Executive Licensing Panel - minutes

Centre 0324 (City Fertility)

Interim Inspection Report

Tuesday, 26 February 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Niamh Marren Howard Ryan	Director of Strategy and Corporate Affairs Regulatory Policy Manager Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Joanne Anton Danielle Vincent Richard Sydee Moya Berry	Senior Governance Manager Policy Manager Communications Manager Director of Finance and Resources Committee Officer

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:

- 9th 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 City Fertility is located in London and has held a licence with the HFEA since 2012. The centre's licence was varied to include embryo testing in 2015 and was renewed from 29 November 2016 for four years, after a licence renewal inspection in June 2016. The centre provides a full range of fertility treatments.

1.2. The panel noted that, in the 12 months to 31 August 2018, the centre had provided 266 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

1.3. The panel noted that, HFEA register data, between 1 July 2017 to 30 June 2018, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.4. The panel noted that, in 2017, the centre reported eighteen cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, between July 2017 and June 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that following issues identified during an inspection at another centre in late 2017, the Executive undertook a review of activities across the sector in relation to the import of eggs, particularly donor eggs, for use in treatment in the UK. As a result of this review and extensive communications with City Fertility, the Executive concluded that the centre had undertaken imports of donor eggs from Ukraine to the UK which were not compliant with General Direction 0006, because the amount of compensation given to the egg donors in Ukraine was not compliant with General Direction 0001. The Person Responsible (PR) was made aware of the concerns and has engaged, providing the Executive with the requested information. The PR applied to the HFEA for Special Directions to export the donated eggs back to Ukraine. In relation to embryos already created using the eggs, Special Direction applications were made to simultaneously export and re-import them back into the UK in a compliant manner, so that the embryos can be lawfully used in treatment. These applications were considered and approved by the Statutory Approvals Committee on 29 November 2018.

1.7. The panel noted that the inspection took place on 20 September 2018.

1.8. The panel noted that at the time of inspection there were four major areas of non-compliance concerning the storage of gametes, medicines management, infection control and premises and facilities. There were also two 'other' areas of non-compliance regarding equipment and materials and donor screening. Since the inspection, the PR has provided evidence that the recommendations, made in the report, have been implemented and has committed to audit, where required, the effectiveness of those actions within the prescribed timescales.

1.9. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the positive comments made by patients in relation to their experience at the centre.

2. Decision

2.1. The panel congratulated the centre on the number of patients providing feedback by means of the 'Choose a Fertility Clinic' facility, available on the HFEA website.

2.2. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

4 March 2019

Interim Licensing Report

Centre name: City Fertility
Centre number: 0324
Date licence issued: 29 November 2016
Licence expiry date: 28 November 2020
Additional conditions applied to this licence: None
Date of inspection: 20 September 2018
Inspectors: Grace Lyndon, Louise Winstone, Sharon Fensome-Rimmer and Nichola Sugden (observer).
Date of Executive Licensing Panel: 26 February 2019

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. The focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experience at the centre.

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

The PR has provided evidence that the following recommendations have been implemented and has committed to audit, where required, the effectiveness of those actions within the prescribed timescales.

Major areas of non-compliance:

- The Person Responsible (PR) should ensure that effective consent is in place for all material in storage.
- The PR should ensure that medicines management procedures are followed in line with regulations and best practice.
- The PR should ensure that infection control practices are compliant with regulatory requirements and best practice guidance.
- The PR should ensure that the centre's premises and facilities are safe for staff and patients.

'Other' areas of practice that require improvement:

- The PR should ensure that CE marked medical devices are used where possible.
- The PR should ensure that the centre's assessment of the suitability of donors includes consideration of the risks of hepatitis A where necessary.

Information about the centre

City Fertility is located in London and has held a licence with the HFEA since 2012. The centre's licence was varied to include embryo testing in 2015 and was last renewed from 29 November 2016 for four years, after a licence renewal inspection in June 2016.

City Fertility provides a full range of fertility treatments.

The centre provided 266 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2018. In relation to activity levels this is a small centre.

Following issues identified during an inspection at another centre in late 2017, the executive undertook a review of activities across the sector in relation to the import of eggs, particularly donor eggs, for use in treatment in the UK. As a result of this review and extensive communications with City Fertility, the executive concluded that the centre had undertaken imports of donor eggs from Ukraine to the UK which were not compliant with General Direction 0006, because the amount of compensation given to the egg donors in Ukraine was not compliant with General Direction 0001. The PR was made aware of the executive's concerns and has engaged with the executive in providing requested information. The PR applied to the HFEA for Special Directions to export the donated eggs back to Ukraine. In relation to embryos already created using the eggs, Special Direction applications were made to simultaneously export and re-import them back into the UK in a compliant manner, so that the embryos can be lawfully used in treatment. These applications were considered and approved by the Statutory Approvals Committee on 29 November 2018.

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 July 2017 to 30 June 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported 18 cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between July 2017 and June 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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[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 to ensure 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: preparation for embryo transfer. The procedures observed were 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. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and the 'bring-forward' system were 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 partially effective, because the centre did not have effective consent for the storage of cryopreserved oocytes from one patient, the storage consent having expired in August 2018. Following the inspection, the PR informed the executive that the eggs have been removed from storage and that the incident was caused by the centre's process not being followed. Actions have been implemented to mitigate the risk of this occurring in the future (recommendation 1).

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 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, traceability, consent and medicines management.

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:

- 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;
- guidance issued on the prevention of Hepatitis A and Zika virus.

The centre is broadly effective in implementing learning from guidance because:

- recent changes to screening requirements involving Hepatitis A screening in certain cases (as discussed in Clinic Focus August 2017), have not yet been incorporated into the centre's practice (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 because:

- the drugs cupboard in the theatre containing non controlled medicines had been left unlocked overnight.
- the times that controlled drugs (CDs) are supplied, administered and discarded are not routinely documented in the CD book.

See recommendation 2.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Infection Control

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

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

- temporary closures are not used on the sharps bins;
- assembled sharps bins in use in theatre are not signed or dated by the member of staff that assembled them;
- the large yellow clinical waste bin situated outside was overflowing and could not be closed or locked;
- leaflets displayed in the centre, particularly in the recovery rooms, are not laminated;
- chairs in the recovery rooms for patients are not wipe clean.

See recommendation 3.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and 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 was reviewed in the course of the inspection. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because the pots used for the collection of sperm are CE marked for in vitro diagnostic use only and not for their designated use, i.e. as a class II medical device (recommendation 5).

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experiences of their clinic. Fifty five patients have provided feedback in the last 12 months regarding their treatment at City Fertility, giving an average 4.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected. Several patients provided individual comments to the HFEA complimenting the friendly staff at the clinic.

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

- treats patients with privacy and dignity;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;

- has staff that treat patients with empathy and understanding.

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's premises are not compliant because:

- The cryostore room has no extractor fan. There is a small extractor on the window, but this has been covered up with plastic bags. Since the inspection visit, the PR has confirmed that the covering has been removed and the air extractor is back in use. The PR has also committed to conducting a risk assessment of the safety and suitability of the cryostore.
- A large gas cylinder stored in the cylinder store was not chained to the wall.
- There are cardboard and plastic boxes of theatre consumables, some flammable, in the cylinder store.
- There is no safety checklist for the equipment used in theatre, to work through prior to procedures being undertaken, to provide assurance that the equipment is working and fit for purpose. Centre staff confirmed that equipment checks are performed by the anaesthetist each day prior to use, but that these checks are not documented.

See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to three major and five 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all recommendations were fully implemented.

On-going monitoring of centre success rates

The centre has not received any success rate related risk tool alerts in the last year.

Provision of information to the HFEA

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

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

Legal parenthood

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in June 2016, legal parenthood consenting processes were found to be robust.

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

Annex 1

Areas of practice that require the attention of the Person Responsible

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 made.

Critical areas of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None noted.			

‘Major’ area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Storage of gametes The centre does not have effective consent for the storage of cryopreserved oocytes from one patient. Schedule 3, 8(1) HF&E Act 1990 (as amended).	The PR should ensure that there is effective consent in place for all material in storage. Following the inspection, the PR informed the executive that the eggs have since been removed from storage and that the incident was caused by the centre’s process not being followed. Actions have been implemented to mitigate the risk of this occurring in the future. Within three months, the centre should carry out an	I acknowledge the presence of a set of oocytes being kept in storage beyond the effective storage consent. City Fertility has 625 sets of cryopreserved gametes or embryos in storage. An error was observed in less than 1% of stored gametes or embryos. Therefore, I do not feel that there is a significant issue with the procedures in place and our team’s ability to evaluate the consent for gametes and embryos in storage. A review of the procedures involved in relevant SOP has been	The inspector acknowledges the PR’s response. The PR has provided the required audit report demonstrating effective consent is in place for all material in storage. **No further action is required.**

	audit to ensure that the corrective actions implemented have been effective in ensuring compliance. A summary of this audit should be provided to the centre's inspector by 20 December 2018.	performed; the matter discussed in team and management meetings. Corrective measures have been made to ensure staff vigilance is heightened and time allocated to ensure that staff involved have sufficient freedom to concentrate on the task at hand and receive overview from senior team members. The root cause of the issue is because the patient has two sets of oocytes. One set of oocytes should have been discarded in August 2018, the consent for the remaining oocytes will elapse in January 2019. The 'bring forward' procedure was not followed to ensure that the oocytes were discarded in the correct time, but confusion was caused by attention being given the second set of 'in date' oocytes. An audit will be performed to assess the consent checking procedure for stored gametes and reported as requested.	

2. Medicines Management On inspection the following issues were noted: • the drugs cupboard in theatre containing non controlled medicines had been left unlocked overnight; • the times that CDs are supplied, administered and discarded are not routinely documented in the CD book. SLC T2. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. Misuse of Drugs (safe Custody) Regulations 2001. Controlled Drugs (Supervision of Management and Use) Regulations 2013.	The PR should ensure that medicines management procedures are in line with regulations and best practice guidelines. The PR should review the centre's security procedures for the drugs cupboard. A copy of the summary of the review should be sent to the centre's inspector by 20 December 2018. Following the inspection, the PR has provided evidence that issues raised with the CD register have been addressed. Within three months, the centre should carry out an audit to ensure that the corrective actions implemented have been effective in ensuring compliance. A summary of this audit should be provided to the centre's inspector by 20 December 2018.	The non-controlled drug cupboard left unlocked overnight: We have now added a point to remind staff to check and lock the non-controlled drug cupboard in the end of theatre closedown checklist record. The CDs An audit has been performed to ensure that the time that CDs are supplied, administered and discarded will be provided as requested. Consideration has been given to include a record of controlled drug handling in an electronic witnessing system to ensure accurate documentation.	The inspector acknowledges the PR's response and the implementation of this recommendation. A summary report of the audit has been provided. **No further action is required.**
3. Infection Control During the inspection, the following issues were noted;	The PR should ensure that infection control practices are compliant with best practice	I do not feel it appropriate to state that Infection Control in City Fertility is a point of Major	The inspector acknowledges the PR's response. The PR has also confirmed that the

• temporary closures are not used on the sharps bins; • assembled sharps bins in use in theatre are not signed or dated by the member of staff that assembled them; • the large yellow clinical waste bin situated outside, was overflowing and could not be closed or locked; • leaflets displayed in the centre, particularly in the recovery rooms, are not laminated; • chairs in the recovery rooms for patients are not wipe clean. DH Health Building Note 00-09: 'Infection control in the built environment' 2013.	guidance. The PR should review infection control practice at the centre. A summary report of this review, including the actions taken to achieve compliance, should be provided to the centre's inspector by 20 December 2018. Three months after the implementation of corrective actions, an audit should be undertaken. The audit summary should be sent to the centre's inspector by 20 March 2019.	concern to the authority. This label will give patients the incorrect perception that treatment at City Fertility could constitute a risk to their health. I acknowledge that staff may be at risk due to negligence with sharp bins not being closed correctly but feel that these points should be listed as other non-compliance. Sharp bin handling has been discussed in team, Quality Management and Management meetings. Clinical and scientific staff have been emailed and informed of the importance of correct handling of sharp safes. Relevant checklists have been modified to include assessment of individual sharp safes and the external clinical waste bin to ensure that they are kept in the correct manner. Check points have been introduced for an assessment of the external clinical waste storage bins. Checklists will	leaflets have been laminated. The issues noted reflect 'other' areas of practice that require improvement, indicating a departure from good practice. The PR is correct that this combination of several 'other' areas of non compliance have been grouped as one major area of non compliance, even though none of which on their own represent a significant concern. This is our standard practice for reporting. The audit of infection control practice, to ensure corrective actions have been effective in achieving and maintaining compliance, due by 20 March 2019 is awaited.

		be modified with an area to report issues with waste disposal, the state of the clinical waste receptacles and the frequency of waste collection to the Infection Control Officer. We have acquired the services of a new cleaning company; therefore, this document is not available at the moment. I can provide evidence, if required, once a review of all cleaning, waste disposable and activity checklists have been reviewed. The non-clean chairs in the recovery rooms have been replaced with wipe clean chairs. The previous chairs that were identified as an infection control risk were recently purchased and in place for the comfort of partners and visitors for patients lying in recovery beds. All patients having procedures are instructed to sit and recline on the beds not the chairs, the beds are maintained in line with good infection control practice.	

4. Premises and facilities During the inspection, the following issues were noted; • the cryostore has no extractor fan. There is a small extractor on the window but this has been covered up with plastic bags; • a large gas cylinder stored in the cylinder store was not chained to the wall; • there are cardboard and plastic boxes of theatre consumables, some flammable, in the cylinder store; • there is no safety checklist for the equipment used in theatre SLC T17; DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).	The PR should ensure that the centre's premises and facilities are safe for patients and staff. Following the inspection, the PR has confirmed that: • work has been performed to modify the bracket for the large gas cylinder and it is now securely chained. • the covering on the cryostore window has been removed and the air extractor is back in use. The PR has also committed to conducting a risk assessment on the cryostore. A copy of this assessment should be provided to the centre's inspector by 20 December 2018. The PR should provide an update regarding the resolution of the other two issues noted here, when responding to this report.	The Extractor fan –The single glazed window, in which the extractor fan was situated in the cryo-store, was covered in an attempt to maintain an acceptable temperature in the room during the summer. The unusually high temperatures and long hours of sunlight had caused an issue. The small extractor fan has been sufficient to reduce the build-up of oxygen during filling events; this was confirmed by Britannia Monitoring Systems when they installed a new oxygen monitor. A further assessment of the area has been requested from Britannia and a risk assessment will be provided as requested. Consideration has been made to change the extraction unit and install secondary glazing with purpose designed film to reduce the effect of direct sunlight. Quotes have been obtained and the work has been scheduled for a quiet period in the next four months. I acknowledge that a J sized	The inspector acknowledges the PR's response. The PR has provided a risk assessment on the cryostore, confirming that existing measures are satisfactory to maintain staff safety. The PR has also provided template safety checklists for equipment used in theatre. **No further action is required.**

		Nitrogen gas cylinder was not chained to the wall in the gas storage room. The cylinder is positioned by the entrance to the room and if not placed accurately in the holding bracket the chain can obscure closing the door. A staff member removed the chain to ensure the door closed effectively, the correct action would be to alert the appropriate team to look into the issue. The bracket has been modified to ensure that the cylinders sit in place easier and the issue with the chain inhibiting the door has been resolved. All relevant staff have discussed this in team meetings and the importance of reporting issues, as opposed to finding short term resolutions, was highlighted. The cylinder was connected to The Beacon Medes gas delivery system by copper piping and effectively securely place in the corner of the door recess. The risk of the item becoming dislodged and falling on a staff member is extremely slim. I do	

		acknowledge that the correct procedure was not observed and action has been taken. All surplus theatre consumables that were temporarily placed in the area have been removed from the gas storage room. Team members alerted in regards to the correct storage of items. Safety checklists for theatre equipment were made available after the inspection. The assessment of a variety of items used in the procedure and recovery rooms has been performed and the modified checklists will be attached to the audit that will be supplied to the authority in March 2019.	

‘Other’ areas of practice that requires improvement

‘Other’ areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. Equipment and materials The pots used for the collection of sperm are CE marked for in vitro diagnostic use only and not for their designated use, i.e. as class II medical device. SLC T30.	The PR should ensure that CE marked medical devices are used where possible.	n/a	Since the inspection, the PR has confirmed that appropriately CE marked sperm pots have been sourced and ordered. The existing stock will be used for diagnostic assays only. **No further action is required.**
6. Donor screening The centre’s donor screening practice does not include an assessment in all donors of hepatitis A infection risk or whether hepatitis A screening is necessary Clinic Focus, August 2017.	The PR should ensure that the centre’s donor screening practice incorporates recent best practice guidance regarding hepatitis A risk assessment and potential screening. Since the inspection, the PR has confirmed that the centre’s processes for donor screening are currently under review. A copy of the centre’s revised	See the attached SOP with details to our approach to adding Hepatitis A to the donor screening panel.	The inspector acknowledges the PR’s response. A revised SOP has been provided. **No further action is required.**

	SOP should be provided when responding to this report.		

Additional information from the Person Responsible
The City Fertility team strive to work with the authority to constantly review and improve our practices. We wish to ensure that the centre performs at the optimum level, which will enable us to ensure that the patient journey is as smooth as possible. We acknowledge that the points detailed in the inspection show areas where our processes need a review. The centre has made some immediate changes to our procedures and will implement all of the recommendations and provide the required information to the authority to demonstrate our compliance to the Code of Practice and guidance.