Executive Licensing Panel - minutes

Centre 0037 (Glasgow Royal Infirmary)

Interim Inspection Report

Wednesday, 11 March 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Anna Coundley Dan Howard	Director of Finance and Resources Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 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 fertility clinic at Glasgow Royal Infirmary has held a HFEA licence since 31 July 1992 and provides a full range of fertility services including storage and embryo testing.

1.2. The panel noted that, in the 12 months to 30 September 2019, the centre had provided 1712 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the period July 2018 to June 2019, show the centre's success rates are in line with the national averages, with the following exception;

- The clinical pregnancy rate for patients aged less than 40 years having frozen embryo transfer is significantly greater than the national average.

1.4. The panel noted that almost all fresh treatments at this centre use ICSI to fertilise eggs. The centre provides too few IVF treatments for the success rates for this treatment to be statistically relevant.

1.5. The panel noted that, in 2018, the centre reported 44 cycles of partner insemination, with three pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that, HFEA register data, between 1 July 2018 and 30 June 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be statically different to the 10% multiple live birth rate target for this period.

1.7. The panel noted that an unannounced inspection took place on 24 October 2019.

1.8. The panel noted that at the time of inspection there were three major areas of non-compliance concerning the quality management system (QMS), medicines management and legal parenthood. There were also four 'other' non-compliances relating to infection control, treating people fairly, premises and facilities and submission of data to the HFEA. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement all the recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.9. The panel noted that, the centre is well led and provides a good level of patient support.

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

2. Decision

2.1. 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

Richard Sydee

Date

18 March 2020

Interim Licensing Report

Centre name: Glasgow Royal Infirmary
Centre number: 0037
Date licence issued: 01January 2018
Licence expiry date: 31December 2021
Additional conditions applied to this licence: None
Date of inspection: 24 October 2019
Inspectors: Grace Lyndon (lead) and Andy Leonard
Date of Executive Licensing Panel: 11 March 2020

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. The current foci for an interim inspection are:

- **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 centre's multiple pregnancy rate reflects performance significantly better than that which would meet the multiple live birth rate target of 10%; and
- The clinical pregnancy rate for patients aged less than 40 years having frozen embryo transfer is significantly greater than the national average.

The centre is well led and provides a good level of patient support.

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

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR must ensure there are effective and robust audit processes.
- The PR should ensure that staff prescribing, administering and witnessing controlled drugs are aware of the relevant record keeping requirements.
- The PR should ensure that the marital status of all patients is established and is clearly and accurately documented in patient records.

'Other' areas of non-compliance:

- The PR should ensure that healthcare waste is labelled in line with waste management regulations.
- The PR should ensure that patients are treated fairly.
- The PR should ensure that compressed gases are stored safely and in line with best practice standards.
- The PR should ensure that IUI annual returns are submitted to the HFEA within the required timescales.

Information about the centre

The fertility clinic at Glasgow Royal Infirmary has held a HFEA licence since 31 July 1992. The centre provides a full range of fertility services including storage and embryo testing.

The centre provided 1712 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2019. In relation to activity levels, this is a large centre.

An application to vary the licence to reflect a change of Person Responsible (PR) was approved in July 2019.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period July 2018 to June 2019 show the centre's success rates are in line with national averages with the following exception: The clinical pregnancy rate for patients aged less than 40 years having frozen embryo transfer is significantly greater than the national average.

The inspection team notes that almost all fresh treatments at this centre use ICSI to fertilise eggs. The centre provides too few IVF treatments for the success rates for this treatment to be statistically relevant.

In 2018, the centre reported 44 cycles of partner insemination with three pregnancies. This represents a clinical pregnancy rate 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 1 July 2018 and 30 June 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be statistically different from the 10% multiple live birth rate.

[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; egg collections. All of the procedures observed were witnessed using an electronic witnessing system, with manual witnessing where necessary, 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, storage records and recent storage audits were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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 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: medicines management; infection control; legal parenthood; witnessing; consent to storage; traceability.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because the audits are not consistently robust:

- The centre's legal parenthood audit did not assess if counselling had been provided before consents were documented and failed to consistently record the marital status of the couples treated, so preventing assessment of whether the patients had completed the correct consent forms. Indeed, the audit failed to list as non-conformances; ten cases involving married patients in which the PBR form was not completed with no mention of the patients choosing not to; a further two cases in which PBR forms were completed by patients whose marital status was unknown, and the completion of PP and WP forms by all married patients.

- The centre has not undertaken audits of the management of controlled drugs and other medicines or of infection control practices in the last two years;
- The audit of the completion of the controlled drugs register looked at only 10 cases without justifying the sample size. The inspection team considered it unlikely that this sample size would effectively assess the centre's performance in this area of practice. Indeed the inspection team has noted concerns in the controlled drugs register, as detailed below in 'Medicines Management'.

Recommendation 1.

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:

- extension of storage consent
- donor screening
- imports of gametes and embryos from outside the EU/EEA
- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued versions of HFEA consent forms

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

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:

- Controlled drugs (CDs) in liquid form are discarded in a sharps bin within the theatre, without a denaturing kit being used.
- The times of supply, administration and discard of controlled drugs are not consistently completed, or countersigned, in the CD register.
- There were a number of illegible entries in the CD register.
- Entries in the CD register were corrected by alteration and over writing, rather by writing anew and footnoting to explain the reason for the change.
- The carry-over of drug stock from one page to another in the CD register is not consistently signed or witnessed by a second checker.

Recommendation 2.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore, requirements related to its use were not relevant at this inspection.

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:

- Three out of four sharps bins awaiting collection for disposal were not labeled with the start and end dates for the period of use or with the location of use.
- Suction tubes were observed on the resuscitation trolley and in the recovery area (one was unwrapped) and were not marked with expiry dates.
- There were cardboard boxes on the store room floor which inhibited adequate cleaning and posed an infection control risk.

Recommendation 4.

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 medical devices used throughout the laboratory was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Five patients have provided feedback to the HFEA regarding treatment at centre 0037 in the last 12 months, 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. Four patients confirmed that they had paid what they expected to.

There were also several negative comments regarding waiting times for treatments. The PR advised the inspectors that actions have already been taken to improve waiting times. The inspection team urges the centre to continue to monitor patient feedback to ensure the actions taken are effective.

No patients were available to speak to inspectors during this visit.

The centre's own audits of patient feedback in 2018 and 2019 were also reviewed. The centre requested feedback from approximately 100 patients for each of these audits and had very high response rates and high levels of patient satisfaction.

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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats 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 is generally compliant with HFEA requirements, except where discussed elsewhere in this report and because:

- Two large cylinders were unchained in the outdoor gas store. One cylinder inhibited access to already piped cylinders and the other remained upright and unsecured on a transportation trolley. There was also no signage on the gas store advising of the hazards associated with the storage of compressed gases (recommendation 5).
- The centre requests marriage and civil partnership certificates from same sex couples but not from heterosexual couples. In the opinion of the inspection team, this does not constitute 'treating people fairly' (recommendation 6).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to one major and seven 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in July 2017, the centre has received five risk tool alerts. Review of the centre's treatment data has indicated that these alerts have all been issued in error and no recommendations are required.

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 broadly compliant with requirements to submit information to the HFEA because it had not to submitted the annual return for partner inseminations in 2018 within the required period.

Recommendation 7.

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 renewal inspection in July 2017, legal parenthood consenting processes were found to be robust.

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. The inspection team also audited five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements. This was because the process for documenting a patient's marital status is not robust.

- When patients declare themselves as 'not married' to the person with whom they are attending for treatment, the centre does not ascertain if either patient is married to someone else.

- If a patient has not disclosed if they are married, the assumption is made by centre staff that the patient is single.

The centre's legal parenthood audit also lacked robustness, notably in assessing if the marital status of patients is documented and the correct legal parenthood consent forms completed, as discussed in 'Quality Management System' and recommendation 1.

Recommendation 3.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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 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 identified			

‘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 partly 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. Quality management system The centre’s procedures for audit and acting on the findings of audits are not consistently robust, for reasons detailed in the relevant area in the main body of this inspection report. SLC T32 & T36.	The PR must ensure there are effective and robust audit processes in place, to improve the quality and effectiveness of the service provided. The PR should conduct a review of the audit processes, to ensure that audits are performed against all regulatory requirements and that corrective actions are implemented, documented and reviewed for effectiveness. The PR should provide details of this review, with actions to be taken and timescales for	1.1 - A desk top review of internal audit process is currently being undertaken and a full report will be submitted, including details of findings and corrective actions, by the 31st of January 2020. 1.2 - A review of the legal parenthood consenting audit will be completed by the 24th of January. A further audit will be planned with revised scope and methodology and completed by 24th April 2020, as outlined in Area of Practice and Reference 3 within this	The Executive acknowledges the actions taken and the commitment to implement this recommendation. The PR has submitted the infection control and non-controlled drugs audits as requested, on 17 January 2020. Now these audits have been received, there is no further action required beyond the submission of audits due by 24 April 2020.

	implementation, to the centre's inspector when responding to this report. The PR should review the most recent legal parenthood consenting and medicines (CD) management audits, taking into account the findings in this report, and should develop and submit to the centre's inspector by 24 January 2020, plans for these audits, including revised scope and methodology. Both should be carried out more frequently than at present. The centre should also undertake audits of non-controlled drugs and infection control practices. Reports of these audits should be provided to the centre's inspector by 24 January 2020.	interim report. 1.3 - A review of the medicines management audit will be undertaken in conjunction with the review of controlled drug management by the 24th of January 2020 as outlined in Area of Practice and Reference 2 within this interim report. Timescales will be in keeping with those outlined in this report. 1.4 - Audits of non-controlled drugs and infection control practices had been undertaken prior to inspection and can be submitted upon request.	
2. Medicines Management CDs in liquid form are discarded in a sharps bin within the theatre, without a denaturing kit being used. The completion of the CD	The PR should ensure that staff prescribing, administering and witnessing controlled drugs are aware of the record keeping requirements related to these activities.	A full review of controlled drug management will be conducted, supported by the local Anaesthetic Department and Lead Consultant Anaesthetist. A report of findings and corrective actions	The Executive notes the PR's response to this non-compliance and the work undertaken in response to the inspection report. After discussions with the PR,

register was non-compliant for a number of reasons, detailed in the 'Medicines Management' area in the main body of this inspection report. Association of Anaesthetists 'Guidelines Controlled drugs in peri-operative care 2019' (section 4). Department of Health (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (sections 4.7.1.1., 4.7.1.2., 4.7.1.3. and 4.7.1.4.).	The PR should review the compliance of CD management practices at the centre against CD regulations and best practice guidelines, including, but not exclusively, the issues identified in this report. A summary report of this review, including any corrective actions, staff training, with timescales, should be provided to the centre's inspector by 24 January 2020. Three months after the implementation of corrective actions, the PR should re-audit to ensure that the corrective actions have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 24 April 2020.	will be provided by the 24th of January and an audit of changes implemented will be provided by the 24th of April, in keeping with the timescales set out by the interim report.	an extension to 14 February 2020 was granted, and the review of controlled drugs management was received as agreed. There is no further action required beyond the submission of summary report of this audits due by 24 April 2020.
3. Legal Parenthood The process for documenting a patient's marital status is not robust because:	The PR should ensure that the marital status of all patients and partners, is clearly and accurately documented in	The following corrective actions were carried out immediately post inspection:	The Executive acknowledges the actions taken and the commitment to implement this recommendation.

• When patients declare themselves as 'not married' to the person with whom they are being treated, the centre does not ascertain if either patient is married to someone else; • If a patient has not disclosed if they are married, it is assumed by centre staff that they are single; • The centre's legal parenthood audit also lacks robustness, as discussed in 'Quality Management System' and recommendation 1. Failure to identify a patient couple's marital status accurately and to act on it appropriately, may undermine the quality and effectiveness of the consents to legal parenthood provided. Section 44(1) of Part 2 of the HF&E Act 2008 (as amended). SLC T61.	patient records. The PR should also ensure that relevant staff understand the impact of marital status on legal parenthood consenting. The PR should review the process for assessing and documenting marital status and provide a summary of actions taken to address this recommendation when responding to this report. The PR should also ensure training is provided to relevant staff regarding legal parenthood and the impact of marital status. The centre's inspector should be advised by 24 January 2020 regarding the completion of this training. Three months after implementation, the PR should audit legal parenthood consenting, to determine the effectiveness of the actions or to take further actions if necessary. A report of the audit should be submitted to the centre's inspector by 24 April 2020.	3.1 - A review of all SOP's and forms relevant to legal parenthood has been completed and key areas of improvement identified in keeping with recommendations of this report. 3.2 - Forms utilised for documentation of marital status have been amended to ensure accurate identification and recording of marital status. 3.3 - Forms utilised for the identification and documentation of acceptance or decline of counselling have been revised to clearly identify the date that patients have received a meaningful opportunity to undertake counselling prior to completion of consent forms. 3.4 - Legal parenthood patient information has been updated to reflect impact of marital status on legal parenthood consenting. 3.5 - Legal parenthood and consent SOP has also been	No further action beyond submission of audit due by 24 April 2020.

		updated 3.6 - Training and communication has been provided to all relevant staff on legal parenthood and the impact of marital status, including group review and training in the updated SOP, forms and patient information. 3.7 - Changes implemented will be audited and a report submitted by the 24th of April 2020 in keeping with the timescales set out in the interim report.	

‘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.

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
4. Infection control • Three out of four sharps bins awaiting collection for disposal were not labeled with the start and end dates for the period of use or with the location of use; • Suction tubes on the resuscitation trolley and in the recovery area (one uncovered) were not marked with expiry dates; • There were cardboard boxes on the store room floor and under shelving, which inhibited adequate cleaning and pose an infection control risk. SLC T2 and T23 NICE [NG139] (2017) ‘Healthcare-associated	The PR should ensure that healthcare waste is labelled in line with waste management regulations and that all stored equipment and materials are stored off the floor. The PR should also ensure that all rescue and emergency equipment are appropriately stored and labelled with their batch number and expiry date. The PR should provide a summary of actions taken to address this recommendation when responding to this report.	All points were rectified immediately post inspection and staff communication carried out to ensure no further deviation from waste management and infection control procedures.	The Executive acknowledges the new implementations the PR’s has already made and the commitment to complete this non-compliance. No further action required.

infections: prevention and control in primary and community care'. (section 1.1.5.2). DH Health Building Note 00-09: 'Infection control in the built environment' 2013 (section 3.105).			
5. Treating people fairly The centre requests marriage certificates for same sex couples but not for heterosexual couples. This does not constitute 'treating people fairly'. CoP guidance 29.9	The PR should ensure that patients are treated fairly. The PR should ensure that marriage certificates, if required, are required from all married couples and not just exclusively from those in same sex marriages. The PR should provide a summary of actions taken to address this recommendation when responding to this report.	This information has been copied from PR comments in the Additional comments table below: 'In ensuring compliance with licence condition T17, it is local policy to request documented evidence in the event that any patient has changed their name. this includes all patients who have been married or entered a civil partnership which has resulted in a change of name or patients who have changed their name via deed poll, regardless of sexual orientation. These cases noted in this report were identified during an audit of patients who had undergone treatment with donor sperm. Within this treating centre, the patient	The Executive notes the PR's comments regarding this non-compliance. The Executive cannot reconcile the PR's response with the extensive discussions that took place at the inspection, with the PR, clinical staff and the quality manager. The inspection team were informed that same sex couples are routinely requested to provide their marriage/civil partnership certificates and heterosexual couples are not. The inspection team's conclusion was evidenced by information sought from both a review of patient records provided by the centre and further information provided by

		population is mostly same-sex women. Therefore, a disproportionate representation was observed in this instance. Centre 0037 is committed to ensuring all patient's are treated fairly and in keeping with the Equality Act. The centre requests that this 'other' area of non-compliance is removed from this interim report.'	the centre staff. No further action required
6. Premises and facilities Two large cylinders were unchained in the outdoor store. One cylinder inhibited access to already piped cylinders and the other remained upright and unsecured on a transportation trolley. There was no signage on the stored gases cage advising the safety hazard. SLC T17. British Compressed Gases Association (BCGA) 2016 Code of Practice 44, 'The Storage of gas cylinders' 6 (6.2).	The PR should ensure that compressed gases are stored safely and in line with best practice standards. The PR should implement this recommendation immediately and inform the centre's inspector of the actions taken when responding to this report.	The following corrective actions were carried out immediately post inspection: 6.1 - Unsecured cylinders were appropriately secured in keeping with guidance. 6.2 - Safety hazard signage specific for gas cylinder storage was reviewed and although present, had been dislodged from the original position and not clearly visible. New safety hazard signage was immediately ordered. 6.3 - The critical gas SOP was reviewed and found to be in keeping with national guidance	The Executive acknowledges the PR's commitment to implementing this recommendation and the actions that have already been undertaken. No further action required

DH (2006) Medical gases Health Technical Memorandum 02-01: Medical Gas Pipeline Systems, Part B		therefore the SOP was panelled at a meeting with key users where safe storage of gas cylinders was highlighted as a reminder to all staff.	
7. Submission of data to the HFEA The centre failed to submit their IUI data for 2018 within the required period. General Direction 0005	The PR should ensure that IUI annual returns are submitted to the HFEA within the required timescales. The centre's inspector should be informed of the actions taken to implement this recommendation in the PR's response to this report.	The centre was unaware that the IUI annual return data had not been submitted. On investigation, it was noted on the HFEA Clinic Portal that the submission was attempted in advance of the deadline, on the 5th of February but was 'unsubmittable'. The centre will ensure future data submission is received by the HFEA in advance of deadlines.	24 October 2019: The inspection team notes that the IUI treatment data for 2018 was submitted by the PR on 30 September 2019. No further action is required beyond the PR taking actions to ensure data is submitted in a timely manner in future.

Additional information from the Person Responsible

Pregnancy Outcomes (Page 3) – the centre has reintroduced IVF and from April 2019 to date, 52 cycles of IVF treatment have been performed. A fertilisation rate of 58.3% has been achieved with a utilisation rate of 49.4% and on-going clinical pregnancy rate of 51.4% per embryo transferred. The centre requests the sentence stating too few IVF for success rates to be statistically significant be amended to reflect current IVF rates.

Quality Management System (page 4) the interim report has found that this audit failed to list 10 cases involving married patients in which the PBR for was not completed with no mention of the patients choosing not to. All 10 patients had undergone IUI treatment only, therefore completion of PBR was not applicable. The centre requests that this interim report is amended to reflect this.

Quality Management System (Page 5) - the interim report states that the centre has not undertaken audits of management of controlled drugs and other medicines or of infection control practices in the last two years. The centre has conducted audits in these areas as per internal audit schedule. The centre also provided evidence of both internal and external peer infection control audits prior to the insepction. The centre requests that this interim report is ammended to reflect this. However, the centre accepts that audit process and methodology will be reviewed and updated as outlined above.

5. Treating People Fairly (Page 10) - The PR response column has not been formatted to allow editing, therefore the response has been included below:

In ensuring compliance with license condition T71, it is local policy to request documented evidence in the event that any patient has changed their name. This includes all patients who have been married or entered a civil partnership which has resulted in a change of name or patients who have changed their name via deed poll, regardless of sexual orientation. The cases noted in this report were identified during an audit of patients who had undergone treatment with donor sperm. Within this treating centre, this patient population is mostly same-sex women. Therefore, a disproportionate representation was observed in this instance. Centre 0037 is committed to ensuring all patients are treated fairly and in keeping with the Equality Act. The centre requests that this 'other' area of non-compliance is removed from this interim report.

Thank you for your additional comments. Many areas of practice are reviewed during an inspection at a centre. The inspection team gains an overview of the centre and relies on the information and documentation supplied by centre staff prior and during the inspection, to provide the inspection team with an insight to how the centre works.

Pregnancy Outcomes
The Executive notes the PR's comments in relation to IVF cycles. The number of licenced cycles undertaken at the centre over the last year up to 30 September 2019 was 1712. In this instance, 52 IVF cycles are a very small proportion (3%) of all treatment cycles undertaken. The PR's comment is noted regarding the fertilisation rate and the ongoing pregnancy rate per embryo transferred.

Quality Management system
The Executive acknowledges the changes the PR's is making and the commitment to make improvements to the quality management system to provide clarity and robustness. After discussions held with the quality manager during the inspection regarding the legal parenthood audit, no explanation was given to explain the audit methodology or results. The Executive is aware PBR forms are not relevant to patients undergoing IUI treatments. During the inspection, it was reviewed that in some cases there was some inconsistencies in practices which showed in some cases, married patients undergoing IUI treatments had used the PBR form, this was noted in the patients notes, however, this is not a requirement for this consent form.

The inspection team were concerned that staff do not understand the requirements and processes entailed in consenting and urge the PR to ensure that all staff members are trained in the correct use of consent forms.

The Executive cannot reconcile with the PR's comments that the requested medicines audits were made available to the inspection team during the inspection. The Executive requested to review the documents, but they were not made available to the inspection team.

Treating people fairly (5)
Please see Inspection team's response to the PR's statement within the main body of the report.