Executive Licensing Panel - minutes

Centre Epsom and St Helier NHS Trust (Centre 0259)

Interim Inspection Report

Thursday, 16 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Anna Quinn Laura Riley	Head of Intelligence Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Richard Chamberlain	Temporary Committee Clerk
Observers	Catherine Burwood	Senior Governance Manager

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 considered the papers, which included an interim inspection report, and licensing minutes covering the last three years:

- 22 April 2016 – variation of licensed activities and variation of premises
- 11 March 2016 – renewal inspection report

1.2. The panel noted that the Assisted Conception unit is located in the St Helier University Hospital NHS Trust in Carshalton, Surrey and has been licensed by the HFEA since 2007. The centre was licensed to provided treatment and storage.

1.3. The panel noted that the centre's current licence was varied April 2016 to provide a full range of fertility services. The application was approved by ELP in April 2016.

1.4. The panel noted that in the 12 months to 31 January 2018, the centre reported 216 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. The panel noted that for IVF and ICSI, HFEA held register data for the year ending October 2017 showing the centre's success rates are in line with the national average.

1.6. The panel noted that between November 2016 and October 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is in line with the 10% multiple live birth rate target for this period.

1.7. The panel noted that the inspection took place on 27 March 2018.

1.8. The panel noted one critical area of non-compliance regarding the safety of premises.

1.9. The panel noted that the Executive acknowledges the PR's response and actions taken to ensure the safety of premises. The PR is due to provide an update to the centre's inspector regarding installation of a permanent low oxygen alarm in the store cupboard by 16 September 2018.

1.10. The panel noted there was three 'major' areas of non-compliance regarding the Quality Management System (QMS), medicines management and premises and facilities. Further action was required in relation to the QMS and medicines management.

1.11. There were two 'other' areas of non-compliance regarding storage consent and premises and facilities. Further action was required in regard to storage consent where the executive recommends that the PR reconsiders the centre's processes and that a full review of storage consent from the date of initial storage is performed. This is to ensure that the centre does not unintentionally store or use material where it is potentially not legal to do so.

1.12. The centre accepted ownership of the points made in the inspection and were working hard with their colleagues within other departments of Epsom and St Helier NHS University Trust to rectify the issues

1.13. The executive recommended the continuation of the licence subject to the centre confirming to the centre's inspector that corrective actions had been taken.

2. Decision

2.1. The panel had regard to its decision tree. They noted that all pregnancy outcomes were in line with national averages, but the safety of premises issues should be resolved by 16 September 2018 through an update to the inspectors, and the QMS non-compliance should have corrective actions confirmed as fully implemented to the centre's inspector by 27 September 2018.

2.2. The panel noted the centre's positive response to the report and were pleased to see that the recommendations were agreed and being implemented by the centre.

2.3. The panel agreed with the executive that the licence should continue to 30 June 2020 subject to the outstanding recommendations being implemented within the prescribed timetable.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

3 September 2018

Interim Licensing Report

Centre name: Epsom and St Helier NHS Trust
Centre number: 0259
Date licence issued: 01/07/2016
Licence expiry date: 30/06/2020
Additional conditions applied to this licence: None
Date of inspection: 27/03/2018
Inspectors: Grace Lyndon (lead), Sara Parlett and Dan Howard (observer).
Date of Executive Licensing Panel: 16 August 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. For 2015-2018 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.

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

Since the inspection visit, the Person Responsible (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.

Critical areas of non compliance:

- **The PR should ensure appropriate immediate action is taken to ensure the safety of staff accessing areas containing liquid nitrogen.**

Major areas of non compliance:

- the PR should ensure that all appropriate theatre staff are working in line with the Misuse of drugs Act when managing controlled drugs pre, during and post operatively;
- the PR should ensure that the clinical waste bins are adequately stored to eliminate any risk or access by the public.

'Other' areas of practice that require improvement:

- The PR should ensure that all fire extinguishers within the centre are serviced in line with current regulations.

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

Major areas of non compliance:

- the PR should ensure that the centre's audit processes are effective in implementing, corrective and preventative actions in response to audit findings;
- the PR should ensure that all appropriate theatre staff are working in line with the Misuse of drugs Act when managing controlled drugs pre, during and post operatively;

'Other' areas of practice that require improvement:

- The PR should ensure that appropriate consent is in place prior to the storage of any gametes or embryos, including where material is transferred from another centre;

Information about the centre

The Assisted Conception Unit at Epsom and St Helier University Hospital NHS Trust located in Surrey has been licensed by the HFEA since 2007. The centre was licensed to provide treatment (insemination using partner/donor sperm) and storage.

In 2015, the centre submitted an application to vary its licence to reflect changes to the licensed premises and licensed activities to provide a full range of fertility services. This application was approved by ELP in April 2016.

The centre provided 216 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 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 year ending October 2017 show the centre's success rates are in line with national averages.

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

Multiple births[2]

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

Between November 2016 and October 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is likely to be in line with the 10% multiple live birth rate target for this period.

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.

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

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

The consent for one set of sperm samples in storage at the centre has not been accurately completed. These samples were originally frozen and stored in 2003 at the Wolfson Fertility Centre - Hammersmith hospital (centre 0078). Half of the patient's samples were transferred to centre 0259 in 2017. Prior to the transfer to centre 0259, in 2016, the patient completed a new LGS consent form to extend the storage period. The LGS consent has a section to be completed by clinic staff – to record both the date gametes were placed in storage and the date gametes can remain in storage until. The date that the gametes can remain in storage until had been incorrectly recorded and related to the day and month of signing of the consent form, rather than the date the samples were frozen. This could be misleading or confusing for the patient. The clinician who completed the accompanying medical practitioner statement had also signed the section of the LGS form that is only for use where the form is completed by someone other than the patient, where the patient is unable to sign for themselves due to physical illness, injury or disability. This was not the case with this patient. The inspection team was concerned that using the patient's consent form in this way is not appropriate and that staff may not fully understand the purpose of this section. It is acknowledged that this consent was completed at another centre. Previous consent forms, to allow for the lawful storage of the samples up until the completion of the new LGS consent form in 2016, were not available for review on this inspection (recommendation 5).

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 interim inspection was carried out at a time when the centre had little activity, therefore there were very few patients seen within the centre and there was no activity undertaken in the laboratory.

The PR assured the inspection team that staffing levels were suitable for the activities carried out. For example, the PR has confirmed that despite one embryologist and two nursing staff on maternity leave, other part time staff have increased their hours and an advert for a qualified nurse is imminent.

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, consent to storage, legal parenthood and medicines management.

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

- it was not clear if the centre is measuring against their own established quality indicators (QIs) and if the QIs are being met.
- where non conformities were identified in the centre's audits, it was not always clear if corrective action had been implemented (recommendation 2).

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 and were found to be compliant, with reference to the following:

- the use of CE marked medical devices
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles related to Ebola and Zika

Medicines management

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

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

- some required areas of the controlled drugs book had not been completed. In one instance the medication administrator had not signed the controlled drugs book to document the supply, administration and discarding of the drug before, during and after the procedure;
- there were no times recorded in the controlled drugs book to indicate when medicines were supplied, administered or discarded by medical personal;
- the disposal of controlled drugs was not always witnessed by a second person (recommendation 3).

A non compliance with the requirement for accurate recording of controlled drugs was found at the centre's renewal inspection in 2015.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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 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 approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of a sample of reagents and plastic ware 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, no patients were available to speak with the inspectors about their experiences at the centre. The centre's most recent survey of patient feedback was reviewed on inspection. A small number of negative trends were noted (for example appointment waiting time delays) and corrective action to address these has been implemented by staff. This demonstrates that the clinic uses feedback to improve its services. The inspection team encourages the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

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

- there is an additional store cupboard outside of the licensed premises, in a main corridor within the hospital. This is used as a store room for other hospital staff too. This doesn't contain any licensed material, but two of the centre's liquid nitrogen tanks are stored there. Safety signs are on the door but there is no low oxygen alarm present. The hospital estates department has been asked to install an alarm, but this has not yet taken place (recommendation 1);

- Dewar's containing gametes and embryos are stored in the laboratory. A low oxygen alarm is in place; however there are no safety signs on the door to the laboratory alerting staff to the presence of liquid nitrogen, or instructions on what to do if the low oxygen alarm sounds (recommendation 1);
- a number of fire extinguishers at the centre were due to be serviced in February 2015 (recommendation 6);
- the external clinical waste bins are stored by an entrance to the hospital and are not secured in line with the HTM 07-01 Safe Management of Healthcare Waste regulation. The large bins lids were down however, the lids were not secured or locked (recommendation 4).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection and the variation of licence inspection in 2015, recommendations for improvement were made in relation to three major and one 'other' area of non compliance and three major and one 'other' area of non compliance respectively.

However non compliance with medicines management requirements has since re-occurred (see recommendation 3).

On-going monitoring of centre success rates

The centre has received two risk tool alerts in the last year related to the provision of ICSI treatment with fresh embryos in women under 38 years.

The PR has responded appropriately, providing evidence and information that the issue is being monitored and addressed.

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.

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

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Safety of Premises There is an additional store cupboard outside of the licensed premises, in a main corridor within the hospital. This is used as a store room for other hospital staff too. This doesn't contain any licensed material, but two of the centre's liquid nitrogen tanks are stored there. Safety signs are on the door but	Since the inspection visit, the PR has provided evidence that appropriate safety procedures have been implemented to mitigate immediate risk. Hospital staff accessing the store cupboard only do so when wearing a personal low oxygen alarm.	The store cupboard is locked with a keypad. Access to the cupboard is restricted to ACU staff. Our signage was strengthened on 27th March (date of inspection).	The Executive acknowledges the PR's response and actions taken to ensure the safety of premises. The PR should provide an update to the centre's inspector regarding installation of a permanent low oxygen alarm in the store cupboard by 16 September 2018.

there is no low oxygen alarm present. The hospital estates department has been asked to install an alarm, but this has not yet taken place. Dewar's of liquid nitrogen containing gametes and embryos are stored in the laboratory. A low oxygen alarm is in place; however there are no safety signs on the doors to the laboratory alerting staff to the presence of liquid nitrogen, or instructions on what to do if the low oxygen alarm sounds. SLC T17.	The PR should ensure appropriate action is taken to ensure the Dewar's containing liquid nitrogen stored outside of the centre's premises, have the necessary low oxygen alarms fitted. The PR is to keep the centre's inspector informed in relation to any progress made when responding to this report. Since the inspection visit, the PR has provided evidence that appropriate safety signs and instructions are now in place on the door to the laboratory. No further action is required.	All staff with access to the store wear a personal low Oxygen alarm. Already actioned.	

‘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
2. Quality Management System For the audits that were reviewed, it was noted that: • it was not clear if the centre is measuring against their own QIs and if the QIs are being met. • where non conformities were identified in the centre’s audits, it was not always clear if corrective action had been implemented SLC T35 and T36.	The PR should review the centre’s audit processes to ensure that they are effective. A summary of the review and any changes implemented as a result should be provided to the centre’s inspector when responding to this report. The PR should review the findings of audits performed since the last inspection to ensure that any corrective actions have been fully implemented. Confirmation that this action has been taken	Audit processes have been examined. QI s had been identified and measured. A new audit template has been introduced to incorporate this suggestion. This has strengthened the audit record by specifying the KPI / QI under review. In addition corrective actions to be taken have been incorporated into the document. Previously these had been summarised and learning disseminated and minuted within the weekly DMT.	The Executive acknowledges the PR’s response. The PR should review the findings of audits performed since the last inspection to ensure that any corrective actions have been fully implemented. Confirmation that this action has been taken should be provided to the centre’s inspector by 27 September 2018. Further action required.

This non compliance is similar in part to the non compliance sited in the previous inspection; The centre has not established QI's for the following activities: • consent • welfare of the child.	should be provided to the centre's inspector by 27 September 2018.	These actions are now ratified within a specific section of audit template which includes the date of the DMT where presentation occurs. The learning is still recorded within the MDT minutes. All audit recommendations to date have already been documented. QI s for consent and welfare of the child (KP!03 and KPI105) are also complete.	
3. Medicines Management There was a number of areas within the controlled drugs book located in main theatres where: • Some documentation and signatory areas within the controlled drugs book were left blank. In one instance the medication administrator had not signed the controlled drugs book to document their supply, administration and discarding of the drug before, during or after the procedure;	The PR should ensure that theatre staff are working in line with the Misuse of Drugs Regulation 2001. The PR should ensure processes are reviewed in theatre and corrective actions implemented. A summary of the findings should be sent to the centre's inspector by 27 July 2018. Three months after implementing corrective actions, the PR should audit its effectiveness. A summary report of this audit should be	Theatre and Anaesthesia within the Trust are managed by the Division of Surgery, Anaesthesia & Critical care. Person Responsible has met with the Clinical Director for Surgical services. During every theatre procedure the WHO theatre checklist is used At entrance to theatre, prior to commencing surgery and at sign out of theatre. Patients cannot leave theatre without the sign out being complete. In order to ensure completion of the CD book this check will now be added	The Executive acknowledges the PR's response and commitment to resolving this non compliance. A summary report of the follow up audit should be provided to the centre's inspector by 27 September 2018. Further action is required.

• There was no documented times in the controlled drugs book to indicate when medicines were supplied, administered/given or discarded by medical personal; • The disposal column was not routinely signed by staff witnessing the disposal of the controlled drugs partly due to some staff members not actually witnessing the disposal. SLC T2. The Misuse of Drugs Regulations 2001 20(c). This non compliance is similar, in part, to a non compliance cited in the centre's last renewal inspection report.	provided to the centre's inspector by 27 September 2018.	to the WHO sign out check. The WHO check is then stored securely in the patients notes. This will serve as an extra reminder to anaesthetists and ODPs within the theatre. Executive approval from the Trusts Medical Directors has also been sought and amended WHO forms will be presented at the first Anaesthetic Quality and Audit meeting following their publication. With these actions being Trust wide and therefore needing to be embedded into a total of 15 theatres this will take some time. As such having been inspected on the 27th March and receiving this report on the 29th May, the PR undertakes to provide a summary report of a controlled drugs audit for IVF patients 3 months after the Trustwide implementation. In the meantime we have implemented this check onto our egg collection sign out sheet and will audit the CD	

		book for our patients in 3 months time. September 2018 Following the non compliance in a previous inspection, the PR contacted the Trust Executive Officer with responsibility for controlled drugs, the Trusts Lead Pharmacist and the Clinical Director for Surgery and Anaesthesia. This resulted in the introduction of a completely new Controlled Drug book being used in all the theatre areas within the Trust. This new book has a separate column to record any unused drug and its disposal.	
4. Premises and facilities. The external clinical waste bins were stored in a patient accessible area. The lids were down however, the lids were not secured or locked. HTM 07-01 Safe Management of Healthcare Waste.	The PR should ensure that the clinical waste bins are adequately stored to eliminate any risk or access by the public. The PR should ensure that the waste bins are securely locked after each use.	Following the visit the cleaning management team were contacted by the unit Quality Manager and the bins immediately locked. Cleaning staff have access to keys and are instructed to lock bins. The 3 waste bins are used by the entire Womens' Health	The Executive acknowledges the new measures the centre has put in place. No further action required.

SLC T2.	The PR should forward a summary of any actions undertaken in line with the regulation given, when responding to this report.	dept and located outside the Womens' Health Block. The Quality Manager has bimonthly walk-abouts with the cleaning supervisor for Womens Health and a bin check has been incorporated into this review. In addition the cleaning supervisor has added a weekly bin check to their schedule. We now also have our own key and can ensure bins are locked.	

‘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
5. Storage consent The consent for one set of stored sperm samples has not been accurately completed. These samples were originally stored in 2003 at the Wolfson Fertility Centre - Hammersmith hospital (centre 0078). Half of the patient’s samples were transferred to centre 0259 in 2017. Prior to the transfer to centre 0259, the patient completed a new LGS consent form to extend the storage period in 2016. The LGS consent has a section to be completed by clinic staff – to record both the date gametes were placed in storage and the date gametes can remain in storage until. The date that the gametes can remain in storage until had been incorrectly	The PR should ensure that appropriate consent is in place prior to the storage of any gametes or embryos, including where material is transferred from another centre. The PR should undertake a review of the centre’s processes for reviewing consent prior to storage of material transferred from elsewhere. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector by 27 May 2018. The PR should also ensure that the consent history for this	With the interim report d being sent to the PR on the 29th of May providing a response by the 27th of May is unachievable however the new form will be completed on the 15th of June at the patients appointment The patient samples were frozen and stored at Hammersmith and the LGS and Medical Practitioner Statement was completed by the Consultant in charge. St Helier staff cannot be responsible for the forms completed by another unit and it appeared the appropriate forms had been signed for legal storage. When the forms were sent it was noted that the signatures	The Executive acknowledges the PR’s response and apologises for the error in giving an unachievable date to respond by. The PR has provided evidence that the patient has now attended the clinic and completed a new LGS consent form. The Executive notes the PR’s response that suggests that if current storage consent forms are valid, any historical issues are not relevant. The Executive considers that this is not the case, since the validity of a current storage consent can only be determined if the full records of consent are present. Furthermore, General Direction 0007, para 2 clearly states:

recorded and related to the day and month of signing of the consent form, rather than the date the samples were frozen. This could be misleading or confusing for the patient. The clinician who completed the accompanying medical practitioner statement has also signed the section of the LGS form that is only for use where the form is completed by someone other than the patient, where the patient is unable to sign for themselves due to physical illness, injury or disability. This was not the case with this patient. The inspection team was concerned that using the patient's consent form in this way is not appropriate and that staff may not fully understand the purpose of this section. It is acknowledged that this consent was completed at another centre. Previous consent forms, to allow for the lawful storage of the samples up until the completion of the new LGS consent form in 2016, were not available for review on this inspection.	patient is reviewed to ensure that there are no gaps and to therefore ensure that effective consent to store is in place. The PR should inform the executive of steps taken when responding to this report.	were not the same as current versions and due to some corrections it was not as neat as we would normally accept. The patient re- signed them in the presence of the embryologist to ensure that it was clear they were his forms and resigned his MT form as normal practice. It was noted on the LGS form that due to the corrections done in 2016 by Hammersmith staff it was a bit messy and needed correction so a blank LGS form was left for the patient to complete when he next attended the unit. It had not been completed at the time of the inspection and has now been placed in the front of the notes for the patients next clinic appointment which is on 15th June 2018. As lawful storage periods have been changed since the patient froze his samples in 2003 to allow for 55 years, the new regulation and guidance supersedes the old. It is reasonable to assume new	'Where the storage period of a person's gametes or embryos has been extended, in accordance with the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, the Person Responsible of the licensed centres at which those gametes or embryos are stored must maintain a record of evidence that the conditions for extended storage of those gametes or embryos have been fulfilled.' In cases where there has been a previous gap in consent or where there has been a failure to ensure that the requirements for the extension of the statutory storage period have been fulfilled, it is not clear whether the period of unlawful storage renders any further storage or use in treatment legally permissible. This is despite any retrospective actions to document consent or to comply with the relevant regulations.

Schedule 3 of the HF&E Act 1990 (as amended) and SLC T42, T57 and General Direction 0007. Consideration was given to this non compliance as being an 'other' as it was considered that the errors on the consent form did not significantly undermine the consent given.		forms supersede the old which were due to expire in 2013. St Helier cannot comment about the time period between 2013 (first 10 years expiry) and 2016. This storage cover was monitored by Hammersmith and St Helier was not sent the forms leading up to the completion of the LGS in 2016. It is not appropriate for the PR to follow another centres storage. It is fortunate that the patient is alive and can complete new forms which can give clarity. However, it is not the centres responsibility to inform a patient that there is a possibility his samples may not have been legally stored over 10 years ago when all his current forms show valid consent. The processes for reviewing consent have been reviewed and a current checklist which is completed by 2 staff , has been added to so that if any form is found to be out of range it can be left for follow up in the lab until it is cleared.	The Executive recommends that the PR reconsiders the centre's processes to ensure that prior to accepting gametes/embryos into storage, a full review of storage consent from the date of initial storage is performed. This is to ensure that the centre does not unintentionally store or use material where it is potentially not legal to do so. The Executive recognises that this is a complex area and the centre's inspector will liaise with the PR outside of this inspection process. Further action required.

		An audit of all imported samples was undertaken. No other issues were found with consent for samples, other than those addressed and resolved with the other centres prior to transfer.	
6. Premises and Facilities A number of fire extinguishers throughout the centre were due for a service in February 2015. Servicing of fire extinguishers should be carried out once a year in line with the standards BS 5306-3:2009. SLC T17.	The PR should ensure that the fire extinguishers within the centre are serviced with immediate effect and at appropriate intervals thereafter. Confirmation that this has been completed should be provided to the centre's inspector by 27 June 2018.	The Trust estates team was contacted immediately following the visit. On the 4th of April 2018 the Fire Extinguishers were changed. These are listed on the Trusts annual fire risk assessment. In addition the IVF Unit's Fire Warden has been tasked with a monthly check and documentation on a spreadsheet. She will then also prompt the Hospitals' Senior Fire Officer 2 months prior to extinguisher check/expiry date.	The Executive acknowledges the PR's response. No further action required.

Additional information from the Person Responsible
We were pleased to welcome the inspection team on the 27th of March 2018. Whilst our inspector did inform us that the report was likely to be delayed beyond the advised 20 working days, we were a little surprised to receive it 41 working days after the visit. I understand this maybe due to IT issues but it is obviously disappointing. We accept ownership of the points made in the inspection and are working hard with our colleagues within other departments of Epsom & St Helier NHS University Trust to rectify the issues.