Executive Licensing Panel - minutes

Centre 0030 (Herts and Essex Fertility Centre) Interim Inspection Report

Wednesday, 19 October 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Jessica Watkin Anna Rajakumar	Director of Strategy & Corporate Affairs Policy Manager Scientific Policy Manager
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser		
Observers		

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 Herts and Essex Fertility Centre is located in Cheshunt, Essex. The centre provides a full range of fertility services and has held a licence with the HFEA since 1992.

1.2. The panel noted that the centre's licence is due to expire on 25 November 2018. The panel noted that the inspection took place on 28 June 2016.

1.3. The panel noted that in the 12 months to 31 May 2016, the centre provided 593 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.4. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 March 2015 to 29 February 2016 showed the centre's success rates were in line with national averages.

1.5. The panel noted that in 2015, the centre reported six cycles of partner insemination with one pregnancy. This is likely to be consistent with the national average.

1.6. Between 1 March 2015 and 29 February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.7. The panel noted that at the time of this interim inspection on 28 June 2016, one critical and four major areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented recommendations to address two of the non-compliances including the critical area of non-compliance. The PR has also committed to fully implementing all of the outstanding recommendations within the prescribed timescales.

1.8. The panel noted that there were positive comments made by patients in relation to their experiences at the centre.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel had regard to its decision tree. The panel noted the non-compliances and encouraged the PR to fully implement the recommendations within the prescribed timescales.

2.2. The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

24 October 2016

Interim Licensing Report

Centre name: Herts and Essex Fertility Centre
Centre number: 0030
Date licence issued: 26 November 2014
Licence expiry date: 25 November 2018
Additional conditions applied to this licence: None
Date of inspection: 28 June 2016
Inspectors: Louise Winstone (lead), Polly Todd and Sharon Fensome-Rimmer (Observer)
Date of Executive Licensing Panel: 19 October 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. In particular we note the positive comments made by patients in relation to their experiences at the centre.

The ELP is asked to note that at the time of inspection there were recommendations for improvement in relation to one critical and four major areas of non compliance.

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

Critical area of non compliance:

- **The PR should conduct an audit of consent to legal parenthood.**

Major area of non compliance

- The PR should ensure that medical gases are stored in line with statutory and regulatory guidance.

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

Major areas of non compliance:

- The PR should review the audit programme to ensure it is compliant in the range of activities audited as well as in the robustness of the audits performed.
- The PR should ensure that medicines management practices are compliant with regulatory standards and practice guidance.
- The PR should ensure that CE marked medical devices are used where possible and that products are CE marked for their designated use.

Information about the centre

The Herts and Essex Fertility Centre is located in Cheshunt, Essex and has held a Treatment and Storage licence with the HFEA since 1992. The centre was formerly known as the Essex Fertility Centre which was located at Holly House Hospital.

The centre provides a full range of fertility services including the storage of gametes and embryos.

The centre provided 593 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2016. In relation to activity levels this is a medium sized centre.

Details of inspection findings

Quality of service

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 March 2015 to 29 February 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported six cycles of partner insemination with one pregnancy. This is likely to be consistent with the national average.

Multiple births[2]

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

Between 1 March 2015 and 29 February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: thawing and freezing of embryos. All of the procedures observed were witnessed using an electronic 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. It enables patients to undergo further fertility treatment without additional invasive procedures

[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 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 $p \leq 0.002$.

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 'bring-forward' system was discussed with the laboratory manager and the audits of stored gametes and embryos were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: 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 standard operating procedures (SOPs) 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 consent to legal parenthood.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because the centre has not within the last two years audited practices related to the management of controlled and non controlled drugs and consent to legal parenthood. It was also noted that the centre does not have documented SOPs for the management of controlled and non-controlled drugs (see recommendations 1 and 3).

The inspection team also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- the centre's audit of legal parenthood;
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures and Zika virus.

The centre has been effective in ensuring compliance with guidance issued by the HFEA with one exception related to the use of CE marked medical devices. See 'equipment and materials' section and 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.

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 (see recommendation 4). This was because:

- the centre does not have a Controlled Drugs Accountable Officer (CDAO) registered with the Care Quality Commission (CQC) or evidence of exemption from this requirement;
- staff have not received training in controlled drugs or general medicines management;
- examination of the controlled drugs register noted that in three entries the drug administered to the patient had been witnessed but the entry had not been signed by the practitioner who administered the drug.

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 all medical devices used by the centre was reviewed on inspection. The inspection team found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices were not CE marked: flush media used during egg collection and protein supplement used in culture media. In addition, the pots used for the collection of sperm to be used in treatment, Oosafe 4-well dishes and Oosafe 5ml andrology tubes were not CE marked at the appropriate level, i.e. they were CE marked for in vitro diagnostic use but not for use as class II medical devices (see recommendation 5).

Patient experience

During the inspection, two patients were available to speak with the inspectors about their experiences at the centre. 41 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive with 34 of the individuals providing written feedback giving compliments 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

From information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, the inspection team identified one further area of practice that could be improved.

Medical gases are stored inside the centre in two cupboards. These storage areas are not compliant with regulatory and best practice guidance because:

- medical gases are stored in cupboards that lack adequate ventilation;
- the gas store is not clearly labelled with the types and contents of cylinders contained within;
- the storage area is not large enough to allow for the appropriate segregation of full and empty cylinders;
- there is no signage prohibiting naked lights within the vicinity of the store;
- there is no information for emergency services regarding the location and contents of the store;
- the location of the storage cupboards is not marked on the site plan for emergency services information;
- there is no 'emergency actions' notice giving details of emergency action procedures and locations of keys and contact numbers on the front of the doors;
- there are no duplicate keys available for fire services in the event of an emergency;
- in one of the cupboards, oxygen cylinders are being stored with combustible materials.

The safety of the gas store cupboard was cited as a non-compliance following the centre's renewal inspection in 2014. Since the inspection, the inspection team have reviewed the safety audit submitted after the last inspection by the centre as evidence of medical gas storage compliance. The inspection team at that time noted that the scope of the audit was insufficient and did not assess compliance against Department of Health (DH) health technical memorandum (HTM) regulatory requirements. The centre was informed of the requirement to do this; however, there is no evidence available to suggest that this has been done (see recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in June 2014, recommendations for improvement were made in relation to six major and three 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales. However, as described in the previous section, at this inspection it became apparent that recommendations regarding the storage of medical gases had not been fully implemented.

On-going monitoring of centre success rates

Since the last renewal inspection in June 2014, the centre has not received any HFEA risk tool alerts relating to success rates. The centre has however, received three multiple pregnancy rate related risk tool alerts between the period February 2015 and August 2015. The PR responded appropriately to these risk tool alerts and has committed to continue to review the centre's multiple birth minimisation strategy.

Provision of information to the HFEA

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

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

Legal parenthood

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The report of the audit was provided to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

Following an application made to court by a couple disputing legal parenthood, it became apparent that the centre had missed this couple from their original audit. The PR was invited to a meeting at the HFEA on 30 September 2015 with the Chief Inspector, clinic inspector and HFEA legal advisor to discuss this case in more detail and to explain the actions taken by the centre since discovering this anomaly. The PR provided assurance that corrective actions were in place and that analysis of the original audit confirmed that this was an isolated case. In response to this meeting the PR also commissioned a root cause analysis (RCA) by an independent professional investigator. The report of this RCA has been provided to the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

On this inspection, we reviewed the centre's last audit of consent to legal parenthood and confirmed that it had been performed according to the method specified by the HFEA in CH (14)01. It was however noted that the last audit was performed in June 2014 and no further audit has been performed since this time; the next legal parenthood audit is not scheduled until October 2016. The inspection team were concerned, as there is no evidence that the centre's corrective actions in response to the audit in 2014 have been effective. Furthermore it undermines the PR's reassurance provided in October 2015 that 'effective audit procedures are in place to ensure on-going compliance with consent taking requirements.'

To seek reassurance regarding on-going practice, the inspection team reviewed 10 sets of records where treatment with donor sperm had recently been provided. Effective consent to legal parenthood with a prior offer of counselling were seen to be in place before treatment in all 10 cases. Only two of these cases involved couples who were not married or in a civil partnership and centre staff confirmed that legal parenthood consent forms are completed by all patients having treatment with donor sperm, regardless of their marital status.

In summary, the inspection team considers that the centre's current processes for obtaining effective consent to legal parenthood appear to be compliant with HFEA requirements. A comprehensive audit of consent to legal parenthood is however needed to confirm this, since the last audit was performed in June 2014. The absence of audits of legal parenthood since 2014 leaves the centre exposed to a risk that the centre's processes may not have been robust at times since 2014 and further cases of anomalous consent to legal parenthood may be present (see recommendation 1).

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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. Legal Parenthood The centre has not conducted an audit of consent to legal parenthood since 5 June 2014 which exceeds the requirement to audit within the last two years. The next audit of consent to legal parenthood is not scheduled until October 2016. This non compliance has been classed as a critical area of non	In order for the centre to provide assurance that the centre's current processes are indeed robust, the PR should conduct an audit of consent to legal parenthood for all patients who have received treatment with donor sperm or with embryos created with donor sperm (fresh or frozen) from 1 January 2016 to date.	'Legal parenthood consent audit was last performed in 2015 and not 2014 (we performed audit following the realisation that a case with missing WP and PP forms had not been identified at the initial audit in 2014). It has therefore not been more than 2 years since the last audit was performed. HFEA legal parenthood audit requested by the HFEA to cover dates 1st Jan 2014 to 31st Dec 2015 and 1st January 2016 to August 2016 have been submitted.	The inspection team requested the most recent audit and were provided with one from June 2014. The PR has taken appropriate action and audited all relevant records from 1 January 2014 to date. One

compliance and cited separately to other requirements for audit within recommendation 3, because it undermines the PR's reassurance, provided in October 2015, that 'effective audit procedures are in place to ensure on-going compliance with consent taking requirements.' It also leaves the centre exposed to a risk that consenting processes may not have been robust at times since 2014 and further cases of anomalous consent to legal parenthood may be present. SLC T36.	Given the relatively small number of cases it is anticipated this would apply to, the PR should provide this audit and details of any actions required as a result of the audit findings to the centre's inspector when responding to this report. It should be noted that this requirement has been communicated to the centre ahead of this report being provided to the PR in order to provide the maximum time available to the centre to complete this. Following the completion of this audit, the PR should bring forward the audit of legal parenthood consents scheduled for October 2016 and should include all cases as described above for the period February 2014 to 31 December 2015. A summary of this audit should be submitted to the centre's inspector by 28 September 2016.	We have identified one case where a patient had entered her date of birth instead of the date of signing the WP form in the declaration section. This has been reported to the HFEA and the patient and her partner have been informed of this anomaly by phone call and also in writing. They are aware that we have sought legal advice regarding the matter and will meet the legal costs for any judicial process required to resolve the matter. As per the HFEA recommendations, we will be performing a monthly audit of legal parenthood consent forms for the next 6 months. These reports will be submitted to the HFEA and once the HFEA are satisfied that our systems are robust, we will revert back to annual legal parenthood audits.	further case was identified but the centre are taking appropriate action to address this anomalous consent. This case will be monitored as part of our normal incident investigation process. No further action is required.

	Given the evident risks associated with obtaining effective consent to legal parenthood as identified at this centre and within the sector as a whole, the PR should review the rationale for only conducting a biennial audit of this area of practice. By 28 September 2016, the PR should provide the centre's inspector with the outcome of this consideration and provide detail of the rationale for any decision regarding the frequency of audit decided.		

‘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. Suitable premises Medical gases are stored inside the centre in two cupboards. These storage areas are not compliant with best practice guidance because: • medical gases are stored in cupboards that lack adequate ventilation; • the gas store is not clearly labelled with the types and contents of cylinders contained within; • the storage area is not large enough to allow for the appropriate	The PR should assess the risk of storing medical gases in this area with specific reference to HTM, BCGA and BOC guidance to ensure that any immediate risk to personnel or patients is mitigated and when responding to this report, provide details of actions taken in this regard. The PR should also seek an urgent independent assessment of the area by a BOC representative and should inform the centre’s inspector of when this is to be conducted when responding to this report.	The suitability of medical gases storage in two manifolds was raised at the last HFEA inspection 2014. We were requested to get a health and safety risk assessment which we did. The independent health and safety assessment report did not find fault with the storage and the response was sent to the HFEA which accepted this in recommending renewal of our licence. We have sought additional advice from a BOC inspector who has done a full inspection and risk assessment in September 2016. He finds no fault with the suitability of gas	The PR has taken appropriate action with regards to the safety of the gas storage cupboard. No further action is required.

segregation of full and empty cylinders; • there is no signage regarding prohibiting naked lights within the vicinity of the store; • there is no information for emergency services regarding the location and contents of the store; • the location of the storage cupboards is not marked on the site plan for emergency services information; • there is no 'emergency actions' notice giving details of emergency action procedures and locations of keys and contact numbers on the front of the doors; • there are no duplicate keys available for fire services in the event of an emergency; • in one of the cupboards, oxygen cylinders are being stored with combustible materials.	The outcome of this assessment and an action plan with time scales for the implementation of corrective actions should be provided to the centre's inspector as soon as they are available but not later than 28 September 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 resulted in the failure to fully implement the requirements of earlier recommendations regarding the safe storage and handling of medical gases. The PR should provide the outcome of this investigation and details of any corrective actions required to the centre's inspector by 28 September 2016. Given failure to implement best practice guidance in the	storage in the manifolds. However, he recommended an additional vent which has been installed. He was also happy with our training records. I have attached the comprehensive BOC inspection report with recommendations, all of which have been implemented). The areas of non compliance from his report, namely signage have been addressed. The BOC inspector requested additional signage which has been ordered and pictures will be sent following replacement of the signage that we have in place (we got new signage following the HFEA inspection, but these are to be replaced by the more detailed BOC recommended ones. The oxygen gas storage manifold has also been partitioned and all the necessary labelling done. (see pictures in the BOC report) Partitioning also segregates	

Department of Health (2006) 'Medical Gases Health Technical Memorandum (HTM) 02- 01: Medical gas pipeline systems; Operational management. British Compressed Gases Association (BCGA) guidance note 2 guidance for the storage of gas cylinders in the workplace revision 5: 2012. BCGA guidance note 23 Identifying gas safety training requirements in the workplace 2012. SLC T2, T17.	management of the gas store, 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.	the full and empty cylinders, with all clearly labelled. Signage prohibiting naked lights within the vicinity has been added. Information for security services about the location and contents of store are available at all fire exit points and at the reception area. Location of storage cupboards has been added onto the site plan for emergency services information (see attached BOC inspection report). Emergency actions notice giving details of emergency action procedures and location of keys and contact numbers and contact numbers have been made and placed on the doors as well as at reception and front office. Duplicate keys are available at the front office and at reception area for the fire services in the event of an	

		emergency. All key staff also have duplicate keys. Consumable materials that had been stored above the oxygen cylinders have been removed. Staff working with medical gases have received the appropriate training and records to support this are attached (see BOC report). We will adhere to the BOC recommended training updates every two years. Recommendations regarding Herts & Essex Fertility Centre have a manifold room to supply gas to the clinical areas, they also store small quantities of medical oxygen cylinders within that manifold room, for the purpose of this audit I have outlined below the compliance required as per HTM 02-01 Part A: Design, installation, validation and verification to ensure the storage of additional cylinders	

		outside of those required for the manifold is compliant and if necessary where improvements are required. Accommodation The manifold room contains 4x single cylinder independent manifolds and also contains sufficient spare cylinders to replace one bank of each manifold as per section 14.11 of HTM 02-01 Part A. Adequate cylinder handling space should be available, upon my site inspection, with the doors open there is a handling space of 1.8m which I would consider sufficient. All doors are locked to prevent unauthorised access and have a documented key cabinet to display which key is required for access. Ventilation requirements for HTM compliance are determined as 1.5% of the total area of the walls and floor, I have carried out the relevant calculations and the	

		existing ventilation is satisfactory. • Required ventilation area = 0.216m2 • Existing ventilation area = 0.425m2 • Recommend installing additional high level vent on front of manifold room door for added air circulation (this has been done). Temperature requirements for medical gas storage must be between 10-40 degrees C. Upon site inspection the temperate was recorded at 22.6 degrees C. Upon inspection of the existing manifold room there are a small amount of medical oxygen ZX cylinders stored within the room, in regard to this I make reference to HTM 02-01 Medical gas pipeline systems Part B: Operational management – Cylinder Storage and handling	

		paragraph 8.43 – “Some sites in the absence of a dedicated building, will also store small cylinders of all medical gas types in medical gas manifold rooms.” Paragraph 8.42 – “There will be small hospitals, dental units and other small sites where division of the storage area into full and empty bays, as described in this section is not feasible”. Herts & Essex Fertility Centre falls into this category as this is not a hospital site. Therefore I am satisfied that the storage of these cylinders within the manifold room is compliant and is being managed appropriately.	
3. Quality Management System The centre‘s audit programme is not suitably robust because an audit of the practices used to manage controlled and non-controlled drugs has not	The PR should review the audit programme to ensure it is compliant with the range of activities to be audited and to ensure that audits are conducted within the required timeframes.	The audit programme has been reviewed and will be submitted. Consent to legal parenthood audit is now a quality indicator and will be performed monthly for the next six months and if satisafactory, annually following that.	The PR has taken appropriate action and the audits and SOPs have been submitted. We await the summary report of the review of the audit programme. Further action is required.

been completed in the last two years. The centre does not have documented SOPs describing the practices used to manage controlled and non-controlled drugs. SLCs T33 (b) and T36.	A summary report of this review, to include the corrective actions with timescales for implementation should be provided to the centre's inspector by 28 September 2016. The PR should perform the medicines management audits identified as outstanding and a summary of these should be provided to the centres inspector by 28 September 2016. The PR should ensure that there are documented procedures for controlled and non-controlled drugs management. A copy of these should be provided to the centre's inspector by 28 September 2016.	Controlled and non-controlled drugs audit has been completed and is attached A copy of the documented procedures for controlled and non-controlled drugs management will be provided to the inspector by 28th September 2016. The centre has controlled and non-controlled drugs management policies. These have been reviewed in september 2016 and are attached.	
4. Medicines Management The following issues were noted during the inspection: • the centre does not have a CDAO registered with the CQC or evidence of	The PR should ensure that medicines management practices are compliant with regulatory standards and professional body guidance.		The PR has taken appropriate action. We await the follow up audit by 28 December 2016. Further action is required.

exemption from this requirement; • staff have not received training in controlled drugs or general medicines management; • examination of the controlled drugs register noted that in three entries the drug administered to the patient had been witnessed but the entry had not been signed by the practitioner who administered the drug. Department of Health (DH) (2007) 'Safer Management of Controlled Drugs; a guide to good practice in secondary care (England). DH (2013) Controlled Drugs (Supervision of management and use) Regulations 2013. Misuse of Drugs Regulations (2001). NMC 'Standards for medicines management' (2010).	The inspection team acknowledge that the centre has made an application to the CQC to register a suitable CDAO but this has not been completed. The PR should provide the centre's inspector with evidence of an exemption or registration of a CDAO by 28 September 2016 at the latest. The PR should ensure that all entries in the controlled drugs register are compliant with statutory, regulatory and best practice guidance. The PR should ensure that all relevant staff are trained in medicines management. The PR should conduct a review of the centre's medicines management procedures; this should include staff training requirements. The findings of the review, including corrective actions and timescales for implementation		

SLCs T2 and T15.	of the corrective actions should be provided to the centre's inspector by 28 September 2016. Three months after the implementation of corrective actions the PR should perform an audit to ensure that these actions have been effective. A summary report of this audit should be provided to the centre's inspector by 28 December 2016.		
5. CE marked devices The flush media used during egg collection and the protein supplement used in culture media are not CE marked. Although the pots used for the collection of sperm to be used in treatment, Oosafe 4-well dishes and Oosafe 5ml andrology tubes are CE marked, this is for in vitro diagnostic use only and not for their designated use, i.e. as class II medical devices. SLC T30.	The PR should ensure that CE marked medical devices are used where possible and that products are CE marked for their designated use. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided. In consideration of this, the PR should provide the centre's inspector with information which should document either the anticipated time by which a CE mark is expected to be obtained or the action that will	15ml and 5ml tubes Repromed 15 ml and 5ml tubes supplied by Hunter Scientifc. CE 0535 MEA tested Semen collection pots Repromed semen collection containers 125ml CE 0535 Not MEA or sperm survival tested. Undergoing in house laboratory validation prior to implementation . 4 well culture dishes Nunc 4 well dishes CE 0535	The PR has taken appropriate action to ensure that all products in use are appropriately CE marked. The PR has submitted a document titled 'laboratory update on the introduction of new CE marked consumables' which states that the centre are currently looking at alternative media. We await confirmation that suitable CE marked products including culture media are in place by 28 December 2016. Further action is required.

	be taken to ensure compliance with this recommendation. This information should be submitted to the centre's inspector by 28 September 2016. It is anticipated that suitable products should be in use no later than 28 December 2016.	MEA tested Undergoing in house validation prior to implementation due to issues reported to the supplier in 2014. Hunter Scientific have confirmed there have not been any further issues and this has been verified by the Lister IVF unit. SPS We have sorced CE marked flush media for double lumen egg collection and will start validation of 1/10/2016 and move towrads using this exclusively by 01/12/2016. We are anxious about making too many changes at the same time as this would make it very difficult to trouble shoot should we have laboratory incidences / concerns with success rates. We are therefore introducing the CE marked consumables one at a time.	

‘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
None			

Additional information from the Person Responsible
The legal parenthood consent audit revealed one invalid consent form (patient wrote her date of birth instead of the date of signing the declaration page. We have informed the couple by phone and in writing. we have sought legal advice awaiting feedback. We have reassured the couple that we will make all the necessary arrangements and meet any leagl costs towards sorting out their legal parenthood status. I will keep the HFEA abreast of developments. We in the meantime will conduct monthly audits of the legal parenthood consents process until the HFEA is satisfied with our processes in order to revert to an annual audit.