Executive Licensing Panel - minutes

Centre 0336 (Simply Fertility)

Interim Inspection Report

Thursday, 8 November 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Research Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Hannah Carpenter	Policy Officer

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Simply Fertility is located in a purpose-built fertility clinic adjacent to Baddow Hospital in Chelmsford, Essex. The centre provides a full range of fertility services.

1.2. The panel noted that the centre initially commenced activity under a HFEA treatment (insemination using partner / donor sperm) and storage licence in August 2013. The centre subsequently became a member of the Fertility Partnership, upgraded the clinical and laboratory facilities and varied their licence in May 2017 to a treatment (including embryo testing) and storage licence.

1.3. The panel noted that, in the 12 months to 31 May 2018, the centre provided 319 cycles of treatment (excluding partner intrauterine insemination). In relation to activity level this is a small sized centre.

1.4. The panel noted that in 2017 the centre reported 5 cycles of partner insemination with no clinical pregnancies.

1.5. The panel noted that, from 1 March 2017 to 28 February 2018, HFEA held register data showed that centre's success rates for IVF and ICSI are in line with national averages, with the exception of the clinical pregnancy rates following IVF in patients aged less than 38 years, which is higher than the national average, at a statistically significant level.

1.6. The panel noted that HFEA held register data between 1 March 2017 and 28 February 2018 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.7. The panel noted that the inspection took place on 26th July 2018.

The panel noted that at the time of the inspection, three major areas of non-compliance were identified concerning the centre's Quality Management System (QMS), medicines management and infection control. There were also two 'other' areas of non-compliance regarding staffing and air quality. Since the inspection visit, the Person Responsible (PR) had provided evidence that the recommendations concerning the QMS and staffing have been implemented. The PR has commenced corrective and preventative actions, and committed to implementing the recommendations regarding medicines management, infection control and air quality, within the specified timeframes.

1.8. The panel noted that the inspectorate recommends the continuation of the centre's treatment (with embryo testing) and storage licence, noting the positive comments made by patients in relation to their experiences at the centre.

2. Decision

2.1. The panel noted the centre's non-compliances, encouraging the PR to ensure the outstanding recommendations are implemented within the prescribed timescales.

2.2. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

13 November 2018

Interim Licensing Report

Centre name: Simply Fertility
Centre number: 0336
Date licence issued: 27/11/2015
Licence expiry date: 26/11/2019
Additional conditions applied to this licence: None
Date of inspection: 26/07/2018
Inspectors: Grace Lyndon (Lead) and Andy Leonard
Date of Executive Licensing Panel: 6 November 2018

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 focus of an interim inspection is:

- **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 Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences at the centre.

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

The PR has provided evidence that the following recommendations have already been implemented to the satisfaction of the inspection team:

Major areas of non compliance:

- The PR should ensure that HFEA guidance is effectively implemented into the centre's practice and that audits are completely effective.

'Other' areas of practice that require improvement:

- The PR should ensure that staff are provided training, and have their competence to perform their duties assessed, at the specified frequency.

The PR has commenced corrective and preventative actions, and committed to implement the following recommendations within timeframes agreed with the inspection team:

Major areas of non compliance:

- The PR should ensure that medicines management practices are compliant with all regulatory requirements and best practice guidance;
- The PR should ensure that the infection control practices are compliant with regulatory requirements and best practice guidance.

'Other' areas of practice that require improvement:

- The PR should validate the air quality monitoring process.

Information about the centre

Simply Fertility initially commenced activity under a HFEA Treatment (insemination using partner / donor sperm) and Storage licence in August 2013. The centre subsequently became a member of the Fertility Partnership, upgraded the clinical and laboratory facilities and varied their licence in May 2017 to a full Treatment (with embryo testing) and Storage licence.

The centre is situated in a purpose-built fertility clinic adjacent to Baddow Hospital in Chelmsford, Essex.

The centre provides a full range of fertility services.

The centre provided 319 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 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 1 March 2017 to 28 February 2018 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate following IVF in women aged under 38 years is higher than the national average at a statistically significant level.

In 2017, the centre reported five cycles of partner insemination with no pregnancies.

Multiple births[2]

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

Between 1 March 2017 and 28 February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

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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%.

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

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

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: The atmosphere in the clinic appeared calm at all times and staff in the laboratory were able to carry out their activities without distraction.

For some activities, for example consenting, clinical assessment and venepuncture, training and competence assessment has not been performed at the frequency specified in staff training procedures, so some training logs and competence assessments are out of date (recommendation 4).

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: witnessing and consent to storage. The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements. This is because the witnessing audit found, in January 2018, that occasional manual witnessing steps were not appropriately documented. The audit report recommended several corrective actions and evidence was available that all but one had been implemented, this being a re-audit of witnessing documentation in March 2018 to verify that the other corrective and preventative actions had been effective. The inspection team was concerned that the follow-up audit had not been performed, given the importance of witnessing, but note that the initial non conformance concerned the documentation of witnessing, rather than witnessing itself, and carried no risk because electronic witnessing had also been performed alongside the manual checks (recommendation 1).

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:

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: screening requirements for hepatitis A introduced via Clinic Focus in August 2017.

The centre is broadly effective in implementing learning from HFEA guidance because recent changes to screening requirements, involving hepatitis A screening in certain cases, have not yet been incorporated into the centre's donor screening processes, procedures and patient information (recommendation 1).

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.

The clinic's processes for medicines management were reviewed and were found to be partially compliant with guidance because:

- The controlled drug register is not completed appropriately, e.g.
    a) Patients are sometimes identified using only one identifier;
    b) Non-approved ink colours have been used;
    c) Some entries have not been countersigned when they should have been, such as controlled drug withdrawal from stock, administration and discard;
    d) Errors in the register have not been corrected in the required manner specified by the centre's own guidance and the Safer Management of Controlled Drugs guidelines;
    e) Staff signatures were not legible.
- Bulk controlled drugs for the day's egg collections are stored in a cupboard in theatre which is not approved by the Home Office for the storage of controlled drugs;

See recommendation 2.

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 inspection team considered that written information provided to patients offered intralipid therapy was compliant with guidance, as was the process for administering and monitoring patients during intralipid infusion. However, record keeping regarding the use of intralipids was partially compliant, because a clear and comprehensive clinical rationale for the prescription of intralipids in patients undergoing fertility treatment is not recorded in their records, even though the use of intralipids in this treatment setting constitutes 'off-licence' use. That the patient had intralipids during a previous fertility treatment cycle does not constitute a clear and comprehensive clinical rationale (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 because;

- The sink in the recovery area used by staff to wash their hands after patient care does not have 'hands free' taps and is small and may not contain water splashes during hand washing;
- The temporary closure was not in place in any of the sharps bins observed in procedure room, the recovery area, or the rooms where bloods are taken;
- There were multiple sharps bins that were in use, located on the waste store room floor;
- The exterior waste store contained a large recycling waste bin and a clinical waste bin which were both over-filled and could not be closed properly and locked.

See recommendation 3.

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 a range of laboratory consumables and culture media was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, we spoke to one couple about their experiences at the centre. On reviewing the centre's own patient feedback, it was positive, with 39 of the individuals providing written feedback giving compliments about the care received. However, 17 out of 39 patients did not agree that their appointments or consultations were punctual. The PR

described the actions he is taking to address this concern, and the inspection team considered those actions proportionate and appropriate.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

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, indicated that the centre is fully compliant with HFEA requirements with one exception in addition to those already highlighted in this report: The air quality monitoring protocol has not been validated. See recommendation 5.

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2017, recommendations for improvement were made in relation to eight major and two 'other' areas of non compliance.

In responding to the report immediately after the inspection, the PR agreed to implement the recommendations. The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last interim inspection in March 2017, the PR has received nine risk tool alerts related to data submission. These alert emails have been issued because of problems with the centre's electronic data interface, the system via which treatment data is communicated to the HFEA. The PR has responded appropriately to these emails and continues to work with the HFEA register team, to ensure the centre's register data is complete.

Provision of information to the HFEA

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

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

Legal parenthood

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

In February 2014, the HFEA asked all 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 did not send an audit report but advised the centre's inspector that it had not undertaken any relevant treatments as it had only been licensed since November 2013. In October 2015, the HFEA requested a full statement from centres to be assured that all errors have been identified and that such errors will not occur in the future. The centre provided a response that they had completed a legal parenthood audit that was comprehensive and that their current procedures for obtaining consent to parenthood were robust.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed the centre's legal parenthood audit and discussed the processes undertaken where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The review indicated that the centre's audit had been performed according to the method specified by the HFEA. No errors were identified; however, there was an occasion where a member of staff presumed a couple were married because they had the same last name. This treatment did not result in a pregnancy. Extra measures have now been put into place to ensure marital status has been assessed and documented effectively. 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
None identified			

‘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
1. Quality management system The centre’s process for implementing learning from HFEA guidance is not completely effective because recent changes to screening requirements, involving hepatitis A screening in certain cases (Clinic Focus, August 2017), have not yet been incorporated into the centre’s donor screening processes, procedures and patient information (SLC T32). The centre’s audit processes are also not completely	The PR should immediately ensure that the centre’s processes for implementing learning from HFEA guidance and the centre’s audit programme are completely effective. The PR should review the current processes and why they have failed, then take appropriate corrective and preventative actions to prevent recurrence. A report of this review including the proposed actions with timescales for implementation should be provided to the centre’s	We accept the points that were picked up when assessing our QMS, however we have been pleased with progress in the development of our QMS in the first 16 months of operation. I can confirm that we have now completed our witnessing re-audit which showed no non conformances and we have closed all other outstanding non conformances and preventative actions. Our QMS is live and driven by Qpulse. All Audits as required by the regulations have been completed and we are in the process of redeveloping our	The inspection team is reassured by the PR’s response and that Qpulse is now being used to direct the QMS and ensure completion of all corrective and preventative actions, as well as the implementation of change in response to regulatory guidance. No further actions are required beyond completion of the audit procedure update, which the PR has committed to provide by 26 October 2018. This will be useful, however the implementation of Qpulse

effective because corrective actions in response to a witnessing audit non conformance have not been implemented in full. Thus, learning from audit findings has not been effective (SLC T36).	inspector by 26 October 2018.	Audit procedure to reflect from the learning so far. We will send an Audit of our QMS report to you by the 26 October 2018	provides the inspection team with assurance that audit findings will be effectively implemented in future.
2. Medicines management The clinic's processes for medicines management were partially compliant with guidance because: • The controlled drug register is not completed appropriately. a) Patients are sometimes identified using only one identifier; b) Non-approved ink colours have been used; c) Some entries have not been countersigned when they should have been, such as controlled drug withdrawal from stock, administration and discard; d) Errors in the register have not been	The PR should ensure that medicines management procedures are followed and are in line with regulations and best practice. The PR should provide a summary of actions taken to ensure compliance in relation to observations made in this report and should include staff training. Within three months of the implementation of corrective actions, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the	All staff have been briefed on the importance of correct and eligible reporting on the use of controlled drugs. All + of our nursing team have since repeated their medicines Management training. We will repeat out audit on medicine management report to you by the 26 November 2018 Intralipids. Two patient records were examined on the day of the inspection which clearly showed that the patients had been tested for Natural Killer Cells and that the results were abnormal indicating that intralipids could be prescribed. All patients are given full written and verbal information	The inspection team is reassured by the PR's response that staff have been 'briefed' and have received further medicines management training. The medicines management audit report, to be provided by 26 November 2018, should reflect significant improvements in the completion of the controlled drug register and the day storage of controlled drugs. Regarding intralipids, the natural killer cell test data may indicate that intralipids can be prescribed, however this is inferential. The PR's comments advise that a clear written statement for the prescription was present in the records, but this was not observed by the inspection team, who do

corrected in the required manner specified by the centre's own guidance and the Safer Management of Controlled Drugs guidelines; e) Staff signatures were not legible • Bulk controlled drugs for the day's egg collections are stored in a cupboard in theatre which is not approved by the home office for the storage of controlled drugs; • Record keeping regarding the use of intralipids did not include a clear and comprehensive clinical rationale for its use. The simple explanation was it was the patients request and they simply stated that the patient had intralipids during a previous fertility treatment cycle at an alternative centre. SLC T2 NICE Guideline [NG46] April	centre's inspector by 26 November 2018.	to the effect that the treatment is not scientifically proven, before embarking on treatment. We have a written statement in each set of records indicating the reasons for prescribing Intralipids. Our Consultants have confirmed that every treatment has been a result of the following test – NK Panel and Cytokines (TH1:TH2 ratio).	expect a clear statement of rationale for the prescription to be documented in the records. The inspection team will discuss further with the PR to resolve this conundrum and to ensure a clear statement of rationale is provided in each and every record recording intralipid prescription. **Further actions are required.**

2016 'Controlled drugs: safe use and management'. Misuse of Drugs (safe Custody) Regulations 2001 Controlled Drugs (Supervision of Management and Use) Regulations 2013.			
3 Infection control Several non compliances related to infection control practice are described in detail in the main body of the report. These involved the centre's waste store (over-filled bins which could not be closed or locked); active sharps bins located on the waste store room floor; failure to use temporary closures on sharps bins in clinical areas; and a sink in the recovery area which did not support effective infection control practice. Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste (2013).	The PR should ensure that the infection control measures and practices are compliant with regulatory and best practice guidance. The PR should provide a summary report of this review, including the actions taken to achieve compliance and timeframes for implementation to the centre's inspector by 26 October 2018. Three months after the implementation, an audit should be undertaken. The audit summary should be sent to your centres inspector by 26 January 2019.	We are fully aware that on the day the main external clinical waste store was unlocked. I can assure you that at all times this is locked and checked again between 6-7pm when our cleaner adds the final bags before leaving the premises. At the time of your inspection you will remember that workman were restricting access for yourselves and our staff and so usual practice of adding waste and locking the lid was not possible. However we are aware that we need a second clinical waste bin and this is currently on order. With the second waste bin we will be able to remove all the smaller patient hand held sharp bins off the floor, currently these are held in a large plastic box.	The inspection team is reassured by the PR's summary report and that a second clinical waste bin is being ordered, that the sharps bins will be removed from the floor, and that staff have been told to use the temporary closures on sharps bins. Similarly that the recovery area sink is being reviewed to address the inspection team's concerns. The inspection team look forward to receiving the report of the audit of infection control practices, by 26 January 2019, and being advised regarding the actions taken to provide a sink in the recovery area which supports effective infection control practices.

Health Building Note 00-10: Part C Sanitary Assemblies (2013).		All staff have been informed of the report and have been briefed on the need to use the temporary closures. The sink in the Recovery area does require attention and we will report back when we have a solution.	**Further actions are 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
4 Staffing For some activities, training and competence assessment has not been performed at the specified frequency, so some training logs and competence assessments are out of date. SLC T12 and T15a. NMC Standards for competence for registered nurses 2015.	The PR should ensure that staff are provided training, and have their competence to perform their duties assessed, at the specified frequency. The PR should review the training for all staff members and ensure that all staff are up to date and signed off as competent in the training undertaken. A training plan should be sent to the centre’s inspector when responding to this report. Evidence of staff training should be sent to the centre’s inspector by 26 December 2018.	We take staff training very seriously and have incorporated a continuous training program which encompasses the mandatory training which all staff have undertaken but also includes all other specialised training related to the tasks performed. Our Training Plan is attached to this report.	The inspection team notes the PR’s response and commitment to effective staff training and the detailed training log provided which shows that all training requirements are up to date. No further actions are required The PR should however reflect on whether the provision of training also assures him of staff competence, or whether other evidence of competence is available, or should be sought.

5 Air quality The air quality monitoring protocol has not been validated for methodology and frequency SLC T72.	The PR should validate the air quality monitoring process so that he is assured that the results of air quality monitoring provide assurance that the critical work areas and laboratory backgrounds meet the air quality requirements at all times. A copy of the validation document should be provided to the centre's inspector by 26 October 2018.	We understand the need to validate the air quality and we are currently sourcing the monitoring equipment to use over a period of time. Due to the lateness of this report we will be unable to furnish you with this validation report within the time period given. However we can assure you that the two air quality assessments in the last 10 months have confirmed that the air quality meets the requirements of Grade D background. A validation report will be available for 15 December 2018	The inspection team acknowledges the PR's response and accepts that using the current testing methodology and frequency, air quality of grade D or better may usually be indicated. However effective validation of the air quality testing protocol is necessary before the test results can be taken to assure that compliant air quality is in place at all times. The PR understands this, hence his commitment to perform the validation. The inspection team apologises for the delays in the PR receiving the report and consider it reasonable to extend the deadline for the implementation of this recommendation to 26 January 2019. **Further actions are required.**

Additional information from the Person Responsible
Thank you for the report which we received 10 weeks post the inspection. We found it to be a fair representation of the unannounced inspection findings. I hope you will consider my responses as fair and ask that you review the intralipid and repeated QMS section before going to license committee. I am pleased that the inspection team could see the great work that our team have done and please to see that the authority have recognised in the report that we have results significantly higher than the national average for IVF patients under 38yrs. This is important as we have no representation on the Choose a Fertility Clinic portal and unlikely to have one in the near future due to an HFEA internal decision making policy as they focus on the new PRISM system. Thank you once again to the HFEA inspection team for their feedback.