Executive Licensing Panel - minutes

Centre 0201 (Edinburgh Assisted Conception Unit) – Interim Inspection Report

Friday, 13 November 2015

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

Panel members	Juliet Tizzard (Chair) Paula Robinson Howard Ryan	Director of Strategy & Corporate Affairs Head of Business Planning Technical Report Developer
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Jessica Watkin Anjeli Kara	Policy Manager 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 Edinburgh Assisted Conception Unit, centre 0201, 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 the centre's licence is due to expire on 28 February 2018.

1.3. The panel noted that the inspection took place on 10 September 2015.

1.4. The panel noted that in the 12 months to 31 July 2015, the centre provided 921 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that HFEA-held register data for the year ending 30 April 2015 showed the centre's clinical pregnancy rate for IVF and ICSI was in line with national averages.

1.6. The panel noted that HFEA-held register data for the year ending 30 April 2015 showed the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 8%. This represented performance that is in line with the 10% maximum multiple live birth rate target for this period.

1.7. The panel noted that for the year 2014, the centre reported 11 cycles of partner insemination with one pregnancy. This was consistent with the national average.

1.8. The panel noted that at the time of the interim inspection on 10 September 2015, a large number of non-compliances were identified, including one critical, four major and two other areas of non-compliance. The panel also noted that the PR has committed to fully implementing all of the recommendations made by the inspectorate within the prescribed timescales.

1.9. The panel noted that there were positive comments made by patients.

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 had regard to its decision tree. Given the number and nature of the non-compliances, the panel discussed whether it had serious concerns about the operation of the centre. The panel noted, however, that since the inspection the Person Responsible (PR) has engaged with the inspectorate and started to address the non-compliances. The Panel was satisfied that the centre was fit to have its treatment and storage licence continued.

2.2. The panel urged the centre to continue to address the non-compliances within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

25 November 2015

Interim Licensing Report

Centre name: Edinburgh Assisted Conception Unit
Centre number: 0201
Date licence issued: 1 March 2014
Licence expiry date: 28 February 2018
Additional conditions applied to this licence: None
Date of inspection: 10 September 2015
Inspectors: Karen Conyers (lead), Susan Jolliffe, Grace Lyndon
Date of Executive Licensing Panel: 13 November 2015

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. In particular we note the positive comments made by patients.

The ELP is asked to note that there are seven recommendations for improvement in relation to one critical, four 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 review whether there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources.

The PR has also given a commitment to fully implementing the following recommendations in the prescribed timescales.

'Critical' area of non compliance:

- **The PR should ensure that incidents are fully investigated in a reasonable timescale.**

'Major' areas of non compliance:

- The PR should ensure that all activities and processes are audited against regulatory requirements.
- The PR should ensure compliance with medicines' management regulations.
- The PR should ensure that CE marked medical devices are used wherever possible.
- The PR should ensure that the centre's website is compliant with requirements.

'Other' areas of practice that require improvement:

- The PR should ensure that all records are stored in areas where access is secure at all times.

Information about the centre

The Edinburgh Assisted Conception Unit is also known as Edinburgh Fertility and Reproductive Endocrinology Centre (EFREC) and is located at the Edinburgh Royal Infirmary. The centre has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing.

The centre provided 921 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2015. In relation to activity levels this is a medium centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes as they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending 30 April 2015 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2014 the centre reported 11 cycles of partner insemination with one pregnancy. This is consistent with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 30 April 2015 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is in line with the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The witnessing practices involved during the thawing of an embryo were observed during the inspection and centre staff were able to describe the witnessing steps undertaken during other procedures (egg collection, sperm sample receipt, insemination, embryo transfer). All of the procedures observed and/or described are witnessed using a manual witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics as 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

[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

[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 10% MLBR target is calculated as equivalent to a MCPR of 13%.

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.

During the inspection, reports of audits of all stored gametes and embryos, the systems used to manage stored samples, consent records and the 'bring-forward' system were reviewed and 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.

At the time of the renewal inspection a large number of cryopreserved sperm samples were identified as being in storage without consent. Following that inspection the consultant embryologist undertook a complete audit of samples, a thorough review of records (circa 900 patients) and the resulting corrective actions have ensured that all samples currently in storage are being stored in accordance with the gamete provider's consent, with the exception of one sperm sample. The gamete provider had requested the discard of his samples and whilst undertaking this disposal the straw was inadvertently lost in the bottom of the tank. The HFEA was advised of this incident and no further action was recommended as the sample cannot be retrieved without emptying the vessel which would compromise all other samples in storage. The gamete provider had been informed of the incident and the actions taken.

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 clinical and laboratory 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.

The centre's quality manager had left the post two weeks earlier and the centre was in the initial stages of recruitment for a replacement.

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 several documents and the following audits of witnessing records and consent to storage. The inspection team considered that the centre's audit practices are partially compliant with requirements, for the following reasons.

- The centre's audits do not include a review of activities and processes against regulatory requirements (see recommendation 2).
- The centre provided an audit of controlled drugs that did not meet the regulatory requirements; the audit was performed by the pharmacy department and was

essentially a review of stock control, not the centre's medicines management practices (see recommendation 3).

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 records and storage records.
- 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.
- the HFEA's reports of adverse incidents from 2010-2012 and 2013.
- the HFEA's Clinic Focus articles.

The centre had failed to implement guidance issued in 2013 clarifying that only CE marked medical devices should be used and requiring centres to source alternatives to any non CE marked devices, or to ensure that the centre's website is compliant with guidance issued in Chair's letter CH(11)02 (see below and recommendations 4 and 5).The centre is therefore only partially effective in implementing learning from their audits and/or guidance provided by the HFEA (see recommendation 6).

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 for the following reason.

- The centre does not record alterations in the controlled drugs register in line with the requirements of the Misuse of Drugs Regulations 2001, schedule 20(c). The inspection team noted 16 separate alterations in the controlled drugs register since 1 June 2015, some of which were not legible and none had been marked with an asterisk or footnote as required (see recommendation 3).

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 the following medical devices was reviewed in the course of the inspection: media and plastic ware used to culture and cryopreserve gametes and embryos. The centre is partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical device is not CE marked: flushing media used for egg collection (see recommendation 4).

Patient experience

During the inspection, we spoke to five patients about their experiences at the centre. Forty-one patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with 33 of the individuals also providing additional written feedback 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 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 inspection indicate that the centre is partially compliant with HFEA requirements in the following areas.

- The centre has not undertaken or documented a root cause analysis of a serious adverse incident reported 10 weeks earlier (see recommendation 1). The inspection team noted that the centre is proactive and engaged in adverse incident reporting and good examples of root cause analyses undertaken following other laboratory incidents were available for review on inspection.
- The centre is storing medical records received following the closure of another licensed centre. The medical records are being stored in boxes in an office and in a filing cabinet in the patient's waiting area. It is acknowledged that this is a temporary measure as off site storage has been organised and the centre is in the process of archiving the records. In the meantime the inspection team was concerned that access to the records is not secure at all times or available only to persons named on the centre's licence or authorised by the PR (see recommendation 7).
- The centre's website is not compliant with requirements of Chair's letter CH(11)02: 'Responsible use of websites: duty of centres' as the data is not less than three years old and does provide a live birth rate per treatment cycle started (see recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in September 2013 recommendations for improvement were made in relation to four major and nine 'other' areas of non-compliance or poor practice.

The PR provided evidence that all of the recommendations had been fully implemented with the exception of the centre's website update which is still not compliant with requirements.

On-going monitoring of centre success rates

Since the last renewal inspection in September 2013 the centre has not received any performance related risk tool alerts. Five risk tool alerts related to register and finance have been issued to which the PR responded appropriately, providing evidence and information that the issue has been 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.

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 submitted a copy of the audit to the HFEA within the required timeframe and it had been performed according to the method specified by the HFEA and actions have 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	Executive review
1. Following a serious adverse incident the centre has not fully investigated or documented the root cause and has not provided a summary of the conclusions and ensuing outcome to the Authority. SLC T118. SLC T119(b).	The PR should ensure that incidents are fully investigated in a reasonable timescale. The PR should provide a root cause analysis including corrective actions with respect to the incident discussed during the inspection when responding to this report. The PR should review the centre's adverse incidents log to determine whether root	The attached email response from Paula Nolan, Clinical Governance Lead, did not indicate a specific time frame for the PR to investigate this serious adverse incident. We don't believe this should be a crtical area of non compliance. This serious adverse incident was DATIX and is investigated independently by the Clinical Management Team (CMT) which reports to the Senior Management Team.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided assurance that the root cause analysis has been carried out and appropriate corrective actions have been implemented. The PR should ensure that a copy of this analysis is provided to the centre's inspector by 20

	cause analyses, corrective actions and learning have been documented and implemented for all adverse incidents. The review should also consider the centre's procedures for handling and investigating adverse incidents to ensure that these are compliant with regulatory requirements and best practice guidance. A summary of the findings of the review, corrective actions and the timescales for implementation should be provided to the centre's inspector by 10 December 2015. Within three months, the centre should carry out an audit of their adverse incident log to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 10 March 2016.	The PR alerted the CMT regarding the serious adverse incident but has no control over the timeframe when the final report will be available. A root cause analysis has now been carried out for this incident by the CMT and the report will be sent to Senior Management for sign off. A copy of the report will be sent to the HFEA when this is available, In addition there has been a multidisciplinary meeting in the Centre to discuss the incident and any improvements to the process which could be identified. It was concluded that excessive bleeding is a recognised complication of oocyte recovery which has never been seen in the unit before (around 10,000 cases), but vigilance is always required for post operative care. Staff are aware that vital observations (SEWS score) have to be done as per protocol and the medical staff alerted, if these are abnormal. It was re-	November 2015. Further action is required.

		iterated that best practice involves a single puncture to each ovary in order to reduce the risk of bleeding, although it was also recognised that this is not always possible and further punctures may sometimes be required. The procedure for oocyte recovery has been reviewed to underline this point (protocol enclosed). The PR will review all incidents in the last year for Root cause analysis carried out along with learning actions and their implementation. In addition, an audit of incidents will be carried out as requested to establish effectiveness of corrective and preventative actions.	

‘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	Executive review
2. The centre’s audits do not include a review of activities and processes against regulatory requirements. SLC T36.	The PR should ensure that all activities and processes are audited against regulatory requirements every two years. The PR should review the centre’s audit schedule to ensure that all processes and activities are audited against regulatory requirements. A summary of the findings of the review including corrective actions identified and timescales for implementation should be provided to the centre's inspector by 10 December 2015. Audits of practice and	Several processes and areas of activity covered by HFEA regulatory requirements are already audited on a regular basis. These include the following: Incidents, Training and Competence in all areas; Third party agreements; Identification and Traceability; Counselling; Information and Consent; Multiple births; The Quality Management System; Witnessing; Complaints; Confidentiality; Document Control; Purchasing and suppliers; Gamete storage; Patient consent; Legal Parenthood; Donor recruitment, assessment and	The Executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. Further action is required.

	processes against regulatory requirements identified should be completed by 10 June 2016. Upon completion the centre's inspector will request a sample to be reviewed.	screening; Equipment maintenance and calibration, Welfare of the Child. Some audits methodically cover all aspects of the Code of Practice whereas others are not comprehensive against the regulations. In addition, there are a few areas of the COP which are not currently covered individually by our audit schedule (eg Staff; Embryo testing) although they may be included in other audits. Therefore, as requested, this review will be carried out, although it is likely to pose some challenges in the short term due to the absence of a Quality Manager (whose role would normally cover this process). The Quality Manager's post has now been sent to recruitment and the new Quality Manager will be able to review and improve (where needed) the audits in place as well as develop new comprehensive audits of practices and processes as requested.	
3. The centre does not record	The PR should ensure	Following the inspection, all	The Executive acknowledges

alterations in the controlled drugs register in line with the regulations. The centre's audit of their controlled drugs did not ensure that the centre's procedures meet the requirements of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 indicating a failure to include a review of compliance with regulatory requirements in their audit SLC T2.	compliance with the medicines' management regulations. The PR should ensure that alterations in the controlled drugs register are made in line with regulations and confirm to the centre's inspector that this action has been implemented when responding to the report. The PR should conduct a review of medicines management procedures. A summary report of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 10 December 2015. Following the implementation of corrective actions the PR should conduct a further audit of medicines management to ensure the corrective actions have been effective. A summary report following the audit should be provided by 10 March 2016.	relevant staff members were provided with a copy of LUHT controlled drugs policy specific to theatres and reminded that their practice should comply with the policy in place. Relevant staff members were informed that alterations made in the drug register must conform with the Trust protocol and regulations. The PR has contacted the Senior Pharmacists to conduct a review of medicines management procedures. The PR has contacted the Senior Pharmacist regarding concerns raised and aim to submit the report by 10 December 2015. An audit will be carried out by a senior Pharmacist to ascertain that the corrective procedures have been effective and submit the audit findings by 10 March 2016.	the PR's response and his commitment to fully implementing this recommendation. Further action is required.

4. The following medical device used by the centre is not CE marked: saline used for flushing during egg collection. SLC T30.	The PR should ensure that CE marked medical devices are used wherever possible. The PR should take action to source a CE marked medium for flushing during egg collection. The PR should provide the centre's inspector with a list of all medical devices indicating the CE mark status of these products. The list should be provided to the centre's inspector by 10 November 2015. It is expected that all medical devices should be CE marked by 10 December 2015.	Indeed, this review took place in 2008, has been ongoing ever since, is enshrined in a laboratory protocol since 2009 and is also the subject of an annual audit (Purchasing and suppliers). The list of laboratory items in use and their current status is included in the protocol which is attached with this report. The only items not CE marked are tips (not currently available CE marked and also batch tested by sperm survival testing in house) and the saline used in theatre, which was retained due to patient safety issues (see below). The use of this reagent will be addressed in the timescale indicated and will require a risk assessment to identify a safe way of changing theatre sterile protocol to address this issue. To my knowledge, it will not be possible to obtain CE marked tips of the correct size by 10th Dec 2015, but we will continue in our efforts to identify these items, we have been doing for all other consumables in use.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The Executive acknowledges receipt of the list of medical devices and their CE mark status and awaits confirmation of the implementation of CE medical device where possible. Further action is required.

5. The centre's website is not compliant with requirements of Chair's letter CH(11)02 'Responsible use of websites: duty of centres' as it did not provide data less than three years old. The inspection team noted that the centre has up-to-date data available and ready to upload. CH(11)02. Code of Practice 4.5 This was identified as an issue in the last inspection.	The PR should take appropriate action to ensure that the centre's website is compliant with requirements and advise the centre's inspector of the actions taken when responding to this report. The update of the website should be completed by 10 November 2015.	Up to date pregnancy and live birth data have now been uploaded on the website. There was a problem with the data previously due to difficulty of updating the website through NHS Lothian's ehealth team. Updating the website is "outsourced" and it is not always easy to get a prompt response to queries. However, we have now managed to obtain "webmaster" status for one of our staff members and we are now able to update items within 24hrs and we are planning to significantly review our website in the next 6 months.	The Executive acknowledges the PR's response and that the main success rates page on the website has been updated. However, 2009 ICSI rates are still referenced on a separate webpage. Further action is 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
6. The centre had failed to implement guidance issued in the Clinic focus April 2013 clarifying that only CE marked medical devices should be used, and requiring centres to source alternatives to any non CE marked devices. Also the PR had failed to ensure that the centre’s website is compliant with guidance issued in Chair’s letter CH(11)02.	The PR should undertake a review to identify why the learning from this guidance was not implemented. A summary report of the findings of this review including corrective actions and the timescale for their implementation should be provided by 10 December 2015. The PR should conduct an audit to evaluate whether guidance and advice issued by HFEA and other relevant stakeholders has been acted on and submit a summary report of the audit findings by 10 June 2016.	A review of materials in use in the laboratory with regards to presence of CE marking was undertaken as early as 2008 to identify consumable items which would require replacement over the longer term. This review has been ongoing and comprehensive and all the consumable plastics and embryo culture medium in use are CE marked, the only exception being plastics used for waste products and the tips used for insemination (which cannot currently be bought as a CE marked item).The list of items in use and their current status is included with this response as requested. We did indeed implement the guidance issued in April 2013 and the reasons	The Executive acknowledges the PR’s response and his assurance that the centre and staff are committed to implementing learning from guidance. In view of this response and assurance the Executive considers that no further action is required.

		for not extending this guidance to the saline used in theatre was down to patient safety considerations. Currently, the saline used for flushing follicles during egg retrieval is not CE marked. When deciding whether to switch to using CE marked follicle flushing medium several key factors were taken into consideration: 1) the saline in use is licensed for intravenous use 2) the saline is sterile and double packaged which makes sterile procedures in theatre much easier than the use of aliquoted flush in non-sterile (once outside their packaging) tubes 3) because the saline is licensed for intravenous use, its use to flush follicles seemed to us much safer than using a flush medium which needed to be aliquoted in house 4) saline had been used for flushing in the unit for many years (>20yrs) and always our results have been "consistent with the National average" or better. Due to the very small quantities used, the small	

		proportion of patients and follicles in which flushing is required, the very brief period to which the oocyte cumulus complex is exposed, the likelihood that the flush will be significantly diluted with other bodily fluids (blood, follicular fluid etc) and the fact that the oocyte is surrounded by cumulus cells which protects it to some degree from surrounding conditions caused us to conclude that a change to proprietary flushing medium would have very little effect on the safety and efficacy of our overall processing procedure and indeed may be materially detrimetal due to the potential change to theatre protocol and the potential for issues with sterility and in vivo use of an in vitro product. However, since this has been raised as a major non-compliance we will need to review this decision and update our procedures accordingly. As stated in the earlier section, the reason for not complying	

		with website guidance was due to issues outside our own control. Therefore, in both these cases we have been aware of guidance and we feel we have a system in place to identify and act on it as it is issued, indeed we take complying with HFEA regulations very seriously and try our utmost to do so at all times, as previous inspections have highlighted. However, we will be happy to provide the audit as requested, although as stated earlier this will be in the remit of the new Quality Manager and will be dependent on their appointment	
7. The centre is storing medical records received following the closure of another licensed centre in boxes in an office and a lockable filing cabinet in the patient's waiting area. This has been classified as an 'other' non compliance because although there was	The PR must have processes in place to ensure that access to a centre's health data and records is secure at all times. The PR should conduct a risk assessment in relation to patient confidentiality, the storage of patient notes and accessibility of the patient notes to those not authorised	Our Centre is storing medical records following closure of another licensed centre and had to accommodate and process these notes for storage in our medical records. Some of these boxes were in a our Secretary's Office and not accessible by patients as this was a non clinical area. We received 800 sets of notes and	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

considered a possible risk of disclosure of identifying information there is no evidence that this has happened. SLCT44.	to access them. A copy of the risk assessment and timescales to archive relevant records should be provided to the centre's inspector by 10 December 2015.	it takes time to integrate these notes into our medical records, as discussed with our inspector. Furthermore, we had to prioritise and ensure that the EDI information, in particular relating to storage of gametes, for the centre which closed is reported to the HFEA.No IVF notes were in the cabinets in the patient's waiting area. The notes in the cabinets in the waiting area are Reproductive Endocrine and Infertility notes and the cabinets are locked when the Receptionist is not available at the desk or before the centre is closed. There is a receptionist at the reception desk until the Centre is closed. All staff members were reminded by email and at the multidisciplinary meetings that the records room door must be kept closed at all times. A risk assessment will be carried out in relation to patient confidentiality, accessibility of the patient notes for those who are not authorised to access	

		them and for storage of notes. Furthermore , a risk assessment of storage and archiving of notes will be completed within the timescales and a report will be sent to the HFEA.	

Additional information from the Person Responsible