 2019. The inspection team acknowledges the actions taken by the centre to address the non-compliance, which has reduced risk, and the centre’s on-going engagement. This non-compliance was	The PR should review the compressed gas storage facilities and ensure they comply with regulatory requirements. The PR should review and risk assess the current practices and take additional risk control measures, as necessary, to ensure safe cylinder storage. The PR should provide the review of the facilities and the risk assessment by 11 May 2020. The PR should also ensure that risk control measures are completed, and evidence of this provided to the centre’s inspector, by 11 May 2020.	The spare and empty small gas cylinders were secured by a chain. The inspector view was that they were not secured enough. Shortly after the inspection we put all the oxygen cylinders with the non-flat base and some of the CO2 cylinders in a metal box to keep them very scure form falling and the remaining 3 CO2 cylinders, with flat base, were tightly secured by the chaines (photos attached). A photo has already been sent to the inspector then. Thank you for the advice.	The Executive acknowledges the PR’s comments and commitment to implementing the changes necessary for compliance with this recommendation, and the images of the management of stored compress gasses at the premises. The centre provided their risk assessment and evidence of risk control measures. No further action

graded as an 'other' non-compliance to reflect this. SLC T17 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006). Section 8.25, 8.29 and 8.78 BCGA Code of practice 44: The storage of cylinders 2016, Section 5, part 5.14.1.			
3. Submission of data to the HFEA The centre failed to submit their IUI data for 2018 within the required period. General Direction 0005	The PR should ensure that IUI annual returns are submitted to the HFEA within the required timescales. The centre's inspector should be informed of the actions taken to implement this recommendation, to ensure data is submitted within the allotted time frame going forward and the outstanding data is submitted when responding to this report.	Does the inspector mean the IUI data for 2018 or 2019? It is confusing as the dates are different in different sections of the report. The data for IUI 2018 were subitted on 9/3/2019 and the IUI data for 2019 were submitted on 13/3/2020. A reminder in the calender has been created to submit the data in Feb every year.	The Executive acknowledges the misprint in the date, which should read 2019. The Executive acknowledges the PR's failure to submit the 2019 IUI data within the required period and also notes that implementations are now in place to ensure that the data is submitted within the allotted timeframe. No further action

Additional information from the Person Responsible
We acknowledge your comments on the following issues: 1- Storage and consent audit: The audit was done end of August 2018 and is due in Aug 2020 2- Signature register for the staff: We have a signatue register in which all previous and current members of staff are registered. 3- Cryo-room warning sign: The one in black and white was replaced by a laminated coloured one as per your advice during the inspection.