Executive Licensing Panel - minutes

Centre 0105 (London Women's Clinic) Interim Inspection Report

Friday, 15 January 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) David Moysen Hannah Verdin	Director of Strategy & Corporate Affairs Head of IT Head of Regulatory Policy
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Anjeli Kara	Regulatory Policy 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 noted that the London Women's Clinic, centre 0105, is part of a nationwide group of centres and has several satellite centres. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.

1.2. The panel noted that centre 0105 currently has an additional condition on its licence. The condition is to suspend the centre using donor sperm following a grade 'A' incident in 2012 (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010.

1.3. The panel noted that the centre's licence is due to expire on 28 February 2018.

1.4. The panel noted that the inspection took place on 27 October 2015.

1.5. The panel noted that in the 12 months to 30 September 2015, the centre provided 2581 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.6. The panel noted that for IVF and ICSI, HFEA-held register data for the period July 2014 to June 2015 showed the centre's success rates were in line with national averages with the following exceptions:

- clinical pregnancy rates following frozen embryo transfer (FET) in patients aged less than 40 years are above average at a statistically significant level.

1.7. The panel noted that in 2014, the centre reported 42 cycles of partner insemination with seven pregnancies, one of which was a twin pregnancy. This was consistent with the national average.

1.8. Between July 2014 and June 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 17%. This means that the centre's multiple live birth rate is likely to meet the 10% maximum multiple live birth rate target.

1.9. The panel noted that at the time of the interim inspection on 27 October 2015, one critical, five major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has started to address the non-compliances and has committed to fully implementing all of the outstanding recommendations within the prescribed timescales.

1.10. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

2.1. The panel noted the non-compliances, in particular the critical area of non-compliance. The panel agreed that, given the nature and number of non-compliances and the fact that a number of recommendations were due to be implemented on 27 January 2016, it would defer its decision for the continuation of the centre's treatment (including embryo testing) and storage licence, until such time after this date, when an update report on the centre's progress can be provided for the Executive Licensing Panel to consider.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

25 January 2016

Interim Licensing Report

Centre name: London Women's Clinic
Centre number: 0105
Date licence issued: 01/03/2014
Licence expiry date: 28/02/2018

Additional conditions applied to this licence:
The following additional condition applies to this licence and was agreed by the Licence Committee granting the licence: to suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.

Date of inspection: 27/10/2015
Inspectors: Louise Winstone (lead), Grace Lyndon and Janet Kirkland MacHattie
Date of Executive Licensing Panel: 15/01/2016

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 2015-2017 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

The inspection team recommends the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to one critical, five major and two 'other' areas of non compliance or poor practice.

In responding to the report the PR has provided assurance that the following recommendation has been implemented.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre's egg donor bank social media advertising is compliant with guidance.

Since the inspection the PR has given a commitment to fully implement all the following recommendations within the prescribed timescales.

'Critical' areas of non compliance:

- **The PR should take immediate action to ensure that medical gases are stored appropriately.**

'Major' areas of non compliance:

- The PR should ensure that CE marked medical devices are used wherever possible.
- The PR should ensure compliance with medicines management regulations and ensure that record keeping in relation to controlled drugs is legible and complete.
- The PR should take action to ensure that the clinical environment meets infection prevention and control requirements.
- The PR should ensure that audits assess compliance with regulatory requirements and should review barriers to implementing learning from guidance provided by the HFEA and other sources.
- The PR should ensure that daily checks of the anaesthetic equipment, resuscitation trolley and oxygen cylinders are carried out and documented.

'Other' areas of non compliance:

- The PR should ensure that the gamete and embryo storage database is completed accurately.

Information about the centre

The London Women's Clinic (LWC) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services to self funded patients. LWC is part of a nationwide group of centres and has several satellite centres.

The centre provided 2581 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2015. In relation to activity levels this is a large centre.

Licensing history

The centre's current licence was varied in July 2014 to reflect a change of premises.

Following a grade 'A' incident in 2012 the additional condition as previously described was imposed on the centre's licence and remains in place.

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 July 2014-June 2015 show the centre's success rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following FET in patients aged less than 40 years are above average at a statistically significant level.

In 2014, the centre reported 42 cycles of partner insemination with seven pregnancies, one of which was a twin pregnancy. This is consistent with the national average.

Multiple births[2]

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

Between July 2014 and June 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This means that the centre's multiple live birth rate is likely to meet the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: egg collection. The procedure observed was witnessed using an electronic witnessing system in accordance 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, the audit reports of stored gametes and embryos were reviewed and the 'bring-forward' system was discussed with staff. While these audits indicated that gametes and embryos are being stored within their consented storage period, a review of the gamete and embryo storage database revealed several errors in the date of storage expiry recorded in the system. In some instances, the date embryos were placed into storage had been entered instead of the storage expiry date, in others the storage expiry date was absent or a question mark was noted. Further discussion provided assurance that all gametes and embryos are currently being stored within the terms of the gamete providers consent. However, the inspection team is concerned that these errors could lead to storage expiry dates being missed during the centre's monthly review of the 'bring forward' system and therefore the centre's system for monitoring storage consent is not robust (see recommendation 8).

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: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed 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, infection control and the management of controlled drugs.

It is noted that the centre's own audits did not identify areas of non compliance observed on inspection in the following areas:

- the consent to storage audit did not identify the deficiencies in the centre's 'bring forward' system;
- the management of controlled drugs audit failed to identify non compliance with regulatory requirements;
- the centre's infection control audit failed to identify areas of poor practice.

On this basis it is concluded that the centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements (see recommendation 5).

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 centre's audits of witnessing, consent to storage, infection control and controlled drugs;
- the use of CE marked medical devices;
- the content of the centre's websites;
- the use of the most recently issued versions of HFEA consent forms;
- the centre's audit of legal parenthood;
- HFEA Clinic Focus articles regarding: screening requirements and equipment failures.

The centre had failed to implement the following guidance:

- guidance issued in 2013 clarifying that only CE marked medical devices should be used (see below and recommendation 2);
- the centre's egg donor bank social media advertising is not compliant with guidance issued in the current HFEA Code of Practice (CoP 13.1) in that the advertisement refers to financial gain (see recommendation 7).

In consideration of the above it can be concluded that some improvement is required in order for the centre to have a fully effective learning culture (see recommendation 5).

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 centre's processes were reviewed for medicines management and the safe storage, disposal and administration of medicines and were considered partially compliant with guidance.

A number of non–compliant practices were observed relating to the management of controlled drugs (see recommendation 3):

- the disposal of any unused portion of a controlled drug drawn up but not administered is not routinely witnessed or documented;
- the time a controlled drug is administered is not routinely recorded;
- patient names recorded in the controlled drugs register are in some instances unclear or illegible. Patient record numbers are not recorded in the controlled drugs register therefore the patient cannot be reliably identified.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

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

A number of non-compliant or poor practices were observed relating to infection prevention and control (see recommendation 4):

- clinical waste, including used sharps bins awaiting collection is stored in a large holding container outside the centre. This container was seen to be overfull and was not locked. This area may be accessible to the public;
- the flooring in some of the clinical areas is not sealed and meets directly with the skirting and at corners creating sharp angles which are difficult to clean;
- hand washing sinks in some of the clinical areas do not have hands free taps;
- some of the chairs in use in clinical areas are not 'wipe clean';
- where disposable privacy curtains are used in the clinical areas, the date on which they had been put up is not consistently recorded. Staff could not confirm when the curtains had been changed. This could present an infection risk;
- there is no documented, monitored cleaning schedule for any of the clinical rooms.

It is however acknowledged that the centre has reported no incidence of infection.

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 all consumables and reagents was reviewed in the course of the inspection. The centre is partially compliant with HFEA requirements to use CE marked medical devices wherever possible. The following medical devices in use are not CE marked: 1ml syringes, 10ml pipettes and vitrification warming solution (see recommendation 2).

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre, however 20 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with seven of the individuals providing written feedback giving compliments and 10 individuals having complaints about the care received.

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

- 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.

The importance of seeking and acting on patient feedback and the negative comments received from the 10 individuals was discussed with the PR during the inspection. She advised the inspection team that the centre's patient coordinator contacts all patients after their initial consultation and then two weeks following treatment to seek feedback on their experience. The responses received following the centre's most recent patient feedback survey were reviewed on inspection. The inspection team is satisfied that the centre is

actively seeking patient feedback and acting upon it, therefore no recommendations are considered necessary at this time. The inspection team urges the centre to continue to monitor patient feedback.

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

From observations during the visit to the centre, the inspection team identified the following non compliances: medical gas cylinders and other supplies not in immediate use are stored in a small, below pavement level vault which is part of, but external to the main building. This area was considered to be overcrowded and unsafe for the following reasons:

- 52 medical gas cylinders were stored in this area, many of which were not secured and at risk of being knocked or toppling;
- proper access to the medical gas cylinders stored in this area was limited by the storage of consumables and cardboard boxes;
- the light fitting was exposed and loose wires were hanging;
- this area is not ventilated and there was no hazard or safety signage to provide an alert to the presence of medical gases;
- there is no fire or intruder alarm installed in this area;
- a large metal cabinet adjacent to the storage vault contains a liquid nitrogen storage tank. This cabinet was unlocked and there was no hazard or safety signage;
- although below street level this area is potentially accessible to the public from street level.

Such was the concern of the inspection team that the PR was required to take immediate remedial action to improve health and safety precautions in this area (see recommendation 1).

Observations in other areas showed the following areas of non compliance or poor practice:

- oxygen cylinders in the ultrasound scan room and IUI treatment room had not been checked and were found to be empty;
- anaesthetic equipment and resuscitation equipment on the emergency trolley had not been checked prior to use on the day of inspection (see recommendation 6).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in October 2013, recommendations for improvement were made in relation to two major and eighteen 'other' areas of non compliance.

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 renewal inspection in October 2013 the centre has received no risk tool alerts relating to performance.

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.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order 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 provided the report of the audit to the HFEA within the required timeframe.

On inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

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 carried out.

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 area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Storage of medical gases: The storage vault containing medical gases was cluttered and overcrowded, cylinders were not being stored securely and the light fitting had exposed wiring. The area was considered at the time of inspection to be unsafe. British Compressed Gases Association (BCGA) guidance note 2 guidance for the storage of gas cylinders in the workplace	Following the inspection, the PR took action to address the immediate safety issues identified. All flammable and non-essential items have been removed from the store. The wiring to the light has been repaired and an appropriate cover fitted. The PR should assess the risk of storing medical gases in this area with specific reference to BCGA and British Oxygen	A full risk assessment, will be completed by BOC on the 7th December and followed up by them on the 14th December. Following BOC input a plan of action will be provided to the HFEA as soon as available. An investigation into the circumstances which led to these risks and corrective actions will be provided to the	The inspector acknowledges the PR's response and awaits the outcome of the risk assessments and reports by 27th January 2016. Further action is required.

revision 5: 2012. BCGA guidance note 23 Identifying gas safety training requirements in the workplace 2012. The metal cabinet which contains a liquid nitrogen storage tank was unlocked.	Corporation (BOC) guidance. The PR has requested an independent assessment of the area by a BOC representative and this date has now been confirmed by the PR as 7 and 14 December 2015. The outcome of this assessment and an action plan with time scales for implementation of corrective actions should be provided to the centre's inspector as soon as they are available but not later than 27 January 2016. In consideration of the significant health and safety risks this non compliance posed, the PR is encouraged to seek learning from this and conduct an investigation into the circumstances which led to these risks only being identified by the inspection team. The PR should provide the outcome of this investigation and details of any corrective actions required to	HFEA by the 27th January 2016. A report detailing the level of existing and where necessary further training for staff in the storage and management of medical gases will be provided to the HFEA by the 27th of January 2016. The Facilities Co-Ordinator has been tasked to find a suitable training course to be attended on site by all relevant staff. The metal cabinet housing the liquid nitrogen cylinder is secure and locked at all times. The filling of the tank can be achieved without unlocking the cabinet.	

	the centre's inspector by 27 January 2016. The PR should provide detail of the level to which staff managing or working in this area have been trained in the storage and management of medical gases when responding to this report. The PR should consider referring to BCGA guidance note 23 when assessing further gas safety training requirements for staff. Since the inspection the PR has provided assurance that the metal cabinet housing the liquid nitrogen tank is secured when not in use by a combination lock.		

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. CE marking: The following medical devices used by the centre are not CE marked: 1ml syringes, 10ml pipettes and vitrification warming solution. SLC T30	The PR should ensure that CE marked medical devices are used where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. When responding to this report, the PR should confirm when the equipment/materials identified in this report will be either replaced with a suitable alternative, or the current products will obtain the appropriate certification. It is expected that suitable products will be in place by 27 April 2016.	The clinical team will review the consumables in use at the present and determine whether a suitable replacement is available and the extent to which this may have an impact on the quality of treatment provided to our patients. A report will be provided to the HFEA by the 27th April 2016. A report to the MHRA has been submitted and we await a response.	The inspector acknowledges the PR’s response and her commitment to fully implementing this recommendation. The PR is asked to provide details of when the equipment/materials identified in this report will be CE marked by 27 January 2016. Further action is required.

	It is unlawful for manufacturer's to make non CE marked medical devices available for human application and in consideration of this, the PR should also submit a notice to the MHRA in accordance with guidance issued in the April 2013 HFEA Clinic Focus article and notify the centre's inspector when this has been done.		
3. Medicines Management: The waste portion of any controlled drug drawn up but not administered is not routinely witnessed or documented in the controlled drugs register. Misuse of Drugs Regulation 2001, schedule 27. The time controlled drugs are administrated is not routinely recorded. Patient names recorded in the controlled drugs register are in places unclear or illegible. The patient's record number is not included meaning that the patient may not be reliably	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should conduct a review of the centre's controlled drugs management procedures to ensure that proper records are kept and that entries into the controlled drugs register are legible and complete. By 27 January 2016, the PR should inform the centre's inspector of the outcome of this review and actions taken to ensure this learning has been communicated to staff and acted upon. Within three months the centre	A summary report of a review of the clinics controlled drugs management procedure, outcome and any CAPA will be provided to the HFEA by the 27th of January 2016. An audit of the CAPA will be conducted 3 months after the initiation of any changes. A summary report will be provided to the HFEA by the 27th of April 2016. The CD book is now completed with the use of typed labels documenting patient details. All columns are now completed.	The inspector acknowledges the PR's response. Further action is required.

identified.	should conduct an audit of their controlled drugs procedures to ensure that any corrective actions have been effective. A summary report of the audit detailing the findings and any further corrective actions and the timescale for their implementation should be provided to the centre's inspector by 27 April 2016.	This will again be discussed with the nursing team on the 10th December 2015.	
4. Infection Control: The clinical waste bins stored outside the centre were overflowing and were not locked. The flooring in some of the clinical areas is not sealed and meets directly with the skirting and at corners creating sharp angles which are difficult to clean. Health building note 00-09: infection control in the built environment (pg20) SLC T17. The hand washing facilities in some of the clinical areas do not have hands free taps.	The PR should conduct a review of infection prevention and control practices to ensure that the clinical environment adheres to regulations and best practice guidance. The outcome of these assessments and details of any action subsequently taken should be provided to the centre's inspector by 27 January 2016. The PR should assess the management of clinical waste and ensure that the clinical waste bins located outside the centre are secured. The centre's inspector must be informed of the actions taken when responding to this report.	All clinical waste bins are now kept locked. A review and assessment outcome of infection control prevention and control practice will be conducted and provided to the HFEA by 27th January 2016. The clinical areas requiring improved flooring have been identified and added to the refurbishment schedule to be carried out in the New Year. An assessment of the management of clinical waste bins has been	The inspector acknowledges the PR's response. Further action is required.

Some of the chairs used in clinical areas are not 'wipe clean'. Where disposable privacy curtains are used the date on which they had been put up is not consistently recorded. Staff could not confirm when these were changed. This could present an infection risk. There was no cleaning schedule to any of the rooms. SLC T2, T17 and T23		carried out. All staff will be advised as to the true definition of clinical waste to ensure appropriate disposal of rubbish. A training session has been scheduled by the Facilities Co-Ordinator together with Initial Waste Management. Retraining of the housekeeping staff has been completed in the use and locking/secure of the clinical waste bins. As discussed at the time of the inspection there is a refurbishment programme in place to be completed by January 2016 which will include the installation of hands free taps. An across centre infection control network has been set up, for joint meetings and shared learning between all JDH centres.	

		Staff have been reminded of the need to accurately label disposable privacy curtains with the date of installation. Regular audits will be made and documented. There is already a cleaning schedule for the relevant clinical rooms. However this was not on display at the time of inspection. These will now be displayed.	
5. Quality Management system: The centre's own audit practices failed to identify significant areas of non compliance or poor practice as identified during this inspection and described in the body of the report. The centre has not fully implemented guidance issued by the HFEA in Clinic focus April 2013 clarifying that only CE marked medical devices should be used, and requiring centres to source alternatives	The PR should conduct a review of the centre's quality management and audit process to ensure that audits are performed against regulatory requirements and corrective actions are documented and reviewed for effectiveness. The outcome of the review and an action plan with timescales for the implementation of any changes should be provided to the centre's inspector by 27 January 2016. The PR should review the process for disseminating information within the team to identify where there are barriers to the implementation	The Audit Schedule and CAPA logging will be refined to ensure that staff recognise the outcomes and actions required following audit. All staff will be re-inducted as to the NCD and CAPA system. The guidance from the HFEA is disseminated via departmental meetings, operational meetings and PR emails. This will be	The inspector acknowledges the PR's response. Further action is required.

to any non CE marked devices. Also the PR had failed to ensure that the centre's egg donor bank social media advertising is compliant with CoP Guidance 13.1. SLC T32	of learning from guidance provided by the HFEA and/or other sources. The PR should provide a summary of the review and detail of any actions taken in response to the centre's inspector by 27 January 2016.	reinforced. The issue with CE marking has been responded to in recommendation 2. The PR corrected the centre's administrative error on the egg bank social media and reported it to the inspectors at the time of inspection.	
6. Emergency equipment: The anaesthetic equipment and resuscitation trolley had not been checked prior to use on the day of inspection. The two oxygen cylinders in the clinical areas had not been checked and were empty. SLC T2	The PR should ensure that all equipment, especially that which relates to patient safety and emergency equipment is demonstrably fit for use. Given that the cylinders had not been used or checked for some time the PR should review the requirement for oxygen to be immediately available in the IUI treatment room and ultrasound scan room and assess any associated risk of not having this oxygen in these rooms. The outcome of that review and detail of any actions resulting should be provided to the centre's inspector when responding to this report.	The anaesthetic equipment and resuscitation trolley is inspected on a daily basis. However on the day of inspection the relevant members of staff had not signed the register. Staff have been reminded to document their checking measures. A summary of an audit of these checks will be provided to the HFEA on the 27th of January 2016.	The inspector acknowledges the PR's response. Further action is required.

	The PR should ensure that daily checks of the anaesthetic equipment, resuscitation trolley and oxygen cylinders are carried out and documented when the centre is operational. Within 3 months of the implementation of the corrective action, the centre should audit these checks and their documentation to ensure effectiveness. A summary of the audit should be sent to the centre's inspector by 27 January 2016.		

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
7. Website: The centre’s egg donor bank social media advertising is not compliant with CoP Guidance 13.1.	The PR should audit the centre’s egg donor bank social media advertising against regulatory requirements. Any changes required to ensure compliance should be made promptly. A summary of changes should be provided to the centre’s inspector by 27 January 2016.	This has been addressed above in recommendation 5. The PR corrected the centre's administrative error on the egg bank social media and reported it to the inspectors at the time of inspection. The link to the corrected site has been provided.	The inspector acknowledges the PR’s response and commitment to ensuring that this non compliance has now been addressed. No further action is required.
8. Gamete and embryo storage database: The inspection team had concerns that the centre’s bring forward system was not sufficiently robust to ensure that no material remains in storage past its consented period. For example, the date of embryo storage was not completed accurately in the embryo storage database or had not	The PR should ensure that gametes and embryos are only stored in accordance with the gamete provider’s consent. In order to determine the accuracy of the storage consent information recorded in the centre’s ‘bring forward’ database, the PR should audit the database against patient / donor primary records. A summary report of the findings		Verbal assurance has been given by the PR to ensure that this non compliance will be addressed. The inspector awaits the outcome of the audits. Further action is required.

been filled in. CoP Guidance 17.17.	of the review including corrective actions and the timescale for implementation of corrective actions should be submitted to the centre's inspector by 27 January 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. A summary of the audit should be provided to the centre's inspector by 27 April 2016.		

Additional information from the Person Responsible