Licence Committee - minutes

Thursday, 5 November 2015

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

Centre 0324 (City Fertility) – interim inspection report

Committee members	Andy Greenfield (Chair) Anita Bharucha Kate Brian Margaret Gilmore	
Members of the Executive	Sam Hartley	Head of Governance and Licensing
Legal Adviser	Graham Miles	Blake Morgan

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

The following papers were considered by the committee:

- Interim inspection report
- Licence Committee minutes for the past three years:
  - 07-08-2015 change of person responsible
  - 07-05-2015 up-date report
  - 12-03-2015 up-date report
  - 15-03-2015 change of person responsible
  - 25-09-2014 licence renewal
  - 18-10-2013 change of licence holder
  - 29-11-2012 initial inspection report

1. Consideration of application

1.1. The committee noted that City Fertility, centre 0324, has held a licence with the HFEA since November 2012 and provides a full range of fertility services. The centre's licence is due to expire on 28 November 2016. The interim inspection took place on 11 August 2015.

1.2. The committee noted that in the 12 months to 30 June 2015, the centre provided 278 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre. The panel noted that HFEA-held register data for the period May 2014 to April 2015 showed the centre's success rates were in line with national averages.

1.3. The panel noted that, in 2014, the centre reported 16 cycles of partner insemination with two pregnancies. This represents a clinical pregnancy rate of 12%, which is likely to be in line with the national average. Between April 2014 and March 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 23%. This means that the centre's multiple live birth rate is likely to meet the 10% maximum multiple live birth rate target.

1.4. The panel noted that the centre was currently operating under a two-year licence (rather than the usual four) due to the number and severity of non-compliances identified at its renewal inspection in 2014. Because of its concerns at renewal in 2014, the Licence Committee had requested progress reports and that a further interim inspection be conducted by September 2015 in order to ensure that the centre was addressing the non-compliances. The committee further noted that since the licence was renewed, the centre's licence has been varied twice to change the person responsible (PR).

1.5. The committee noted that, at the time of the interim inspection on 11 August 2015, one critical, four major and two other areas of non-compliance were identified. The centre had shown progress in addressing the non-compliances identified at the renewal inspection, of which there were four critical, 14 major and eight other areas of practice that required improvement.

1.6. The committee noted that the recommendation from the inspectorate was that the centre's licence be continued without any additional conditions.

2. Decision

2.1. The committee remain deeply concerned about the number and type of non-compliances at this centre. It recognised the recent progress made in addressing the non-compliances identified at the renewal inspection in 2014. However, the continued and cumulative effects of the non-compliances were cause for significant concern about the operation of this centre.

2.2. Notwithstanding its serious concerns about the operation of this centre, the committee agreed that, on balance and in light of the progress shown in addressing some of the non-compliances, the proportionate action in this case was to allow the continuation of the licence for the remainder of its term, until November 2016. The committee noted that a full renewal inspection would be necessary in the first half of 2016 and expected the centre to urgently address all non-compliances, at the least implementing all corrective actions by the renewal inspection. It urged the inspectorate to continue its monitoring of this centre and to revert to the Licence Committee if it had further serious concerns about the operation of this centre. In any case, the renewal report for this centre must be put to Licence Committee, and not delegated to the Executive Licensing Panel.

3. Chair's signature

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

Signature

Name

Andy Greenfield

Date

13 November 2015

Interim Licensing Report

Centre name: City Fertility
Centre number: 0324
Date licence issued: 29 November 2014
Licence expiry date: 28 November 2016
Additional conditions applied to this licence: none
Date of inspection: 11 August 2015
Inspectors: Douglas Gray (lead), Neil McComb
Date of Licence Committee: 5 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 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 Licence Committee with information on which to make a decision about the continuation of the licence.

Summary for the Licence Committee

The inspection team recommends the continuation of the centre's licence. The committee is asked to note that there are recommendations for improvement in one critical and four major areas of non compliance, and two 'other' areas of practice as follows:

Critical areas of non compliance:

- The PR should ensure that embryos are only used for training activities that have been expressly authorised by the Authority, and with the consent of both gamete providers.

Major areas of non compliance:

- The PR should ensure equipment and materials are designated for their purpose and, if necessary, CE marked.
- The PR should ensure evidence is available that all imports satisfy the requirements of General Directions 0006.
- The PR should ensure validations outstanding from their previous renewal inspection are complete.
- The PR should ensure that information is kept confidential and only disclosed in circumstances permitted by law.

'Other' areas of practice that require improvement:

- The PR should audit the centre's website against the regulatory requirements.
- The PR should review barriers to implementing learning from guidance provided by the HFEA or other sources.

The PR has made significant progress in implementing the recommendations made in this report and has given a commitment to fully implementing the remainder of all of the recommendations. The centre's inspector will monitor progress towards full implementation.

Information about the centre

City Fertility is located in central London and has held a HFEA licence since November 2012. The centre provides a full range of fertility services.

The centre provided 278 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2015. In relation to activity levels this is a small centre.

Following a renewal inspection in June 2014, a licence was granted for two years (rather than four) due to the number and severity of non compliances identified. The Licence Committee requested that a further inspection took place by September 2015 and that prior to this the executive provide it with an update on the centre's progress with implementing the recommendations made in the report. Progress reports were considered by Licence Committee in March and May 2015.

Since the renewal inspection, the centre's licence has been varied twice to change the person responsible (PR). The centre is also in the process of applying to have their licence varied to allow treatment involving embryo testing.

This inspection focused on compliance with recommendations outstanding from the 2014 inspection and the current interim inspection themes.

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 May 2014 to April 2015 show the centre's success rates are in line with national averages.

In 2014 the centre reported 16 cycles of partner insemination with two pregnancies. This represents a clinical pregnancy rate of 12%, which is likely to be in line with the national average.

Multiple births[2]

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

Between May 2014 and April 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. This means that the centre's multiple live birth rate is likely to meet the 10% multiple live birth rate target.

[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%.

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: frozen embryo transfer. The procedure observed was witnessed using a manual 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 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 accuracy of storage logs and consent records were reviewed, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: the atmosphere in the clinic appeared calm at all times; 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, provision of information, patient records, screening, welfare of the child, legal parenthood and use of embryos in training.

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

- audits reviewed as part of the assessment of compliance with recommendations made at the time of the centre's last inspection
- the use of CE marked medical devices
- the content of the centre's website
- the centre's audit of legal parenthood

- HFEA reports of adverse incidents
- guidance on the confidentiality of data accessible on software driven systems.

A recommendation has been made below relating to the use of CE marked medical devices (see recommendation 2) and the centre's website (see recommendation 6). In consideration of this it can be concluded that some improvement is required for the centre to have a fully effective learning culture (see recommendation 7).

Medicines management
The centre's management of medicines was not reviewed during this inspection.

Infection Control
The centre's infection control procedures were not reviewed during this inspection.

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 because the following medical devices were not CE marked: 5 ml round bottom tubes used during the retrieval of eggs, and a protein supplement added to embryo culture media (see recommendation 2). In addition, gases (carbon dioxide and nitrogen) used during medical procedures were not suitably designated for medical use.

Patient experience
During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Twenty two patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 14 of the individuals providing written feedback giving compliments about the care they received.

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

- 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.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is not compliant with the following HFEA requirements:

- Information provided to patients on a centre's website should be reliable and accurate (CoP Guidance Note 4.5). A review of the centre's website against guidance showed:
  - the live birth rate per treatment cycle is not given for each age and treatment category, and
  - a like-for-like national rate is not provided (recommendation 6).

- In 2013, centres were alerted to the potential for inadvertent breaches of patient confidentiality when third parties access software-driven systems remotely or on the licensed premises of clinics so that their applications can be supported, upgraded and/or repaired (Clinic Focus, December 2013). An embryoscope is used in the laboratory. Staff were unsure to what extent third parties, such as the manufacturer, could access identifying information (recommendation 5). Similarly, the centre's email server is based in another country (at the Head Office of the parent company). There had been no assessment of what information could be accessed by what staff there.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in relation to four critical, 14 major areas of non compliance and eight 'other' areas of practice that required improvement. At the request of the Licence Committee, the executive provided an up-date report on the implementation of recommendations at the March 2015 committee meeting. The following recommendations were fully implemented, within the agreed timescales, at the time of that meeting:

'Critical' areas of non compliance:

- **The PR is to ensure that the premises and facilities are secure and that patient and donor information, medicines and other materials are not at risk of loss or harm.**
- **The PR should urgently review current practice and establish robust procedures to ensure that satellite IVF providers are fulfilling HFEA requirements and that the terms of the satellite agreements are being met.**
- **The PR is required to take immediate steps to ensure that all medicines are managed and stored appropriately.**
- **The PR should undertake an urgent review of processes and procedures relating to the surgical pathway to ensure good practices are demonstrated and that record keeping is complete and accurate.**

'Major' areas of non compliance:

- The PR should ensure that the disposal of eggs that are not used in treatment is witnessed with immediate effect. The PR should review witnessing practices in consideration of the requirements of SLC T71 and CoP Guidance 18.4j and 18.8b.
- The PR should take immediate action to ensure that clinical waste is managed and medical gasses are stored appropriately.
- The PR should ensure that all patient and donor screening is conducted by a suitably accredited laboratory.
- The PR should undertake an audit of the implementation and effectiveness of the centre's multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre.
- The PR should ensure that staff are competent in all of the tasks that they perform.
- The PR should ensure that audits of the provision of information and donor screening procedures against compliance with the approved protocols, the regulatory requirements and quality indicators (QIs) are performed.

'Other' areas of practice that require improvement:

- The PR should review the process by which she may be assured that donor compensation and benefits in kind are made to all donors in accordance with Directions 0001.
- The PR should review the process for the provision of information to be provided to donor egg recipients to ensure that where treatment is offered with previously frozen donor eggs, the recipient is fully informed of all factors regarding this treatment and the centre's current post thaw survival rates.

- The PR should review process for seeking consent to disclosure from donors to ensure the consent to disclosure decision is recorded in the donor records and that decision is provided to the HFEA for inclusion on the HFEA Register.
- The PR should commission a patient / donor satisfaction survey.
- The PR should review the process for submitting data to the HFEA to ensure that information is provided within the timescales required by Directions 0005.

The following actions were outstanding at the time of the current inspection. Following a review of the available evidence these recommendations have been fully implemented:

'Major' areas of non compliance:

- The PR should ensure that prior to the use and/or storage of donor gametes, all of the laboratory tests required by SLC T52 are performed and within the timeframes set by the Authority.
- The PR should ensure that gametes and embryos are processed in an environment of appropriate air quality.
- The PR should take immediate action to ensure that all incidents are reported to the HFEA; are thoroughly investigated; and also that patients should be informed as necessary. Relevant incidents should be reported to the HFEA retrospectively.
- The PR should ensure effective consent to legal parenthood is obtained where applicable before treatment is provided.
- The PR should conduct a review of the process for completing medical records to ensure that the justification for treatment is documented appropriately.

'Other' areas of practice that require improvement:

- The PR should review the process for assessing Welfare of the Child (WoC) and completion of the supporting documentation to ensure that all couples are suitably assessed and that a review of the assessment is documented prior to licensed treatment being provided.
- The PR should ensure that all third party agreements (TPAs) are reviewed within the specified timeframe.

Evidence had been provided to the executive that the following recommendations had been fully implemented, but observations during the current inspection show that further action is required:

'Major' areas of non compliance:

- The PR should develop a documented standard operating procedure (SOP) and patient information for the use of embryos in staff training.

  An SOP was drafted and an audit of compliance against the revised SOP was submitted within the required timeframe. The notes of five sets of patients that had donated their embryos for use in training were reviewed on inspection. The embryos of three patient couples had been used with the consent of the gamete providers for training purposes. During this audit, it was noted that for two out five sets of patients, their embryos were logged as having been used for validation purposes (see recommendation 1). The Act does not permit the use embryos for validation. A further review of all embryos used during the past year showed that in total 50 embryos from 14 patient couples had been used for validation.

‘Other’ areas of practice that require improvement:

- The PR should ensure that, prospectively, written confirmation to satisfy all points of Directions 0006 is obtained prior to the import/export of any sample.

  A review of three imports of embryos that took place since the last inspection showed that in all instances evidence to satisfy the requirements of General Directions 0006 was not available (see recommendation 3). For two imports from the EEA, all evidence was in the native language of the exporting centre and the PR had not assessed its suitability. For the third import reviewed, in which embryos were imported from outside of the EEA, the PR was unable to find any evidence to satisfy the requirements of the Directions.

The following recommendations were outstanding at the time of the inspection and still require further action:

‘Major’ areas of non compliance:

- The PR should ensure that wherever possible CE marked medical devices are used.

  This recommendation related to the use of an incubator and vitrification kit. During the inspection it was confirmed that the incubator had carried a CE mark at the time of the renewal inspection. The vitrification kit that was not CE marked has been replaced with a suitable alternative. During the inspection, additional medical devices that were not CE marked were in use as described above (see recommendation 2).

- The PR should ensure that all critical clinical and laboratory processing procedures are validated.

  In response to the renewal inspection report, the former PR provided a list of critical processes that required validating. In February 2015 validations were provided for most of these processes, but they did not contain a retrospective evaluation of the centre’s own data. At this inspection, the PR provided suitable evidence that all but two processes had now been suitably validated including reference to their own data. The two outstanding validations are for the following processes identified as critical in response to the renewal inspection report: standard insemination and stimulation protocol (see recommendation 4).

On-going monitoring of centre success rates

Since the last renewal inspection the centre has received one risk tool alert relating to multiple pregnancy rates to which the PR has responded and, during discussions at the time of the inspection, provided a commitment to keep their multiple pregnancy rate under review.

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 sent the report of the audit to the HFEA within the required timeframe. The centre's audit was reviewed at the 2014 renewal inspection and a recommendation was made that was fully implemented within the required timeframe.

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. Research and training The Act permits the use of embryos in training for purposes expressly authorised by the Authority (Schedule 2 (1)(ca) and 4A). Embryos have been used for validation: the use of embryos for this purpose is not permitted by the Act or authorised by the Authority (SLC T93).	The PR should take immediate action to ensure that embryos are not used for validation. Confirmation that this action has been taken should be given when responding to this report. The PR should contact those patients whose embryos were used for a purpose not permitted by the Act to offer an explanation and apology. The PR should review the	An action point in the renewal inspection report from 2014 directed a change in vitrification media and therefore the procedure. An evaluation of vitrification systems was completed, a number of products were selected and a staff training program was organised to enable compliance to be achieved within the given timescale. Gametes and embryos that were donated for use in research and training were used in training	The PR has stated that embryos, recorded as being used for validation purposes, were instead primarily used for training purposes which is permissible under the Act. Given this, it would not be necessary for patients to be contacted in order to explain their donated embryos had been used for a purpose that was not permissible. Based on the findings of this inspection, the executive

	centre's processes to ensure that embryos are only used for training activities that have been expressly authorised by the Authority and in accordance with the consents of both gamete providers. A summary report of both reviews including corrective actions and the timescales for their implementation should be provided by 11 November 2015. Six months after that, the PR should audit the use of embryos in training and provide a summary to their inspector by 11 May 2016.	embryology team members in the 'new' vitrification protocols. The results obtained from the test vitrification events were subsequently used as a demonstration to the authority that the process has been assessed thoroughly before implementation. In view of the use of a culture media with a non CE marked protein source, an assessment of alternative media systems has been performed. Training was arranged from company representatives to handle these alternative CE marked culture media systems. Once a system was selected gametes and embryos were used when training to simulate the preparation of culture dishes for the modification of the culture SOP. See attached SOP LABSOP12b LABORATORY SETUP (VITROLIFE). The results obtained from the test culture dish preparation were subsequently used as a demonstration to the authority that the process has been assessed thoroughly. The records that suggest embryos were used for	considers it reasonable to make a further recommendation here to corroborate the assurance given by the PR. The PR should submit a copy of the centre's training log and training records to the centre's inspector by 11 January 2015.

		validation should have stated training not validation. See attach audit (EM14b USE OF EMBRYOS IN TRAINING) for the use of embryos in training and amended validation form LABFORM23 Validation of critical Process Report V4 30 09 2015 stating clearly that embryos will not be used in validation, but results that are collected during a training process can be subsequently used to demonstrate effective implementation and process validation. PR to complete additional audit on the use of embryos in training by 11 May 2016.	

‘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. Equipment and materials The following medical devices are not CE marked: 5 ml round bottom tubes used during the retrieval of eggs, and a protein supplement added to embryo culture media (SLC T30). Gases used for medical procedures were not appropriately designated for medical use (SLC T23).	The PR should ensure equipment and materials are designated for the purpose and, if necessary, CE marked. We would not however recommend the implementation of precipitous changes that might impact on the quality of treatment that you are providing to your 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	Use of non CE marked 5ml round bottom tubes: PR has modified the sperm preparation SOP to remove the use of NUNC 5 ml round bottom tubes as directed. Implementation of this change will be in place by the 11th November. 5ml round bottom tubes are not used in the egg collection procedure. See the section 5.4. Sperm Preparation in the attached amended SOP; LABSOP14 Semen Analysis, Sperm Freezing and Sperm Preparation Methods . Vitrolife culture ware has been assessed at City and training has been provided by company representatives, reintroduction of a 5ml round	The PR has provided a commitment to using CE marked medical devices. We will continue to liaise with the PR to ensure the gases being used meet the necessary safety standards. We request that the PR provides an up-date on their progress by 11 November 2015.

	will be in place by 11 November 2015. This timescale has been set taking into account that a recommendation was made at the centre's previous inspection relating to the use of non-CE marked products.	bottom tube will occur once this product is released by Vitrolife with a CE mark. Use of a culture media which requires a non CE marked protein supplement: FutureLife Holdings has selected COOK Medical Ltd as a preferencial supplier of IVF products for our group of clinics. But Vitrolife culture media has been assessed at City and training provided by company representatives. This evaluation will allow for the adoption of Vitrolife CE marked products in the future. Implementation of a change of SOP will occur by the 11th November. See SOP12b LABORATORY SET UP (VITROLIFE). Further literature validations will be performed to assess further culture media suppliers and a media trial will be started in November 2015 with the CE marked Gynemed media of range. Use of non Medical grade gases. D and L Medical have been engaged to assess the Beacon	

		Medaes medical gas supply system, manifolds, changeover units and regulators. To change the gas supply from high purity industrial grade to medical grade gas may require extensive modifications. The gas handling system used to carry the gases from the tank storage room on the second floor to the laboratory on the third floor will be assessed. New regulators and an increase in presssure to the change over units may also be required. New gases will be ordered by the specified date, but City may require additional time to become fully compliant, the 11th November may not be a realistic timeframe. Further information will be provided after a site visit from the engineers on the 13th October 2015.	
3. Imports and exports The centre cannot provide evidence that they have complied with all the requirements of Directions 0006. An 'other' recommendation	Before any further import of gametes or embryos, the PR should review the centre's procedures for import to ensure compliance with the requirements of General Directions 0006. Confirmation that this action will be taken should be given when	PR has modified the procedure for the review process for the import and export of gametes and embryos. See the modified SOP, communication (letters) and modified review form LABFORM27 IMPORT OF SAMPLES WITNESS FORM. SOP10 NATIONAL AND INTERNATIONAL	The documents provided by the PR address our recommendation to review processes for import. The inspector has some concerns from the PR's response and documents provided relating to their understanding of import under the auspices of General

was made with respect to a similar non-compliance at the time of the last inspection and given that no progress appears to have been made, this has been graded as 'major'.	responding to this report. The PR should review the documentation relating to all imported gametes and embryos. The HFEA should be provided with a report documenting the status of each import in terms of compliance with Directions 0006; whether the gametes or embryos have been used in treatment, and; where treatment has been provided, the outcome of that treatment in terms of live birth, ongoing pregnancy and/or creation of frozen embryos. This report should be provided by 11 November 2015. On receipt of the information the executive will liaise with the PR to determine a proportionate recommendation about the subsequent use of gametes and or embryos created using the imported gametes. The PR should review all processes relating to import, to ensure compliance with Directions 0006. A summary report of the findings of that	TRANSPORTATION OF GAMETES AND EMBRYOS A review of all imports will be performed and a report will be submitted within the specified time scales. The import of Embryos from our sister IVF units in Prague are covered by the directions relating to the movement of gametes and embryos from countries within the EEA. A General Direction is not required. Ceczh staff within the unit, such as the General Manager, Lukas Beranak or the Nominal Licensee Matej Stejskal are able to reassure the PR that the information within documents that are written in Czech are valid and satisfy the details in Directions 0006. Documents from other countries where a native speaker is not able to summarize a document will be translated in English to ensure that the PR is able to complete a thorough evaluation.	Directions, especially their reference to imports from within the EEA not requiring a General Direction. We will work with the PR to ensure the requirements of General Directions are fully understood. Further action is required by the PR to provide the information requested by 11 November 2015.

	review and any corrective actions identified and the timescale for their implementation should be provided by 11 November 2015. Six months after the implementation of corrective actions the PR should audit and the effectiveness of these actions in ensuring compliance: a summary of the audit should be provided by 11 May 2016.		
4. Processing, procuring and transporting gametes and embryos. Validations were not available for the following critical processes identified by the PR: standard insemination and stimulation protocol. (SLC T72)	The PR should ensure validations outstanding from their previous renewal inspection are complete and copies forwarded to their inspector by 11 November 2015. Validations should be based on published literature and include an analysis of the centre's own data. This timescale has been set taking into consideration this recommendation remains outstanding from the centre's previous inspection.	See attached documents. I apologise for the omission of The stimulation protocol validation report at the inspection. The standard insemination validation report that was prepared by the previous laboratory manager and submitted by a previous PR has details of a validation based on published literature and a retrospective anaylsis of results obtained at City Fertility.	The validations have been reviewed and no further action is required.
5. Confidentiality and privacy	The PR should ensure that information is kept confidential	The previous PR investigated this point.	We can confirm that the centre does not have an electronic

Patient identifying information in software driven systems may not be being kept confidential and only disclosed in circumstance permitted by law. (SLC T43, T44 and T45)	and only disclosed in circumstances permitted by law. The PR should seek confirmation from the manufacturers of their electronic witnessing system, and those responsible for their email server, of what data may be accessed remotely. The PR should provide a summary of their investigation and any remedial steps when responding to this report.	PR can confirm that only City Fertility staff, named database engineers and GENNET Archa IT team members have access to our electronic patient records. All staff who have access to sensitive information stored electronically are listed on the portal. The centre does not have an electronic witnessing system.	witnessing system, and reference in this report to that should be to their embryoscope. We request that the PR provides a similar up-date in relation to their embryoscope by 11 December 2015.

‘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
6. Information Success rates on the centre’s website are not presented in accordance with HFEA guidance. (Code of Practice, Guidance Note 4.5)	The PR should audit the centre’s website against the regulatory requirements and arrange for any amendments required to be made promptly. A summary of changes should be provided by PR by 11 February 2016. The Executive may choose to re-audit the centre’s website at this point.	The centre's website has been modified.	The centre’s amended website has been reviewed. All success rates have now been removed from the website with a statement that: ‘we cannot provide our live birth data and the HFEA will not proide data throught „choose a clinic“ until later this year.’ [sic] We are concerned that these amendments are not in the best interest of patients and are potentially misleading. Whilst our guidance is that live birth data should be presented, this does not prevent the centre presenting other data (such as clinical pregnancy rates), alongside this. Of course, if live birth data are not available, this should be explained. The PR is encouraged to reconsider information on their website and provide an up-date by 11 February 2016.

7. Quality management system The centre has not fully implemented guidance issued by HFEA, including that on the topic of CE marking, confidentiality of data on software driven systems and information presented on websites. (SLC T32)	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 should provide feedback on this review to the centre's inspector by 11 February 2016.	An extensive review of the QMS is in progress, the completion date is December 2016. A report of the changes will be submitted as directed on completion. Modifications to the QMS have already been implemented to enable a review and action of all guidance issued by the HFEA, and other regulatory bodies, within a timely manner. Modifications to weekly, monthly and periodic team and individual departmental meetings has been made. Formation of multidiscplinary working groups and the better utilisation of enhanced QMS software will enable this point to be met in the near future. City aims to review practices within the unit in view of starting the process to obtain ISO accreditation in the last quarter 2016 and first quarter 2017. This will require a detailed analysis and modification to a number of working procedures throughout 2016.	We acknowledge the measures taken by the PR and we await the summary report.

Additional information from the Person Responsible
The inspection process has allowed the team at City Fertility to review our practice. We hope with continued reflection and evalutaion of our processes, with best practice at the as the driver for change, we will be able to address the areas that require attention to improve the quality of care for our patients. We have made some immediate changes to our procedures and will implement all recommendations and provide necessary information to ensure our compliance.