Licence Committee - minutes

Centre 0341 (The Fertility & Gynaecology Academy) Executive Update

Thursday, 7 November 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

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

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:

- Executive update
- 5 September 2019 - Licence Committee Minutes - Interim
- Papers considered by the Licence Committee on 5 September 2019 including:

    - 28 March 2019 - Targeted Interim Inspection Report
    - 14 July 2017 - Executive Licensing Panel Minutes - Executive update
    - 24 March 2017 - Executive Licensing Panel Minutes - Renewal
    - 29 July 2016 - Executive Licensing Panel Minutes - Interim

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 four years in 2017 and is due to expire on 21 May 2021.

History of Non-Compliance

Licence Committee Decision – 5 September 2019

1.3. At its meeting on 5 September 2019, the Licence Committee considered the report of the unannounced interim inspection carried out on 28 March 2019 at centre 0341.

Consideration

1.4. The Licence Committee noted that at the time of the inspection there were two critical and four major areas of non-compliance identified:

Critical areas of non-compliance:

- The Person Responsible (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.

1.5. The Licence Committee noted that significant improvement is required in order for the centre to reflect suitable practices.

1.6. Since the inspection, the PR addressed the major non-compliance relating to gas storage facilities and committed to fully implementing the outstanding recommendations.

1.7. The Executive was concerned that relevant staff may not have the appropriate knowledge and skills to provide care to patients undergoing intralipid infusion treatment. Therefore, the committee recommended a voluntary cessation of intralipid treatment for all patients until the Executive was satisfied that the centre is following HFEA guidance and has implemented the recommendations.

1.8. The committee acknowledged that since the inspection the centre had appointed an infection control lead and Quality Manager. The committee requested an Executive update at the Licence Committee meeting in November 2019, with 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.

1.9. The committee also asked to see the centre's independent review summary report with corrective action plan to address the issues relating to medicines management, which the Executive reported was already overdue, and the summary report after corrective actions at the Licence Committee meeting scheduled in November 2019.

Licence

The committee agreed to the continuation of the centre's licence.

Inspection

1.10. Due to the centre's history of non-compliance, 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 would 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 requested that the report of the unannounced interim 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. The committee confirmed that failure to comply with the recommendations may result in more formal regulatory action.

1.11. The Executive has provided an update for the Licence Committee's consideration.

2. Consideration of application

2.1. The committee noted the Executive update.

2.2. The committee noted that the PR has implemented recommendations to address the two critical and four major non-compliances detailed in the unannounced interim inspection report. One action remains to be completed to close the major non-compliance related to staffing, i.e. the submission of formal contingency agreements with other licensed centres. These areas of practice will be a focus during the next inspection.

Critical Areas of Non-Compliance

Medicines Management

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

2.4. The committee noted that in England, the Home Office licenses medical and other establishments to hold and use controlled drugs (CD).

2.5. The Home Office undertook its four-yearly planned assessment of practices related to CD management at centre 0341 on 9 August 2019. The Home Office disclosed to the Executive that it reviewed the centre's Standard Operating Procedures (SOPs) for CD transportation, receipt and management processes, CD audits were reviewed for completeness and the CD Register was reviewed for inconsistencies and errors. On the day of the visit, the identity of staff who were using the CD cupboard was checked. The Home Office made no recommendations for corrective and preventative actions, and the CD licence was approved. The Executive was unable to provide the Licence Committee with a Home Office report as they do not publish them.

2.6. The Executive noted that the non-compliances identified by the HFEA were all associated with documenting controlled drug use in the CD register. The PR did not seek an independent review of medicines management, considering that the Home Office review of controlled drugs use was enough to evidence implementation of this recommendation. The Executive agreed that the Home Office review could be considered to satisfy HFEA's recommendation for an independent review.

2.7. The PR has confirmed that centre staff have undertaken medicines management training, and that corrective actions have been taken to address the non-compliances identified during the HFEA inspection. The PR has also confirmed that an audit of the CD Register in June 2019 found no new non-compliances.

2.8. This area of practice will be reviewed at the additional unannounced interim inspection to be performed by 28 March 2020.

Prescription of Intralipid 'off label'

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

2.10. The Executive noted the PR's assertion that his staff had enough knowledge about intralipid infusion treatment within their roles. The PR has confirmed that relevant staff have had a refresher update session on reproductive immunology and intralipid therapy.

2.11. Patient information and consent forms regarding intralipid use have been updated so that intralipid infusion times are consistent.

2.12. The Executive has further discussed with the PR the HFEA's interpretation that intralipid therapy, provided during licensed fertility treatment, cannot be considered in isolation from the licensed fertility treatment, and it is considered an 'add on' to the fertility treatment, as such, it is subject to HFEA regulation.

2.13. This area of practice will be reviewed at the additional unannounced interim inspection to be performed by 28 March 2020.

Major Areas of Non-Compliance

Staff

2.14. The committee noted that further action is required.

2.15. The PR has appointed a Quality Manager and the infection control lead has been identified. The PR has also provided the centre's Staffing and Locum/Emergency Staff Policy. This highlights the number of staff required in each discipline as well as their level of training. Laboratory staffing levels have been set according to recommendations from the European Society of Human Reproduction and Embryology (ESHRE). The Quality Manager will monitor staffing levels on a regular basis and will organise the replacement of staff who leave the centre.

2.16. The PR is developing contingency arrangements with other HFEA licensed centres, to obtain nursing, clinical and laboratory staff if staffing resources are stressed by emergencies or illness.

2.17. The PR should provide the inspectorate with the contingency agreement(s) when they are formalised. The PR should also advise the inspectorate of his plans to test the agreements to ensure they are functional. The PR should do this at the earliest opportunity.

2.18. Staffing will be reviewed at the additional unannounced interim inspection to be performed by 28 March 2020

Quality Management

2.19. The committee noted that further action is required.

2.20. The centre has employed a Quality Manager who works for the centre two days a week. The PR and the Quality Manager are carrying out a vertical audit of the centre's processes against all Code of Practice requirements. This is a time-consuming task and the Quality Manager has advised that it will not be finished until at least the end of quarter one of 2020. The Executive has accepted 31 March 2020 as a revised completion date for this recommendation as the Quality Manager appointed is known to the Executive and should be effective and ensure that the Quality Management System (QMS) functions in a compliant manner. Furthermore, the Quality Manager has implemented recent changes in CoP requirements into the centre's processes. The vertical audit will ensure that the centre's processes are completely compliant with all CoP requirements.

2.21. No further actions are required beyond completion of the vertical audits of the centre's processes.

2.22. The completion of the vertical audits as well as the efficacy of the QMS, will be reviewed at the additional unannounced interim inspection to be performed by 28 March 2020.

Infection Control

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

2.24. The Executive acknowledged the infection control audit provided by the PR after the inspection.

2.25. The PR has confirmed to the inspectorate that he has discussed with centre staff the importance of undertaking and documenting routine checks, such as the emergency trolley/bag, maintaining daily cleaning records and of ensuring the secure storage of clinical waste.

2.26. The PR has confirmed that the recovery room has now been sealed in line with infection control requirements.

2.27. Infection control practices will be reviewed at the additional unannounced interim inspection to be performed by 28 March 2020.

Compliance with HFEA standard licence conditions

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

2.29. The Executive acknowledged the PR's commitment to implementing this recommendation.

Recommendation

2.30. The committee noted that, in summary, the PR has addressed the recommendations with some outstanding actions to complete. The Executive recommends that these areas of practice are points of focus during the additional unannounced interim inspection to be completed before 28 March 2020.

3. Decision

3.1. The committee noted the centre's progress with implementation of the recommendations made in the report of the unannounced interim inspection, carried out on 28 March 2019.

3.2. The committee noted that the PR needed further guidance from the Executive in the area of intralipid infusion and was satisfied that the Executive has reiterated 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.

3.3. The committee was satisfied with the areas of focus planned for the additional unannounced interim inspection and looks forward to receiving the report for consideration at a future meeting, including an update on compliance of the centre's website information. The committee expects to see continued improvement and accurate patient information.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

3 December 2019

Executive Summary for Licence Committee
7 November 2019

Centre	The Fertility & Gynaecology Academy
Centre number	0341
Person Responsible	Dr Amin Gorgy
Inspector	Grace Lyndon

1. The Licence Committee on 5 September 2019 considered the report of an interim inspection at The Fertility and Gynaecology Academy (centre 0341) on 28 March 2019. This centre is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since May 2015. It provides a full range of fertility services.

2. The committee were concerned about the two critical and four major areas of non-compliance identified in the inspection report and the implementation of recommendations to address them. The committee requested an update be provided to them at their meeting in November 2019, notably around the implementation of recommendations in the area of medicines management and the prescription of intralipid 'off label'. Concerns in these areas had also been identified at the renewal inspection in 2017.

3. The Executive has continued to liaise with the PR to assess the implementation of the inspection report's recommendations. An update on these activities is included in Annex 1 below, notably in the column 'Inspection team's response to the PR's statement'.

4. In summary, the PR has implemented recommendations to address the two critical and four major non compliances detailed in the interim inspection report. One action remains to be completed to close the major non compliance related to staffing, i.e. the submission to the executive of formal contingency agreements with other licensed centres. The remaining non compliances have all been addressed. These areas of practice will however be points of focus during the additional inspection, required by the Licence Committee at the recommendation of the inspection team, to be performed before 28 March 2020.

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	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.	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 informed and he would take the	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 regarding the documentation of errors and explanation given in the controlled drugs register being compliant. This

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. • 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 PR should follow best practice for medicines 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	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 the internet.	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 **28 October 2019: Update for Licence Committee** In England, the Home Office licenses medical and other establishments to hold and use CDs. The Home Office undertook their four-yearly planned assessment of practices related to CD management at centre 0341 on 9 August 2019, reviewing record keeping, safe custody arrangements and procedures. The centre was

• 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. 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	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 by the Home Office that 'they are all in order', no recommendations for corrective and preventative actions were made, and the centre's CD licence has been re-approved. The Home Office disclosed to the Executive that they reviewed the centre's SOPs for CD transportation, receipt and management processes, checked the identities of staff on the day of the visit who were using the CD cupboard, and reviewed CD audits for completeness and the controlled drugs register for inconsistencies and errors. The Home office does not publish reports of these visits so the Licence Committee cannot be provided with a report. The PR has not sought an independent review of medicines management, considering that the Home Office review of CD use is enough to evidence implementation of this recommendation. The PR has confirmed that centre staff have undertaken medicines management training, and that corrective actions have been taken to

			address the non-compliances identified during the inspection. The PR has also confirmed that an audit of the CD register in June 2019 found no new non compliances. The Executive notes that the non-compliances identified were all associated with documenting CD use in the CD register. Therefore, the Home Office review was likely to be useful and could be considered to satisfy the recommendation of the report regarding 'an independent review'. The inspector also notes the additional training provided to staff. No further actions are necessary. This area of practice will be reviewed at the additional inspection to be performed by 28 March 2020.
2. Prescription of intralipid 'off label' It was noted that; • Written information provided to patient's states that the intralipid infusion is administered over	The PR should ensure the information about reproductive immunology treatments provided to patients is compliant with HFEA guidance.	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	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

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. This leads the inspection team to be concerned that relevant staff may not have the appropriate knowledge and skills to provide care to	The PR should revise patient information describing 'add-on' treatments, and ensure it complies with the 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	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 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	why the PR 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 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.

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 clarity of the written information and the clear lack of strong evidence of the use immunology therapies	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 recommendation by 28 June 2019.	been revised and updated to include details on the timing of Intralipid treatment, the same as clearly documented in the patient informed 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	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 **28 October 2019: Update for Licence Committee** Patient information and consent forms regarding intralipid use have been updated so that intralipid infusion times are consistent. The Executive has further discussed with the PR the HFEA's interpretation that intralipid therapy provided during licensed fertility treatment, cannot be considered in isolation from the licensed fertility treatment, but is rather considered an 'add on' to the fertility treatment. As such, it is subject to HFEA regulation. The Executive notes the PR's assertion that his staff have enough knowledge about intralipid 'within their roles'. However, he has also advised the centre's inspector that the 'refresher' update session regarding

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		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. 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.	reproductive immunology and intralipid therapy has been held with relevant centre staff. No further actions are required. This area of practice will be reviewed at the additional inspection to be performed by 28 March 2020.

‘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	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	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. Training and competence	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 PR should provide the Executive with evidence of the process he has in place to ensure staffing levels are

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. SLC T12; CoP 23.3 (a)&(d)	arrangements in place to manage staff absence and annual leave. The PR should inform the centre's inspector of the actions taken to implement 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.	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.	regularly reviewed and maintained and the arrangements in place for covering sickness and annual leave by 28 September 2019. Further action required **28 October 2019: Update for Licence Committee** The PR has appointed a quality manager and the infection control lead is now identified. The PR has also provided the centre's 'Staffing and Locum/Emergency Staff Policy'. This highlights the number of staff required in each discipline as well as their level of training. Laboratory staffing levels have been set according to recommendations from the European Society of Human Reproduction and Endocrinology. The quality manager will monitor staffing levels on a regular basis and will organise the replacement of staff who leave the centre. The PR is developing contingency arrangements with other HFEA licensed centres, to obtain nursing, clinical and laboratory staff if staffing resources are stressed by

			emergencies or illness. The PR should provide the centre's inspector with the contingency agreement(s) when they are formalised. The PR should also advise the inspector of his plans to test the agreements to ensure they are functional. The PR should do this at the earliest opportunity. **Further actions are required.** Staffing will be reviewed at the additional inspection to be performed by 28 March 2020.
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.	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 clinic practice against the HFEA CoP (in addition to the vertical audit planned	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. Further action required

	The PR should ensure that guidance received from the HFEA identified in this report (but not exclusively) is 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.	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.	**28 October 2019: Update for Licence Committee** The centre has employed a quality manager who works for the centre two days a week. The PR and the quality manager are carrying out a vertical audit of the centre's processes against all Code of Practice requirements. This is a time-consuming task and the quality manager has advised that it will not be finished until at least the end of Q1 2020. The Executive is accepting of the 31 March 2020 as a revised completion date for this recommendation. This is because the quality manager appointed, who is known to the executive, should be effective and will ensure that the QMS functions in a compliant manner. Furthermore, the quality manager has implemented recent changes in CoP requirements into the centre's processes. The vertical audit will ensure that the centre's processes are completely compliant with all CoP requirements. No further actions are required beyond completion of the vertical audits of the centre's processes.

	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 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.		The completion of the vertical audits as well as the efficacy of the QMS, will be reviewed at the additional inspection to be performed by 28 March 2020.
5. Infection Control • The clinical waste bins are not in a locked area and one of the bins remained open;	The PR must ensure compliance with the requirements of clinical waste and infection control regulations.	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	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

• 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 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. Three months after the implementation of any corrective actions, the PR must audit infection control practices including, but not	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 (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.	**28 October 2019: Update for Licence Committee** The Executive acknowledges the infection control audit provided by the PR after the inspection. The PR has confirmed to the centre's inspector that he has discussed with centre staff the importance of undertaking and documenting routine checks, such as of the emergency trolley/bag, of maintaining daily cleaning records and of ensuring the secure storage of clinical waste. The PR has confirmed that the recovery room has now been sealed in line with infection control requirements. No further actions are required. Infection control practices will be reviewed at the additional inspection to be performed by 28 March 2020.

	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.		
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	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	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 requested.	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 already been undertaken. No further action required

to indicate there was a fire risk. SLC T17 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).	completed. It is expected that this will be by 28 September 2019.		

‘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			