Executive Licensing Panel - minutes

Centre 0254 (The Agora Gynaecology and Fertility Centre)

Interim Inspection Report

Tuesday, 26 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Yvonne Akinmodun Laura Riley	Director of Strategy and Corporate Affairs Head of Human Resources Head of Regulatory Policy
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 The Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has held a treatment and storage licence with the HFEA since 2007. The centre provides a full range of fertility services to self-funded and NHS patients. The centre is also registered with the Care Quality Commission (CQC). The last CQC inspection was in 2013, and all standards inspected against were met on that occasion.

1.2. The panel noted that, in the 12 months to 30 June 2019, the centre had provided 901 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, HFEA register data, for the period May 2018 to April 2019, 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 2018, the centre reported 31 cycle of partner insemination, with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, for the period May 2018 to June 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 20 August 2019.

1.7. The panel noted that at the time of inspection there were two major areas of non-compliance concerning medicines management and legal parenthood. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement both recommendations made in the report. In respect of the non-compliance regarding legal parenthood, the PR will submit a summary report of the follow-up audit in February 2020. It was also noted that a senior member of the nursing staff will attend a medicines management course in April 2020.

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

2. Decision

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

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

4 December 2019

Interim Licensing Report

Centre name: The Agora Gynaecology and Fertility Centre
Centre number: 0254
Date licence issued: 1 February 2018
Licence expiry date: 31 January 2022
Additional conditions applied to this licence: None
Date of inspection: 20 August 2019
Inspectors: Sandrine Oakes (lead), Louise Winstone, Janet Kirkland MacHattie
Date of Executive Licensing Panel: 26 November 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. 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 – pre review of draft by PR

The inspection team recommends the continuation of the centre's licence.

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

Major areas of non-compliance:

- The Person Responsible (PR) should ensure that practices regarding the safe custody and access to controlled drugs (CD) are compliant with regulatory requirements and best practice guidance.
- The PR should ensure that legal parenthood consenting practice and procedures and auditing are robust and compliant with CoP requirements and guidance.

Information about the centre

The Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has held a Treatment and Storage licence with the HFEA since 2007. The centre provides a full range of fertility services to self-funded and NHS patients.

The centre provided 901 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2019. In relation to activity levels this is a medium centre.

The centre is also registered with the Care Quality Commission (CQC). The last CQC inspection was in 2013, all standards inspected against were met on that occasion.

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 2018 to April 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 31 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our Quality Management Systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our Quality Management Systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

Between May 2018 and April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents a performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

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. This was witnessed using an electronic witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures 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 centre's report of the audit for all cryopreserved gametes and embryos, the accuracy of storage logs and consent records 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: 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: legal parenthood; witnessing; consent to storage; traceability; medicines management; infection control.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the exception noted in the legal parenthood section of this report.

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:

- leadership
- patient support
- information provision
- implications of treatment and consent
- extension of storage consent
- consent
- data submission to the HFEA
- the use of CE marked medical devices
- the centre's audit of legal parenthood

The centre has been effective in ensuring compliance with guidance issued by the HFEA with the exception noted in the legal parenthood section of this report.

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:

- access to CD is not restricted to appropriate, designated and legally authorised personnel in that two doctors (including the PR who is acting as the Controlled Drugs Accountable Officer (CDAO)) are named authorised staff; and a spare key to the CD cupboard is kept locked at [redacted].

See recommendation 1.

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.

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 compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all medical devices 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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their centre. Only 28 patients have provided feedback in the last 12 months, giving an average 4.5-star rating to the centre. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The inspection team discussed this with the PR. She felt the clinic was actively seeking patients' feedback and promoting the HFEA website. The process was reviewed three months ago and it will be kept under review. The inspection team was reassured that the PR is taking appropriate actions to remedy the low feedback rate.

The centre's own most recent patient survey responses (June-July 2019) were reviewed. The responses measured 'patient experience' over three different stages of the patient care journey. The majority of patients were satisfied with 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:

- 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 fully compliant with HFEA requirements, with the exceptions noted elsewhere in the report.

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 critical, four major and five 'other' areas of non-compliance or poor practice.

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

On-going monitoring of centre success rates

Since the last renewal inspection in 2017, the centre has not received any performance related risk tool alerts.

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 the last inspection in 2017, legal parenthood consenting processes were found to be robust.

On this inspection, we reviewed the centre's most recent audit of consent to legal parenthood and we found it lacked robustness in that it had not been performed according to the method specified by the HFEA.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff. Four randomly selected sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team and the following issues were noted:

- in two cases, the marital status of the patients being treated was not clear;

- in one case (married couple), the WP ('Your consent to your partner being the legal parent') and PP ('Your consent to being the legal parent') consent forms were both completed and signed by the patient in 2015 when the PP form should have been completed by the spouse. The couple had a live birth. The couple returned for further treatment in 2018 and subsequently had a live birth; however, there was no evidence that the consent forms had been reviewed taking into consideration the marital status of the couple; the WP and PP forms anomalies were not rectified and a PBR form ('Your consent to being registered as the legal parent in the event of your death') was not completed.

The inspection team was concerned by the lack of consistency between staff regarding the consent process in that, in the case of patients returning for further treatment, a check of the accuracy of consents was not performed in all cases.

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.

See recommendation 2.

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			

‘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. Medicines Management On inspection, the following issue was noted: ▪ access to CD is not restricted to appropriate, designated and legally authorised personnel in that two doctors (including the PR who is acting as the CDAO) are named authorised staff and a spare key to the CD cupboard is kept locked at [redacted].	The PR should ensure that practices regarding the safe custody and access to CD are compliant with regulatory requirements and best practice guidance. The PR should review the current practices with regards to the safe custody and access to CD. The PR should provide a summary report of this review to the centre’s inspector by 20 November 2019.	The PR has reviewed current practice for the safe custody and access to CD and a full report will be provided by November 20th. The Medicines Management SOP has been revised and crossed referenced against current regulatory requirements including the Department of Health document for the Safer Management of Controlled Drugs. The revised SOP complies with all current regulatory requirements and best practice guidance and	The executive acknowledges the PR’s response, review of processes and actions taken in implementing this recommendation. The PR has provided a summary of her initial review of this area of practice. Further information is to be provided by 20 November 2019. **Further action required.**

SLC T2, sections 2.4, 3.14, 4.1.1, 4.5.2 and 4.5.4 Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007).		includes a list of appropriate, designated and legally authorised personnel who can access the CD. Access is limited to Registered Nurses, Registered Midwives and staff working under their authority (eg ODP). The key safe for the key to the CD cupboard has been moved to a more suitable location within a structurally solid wall which can only be accessed by appropriate, designated and legally authorised personnel through a door with a keypad entry. The key safe houses two copies of the CD cupboard key. A third copy of the CD cupboard key is kept in a different location within the clinic in a key safe within a structurally solid wall and is also only accessible by appropriate, designated and legally authorised personnel through a door with a keypad entry.This copy would only be accessed in the event of a major disaster affecting the primary keysafe.	

2. Legal parenthood On inspection, the following issues were noted: ▪ the centre's own legal parenthood audit conducted lacked robustness in that it had not been performed according to the method specified by the HFEA; ▪ in two cases, the marital status of the patients being treated was not clear; ▪ in one case (married couple), the WP and PP consent forms were both completed and signed by the patient in 2015 when the PP form should have been completed by the spouse. The couple had a live birth. The couple returned for further treatment in 2018 and subsequently had a live birth; however, there was no evidence that the consent forms had	The PR should ensure that legal parenthood consenting practice and procedures and auditing are robust and compliant with CoP requirements and guidance. The PR should review practices and procedures relating to legal parenthood consenting, including the process for patients returning for further treatment; a summary report of this review should be provided to the centre's inspector by 20 November 2019. The PR should review whether the issues identified in this report had been identified in a previous audit and whether any corrective actions had been recommended and implemented. The PR should provide the findings of that review to the centre's inspector by 20 November 2019. The PR should ensure that legal parenthood is audited as	A full review of all practice and procedures relating to legal parenthood has been carried out and the following changes in practice implemented. A FET checklist is now in use by all nursing staff to ensure compliance. All returning patients are asked to complete new CD and WOC forms. Marital status is confirmed and new legal parenthood consent forms are completed to show this has been reassessed. Counselling is also offered and documented. All staff have been reminded of the need to complete PBR forms for all married patients with frozen embryos created using donor gametes as PBR forms were not necessarily in use when the embryos were created, as in the case identified in the report.	The executive acknowledges the PR's response, review of processes and actions taken in implementing this recommendation The PR has provided a summary of her initial review of this area of practice. Further information is to be provided by 20 November 2019. The PR will provide a summary report of the issues identified in this report by 20 November 2019. The PR will provide a summary report of a legal parenthood audit of all remaining records since 2017 by 20 November 2019. Three months after implementation of corrective actions, the PR will provide a summary report of legal parenthood practice and procedures by 20 February 2020. **Further actions required**.

been reviewed taking into consideration the marital status of the couple; the WP and PP forms anomalies were not rectified and a PBR form was not completed. The inspection team were concerned that, if the couple had been unmarried, this would have potentially posed a legal challenge. ▪ the inspection team was concerned by the lack of consistency between staff regarding the consent process in that, in the case of patients returning for further treatment, a check of the accuracy of consents was not performed in all cases. The inspection team has noted the recurrence of a non-compliance related to record keeping (the marital status could not be determined). On discussion, staff explained	per recommended scope and methodology to ensure compliance. Since the inspection, the PR has provided a legal parenthood audit which follows the recommended scope and methodology. Of 60 patients randomly audited, where consent to legal parenthood was required (IVF, ICSI and /or DI) using donor sperm in the last two years, no anomalies were found. To ensure full compliance, the PR should conduct a legal parenthood audit of all remaining records since 2017; especially but not exclusively, records where a live birth occurred and ascertaining marital status; a summary report of this audit and actions taken to remedy any anomalies found should be provided to the centre's inspector by 20 November 2019.	A legal parenthood audit of 60 cycles has already been performed with 100% compliance. A full audit of all cycles from 2017 will be completed by 20th November and a full report of the review of legal parenthood practice will also be provided at that time.	

that the cases audited by the inspection team were prior to the introduction of a new checklist where marital status is now evidenced; but that, for returning patients, the new form may have not been used. Section 44(1) of Part 2 of the HF&E Act 2008, CE(14)01, CoP 31.9, 'Consent forms: A Guide for Clinic Staff', HFEA (2019).	Three months after the implementation of corrective actions, the PR should audit legal parenthood practice and procedures to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this follow-up audit should be provided to the centre's inspector by 20 February 2020.		

‘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
None			

Additional information from the Person Responsible
The PR on behalf of all the team at The Agora Clinic thank the inspectors for a thorough and constructive inspection. We look forward to building on your feedback. The team was inspired and motivated in their continued endeavour of excellence in patient care and satisfaction.

Executive Update for Executive Licensing Panel
26 November 2019

Centre number	0254
Centre name	The Agora Gynaecology and Fertility Centre
Person Responsible	Dr Carole Gilling-Smith

Update on recent actions to address recommendations in the interim inspection report

1. The executive submitted papers to the Executive Licensing Panel (ELP) secretary on 21 October 2019 for the interim inspection that took place on 20 August 2019.

2. The PR at centre 0254 submitted further information on 19 November 2019 regarding actions taken to address two major non compliances detailed in the interim inspection report.

3. The inspection team's consideration of these actions is included in the executive review column in Annex 1 below. Comments are dated 19 November 2019 and are in bold text.

4. The inspector confirms that there is no change to the licensing recommendation set out in the interim inspection report.

Sandrine Oakes
Clinical Inspector
21 November 2019

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			

‘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. Medicines Management On inspection, the following issue was noted: ▪ access to CD is not restricted to appropriate, designated and legally authorised personnel in that two doctors (including the PR who is acting as the CDAO) are named authorised staff and a spare key to the CD cupboard is	The PR should ensure that practices regarding the safe custody and access to CD are compliant with regulatory requirements and best practice guidance. The PR should review the current practices with regards to the safe custody and access to CD. The PR should provide a summary report of this review to the centre’s	The PR has reviewed current practice for the safe custody and access to CD and a full report will be provided by November 20th. The Medicines Management SOP has been revised and crossed referenced against current regulatory requirements including the Department of Health document for the Safer Management of Controlled Drugs. The revised SOP	The executive notes the PR’s response, review of processes and actions taken in implementing this recommendation. The PR has provided a summary of her initial review of this area of practice. Further information is to be provided by 20 November 2019. **Further action required.**

kept locked at [redacted]. SLC T2, sections 2.4, 3.14, 4.1.1, 4.5.2 and 4.5.4 Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007).	inspector by 20 November 2019.	complies with all current regulatory requirements and best practice guidance and includes a list of appropriate, designated and legally authorised personnel who can access the CD. Access is limited to Registered Nurses, Registered Midwives and staff working under their authority (eg ODP). The key safe for the key to the CD cupboard has been moved to a more suitable location within a structurally solid wall which can only be accessed by appropriate, designated and legally authorised personnel through a door with a keypad entry. The key safe houses two copies of the CD cupboard key. A third copy of the CD cupboard key is kept in a different location within the clinic in a key safe within a structurally solid wall and is also only accessible by appropriate,	**19 November 2019: The PR provided evidence that she reviewed the current practices with regards to the safe custody and access to CD. The PR provided a new CD SOP, which incorporates the regulatory requirements and best practice guidance as recommended.** **The PR also informed the executive that a senior member of the nursing team is to attend a medicines management course in April 2020.** **No further actions are required.**

		designated and legally authorised personnel through a door with a keypad entry.This copy would only be accessed in the event of a major disaster affecting the primary keysafe.	
2. Legal parenthood On inspection, the following issues were noted: ▪ the centre's own legal parenthood audit conducted lacked robustness in that it had not been performed according to the method specified by the HFEA; ▪ in two cases, the marital status of the patients being treated was not clear; ▪ in one case (married couple), the WP and PP consent forms were both completed and signed by the patient in 2015 when the PP form should	The PR should ensure that legal parenthood consenting practice and procedures and auditing are robust and compliant with CoP requirements and guidance. The PR should review practices and procedures relating to legal parenthood consenting, including the process for patients returning for further treatment; a summary report of this review should be provided to the centre's inspector by 20 November 2019. The PR should review whether the issues identified in this report had been	A full review of all practice and procedures relating to legal parenthood has been carried out and the following changes in practice implemented. A FET checklist is now in use by all nursing staff to ensure compliance. All returning patients are asked to complete new CD and WOC forms. Marital status is confirmed and new legal parenthood consent forms are completed to show this has been reassessed. Counselling is also offered and documented.	The executive notes the PR's response, review of processes and actions taken in implementing this recommendation The PR has provided a summary of her initial review of this area of practice. Further information is to be provided by 20 November 2019. The PR will provide a summary report of the issues identified in this report by 20 November 2019. The PR will provide a summary report of a legal parenthood audit of all remaining records since 2017 by 20 November 2019.

have been completed by the spouse. The couple had a live birth. The couple returned for further treatment in 2018 and subsequently had a live birth; however, there was no evidence that the consent forms had been reviewed taking into consideration the marital status of the couple; the WP and PP forms anomalies were not rectified and a PBR form was not completed. The inspection team were concerned that, if the couple had been unmarried, this would have potentially posed a legal challenge. ▪ the inspection team was concerned by the lack of consistency between staff regarding the consent	identified in a previous audit and whether any corrective actions had been recommended and implemented. The PR should provide the findings of that review to the centre's inspector by 20 November 2019. The PR should ensure that legal parenthood is audited as per recommended scope and methodology to ensure compliance. Since the inspection, the PR has provided a legal parenthood audit which follows the recommended scope and methodology. Of 60 patients randomly audited, where consent to legal parenthood was required (IVF, ICSI and /or IUI) using donor sperm in the last two years, no anomalies were found. To ensure full compliance, the PR should conduct a	All staff have been reminded of the need to complete PBR forms for all married patients with frozen embryos created using donor gametes as PBR forms were not necessarily in use when the embryos were created, as in the case identified in the report. A legal parenthood audit of 60 cycles has already been performed with 100% compliance. A full audit of all cycles from 2017 will be completed by 20th November and a full report of the review of legal parenthood practice will also be provided at that time.	Three months after implementation of corrective actions, the PR will provide a summary report of legal parenthood practice and procedures by 20 February 2020. **Further actions required**. **19 November 2019: the PR provided the findings of her review of practices and procedures and a summary report of all remaining records since 2017 relating to legal parenthood consenting. The review included corrective actions and a re-audit in January 2020.** **The centre has taken actions to implement all aspects of this recommendation. The inspector will follow up with the centre to ensure actions are complete and robust.**

process in that, in the case of patients returning for further treatment, a check of the accuracy of consents was not performed in all cases. The inspection team has noted the recurrence of a non-compliance related to record keeping (the marital status could not be determined). On discussion, staff explained that the cases audited by the inspection team were prior to the introduction of a new checklist where marital status is now evidenced; but that, for returning patients, the new form may have not been used. Section 44(1) of Part 2 of the HF&E Act 2008, CE(14)01, CoP 31.9, 'Consent forms: A Guide for Clinic Staff', HFEA (2019).	legal parenthood audit of all remaining records since 2017; especially but not exclusively, records where a live birth occurred and ascertaining marital status; a summary report of this audit and actions taken to remedy any anomalies found should be provided to the centre's inspector by 20 November 2019. Three months after the implementation of corrective actions, the PR should audit legal parenthood practice and procedures to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this follow-up audit should be provided to the centre's inspector by 20 February 2020.		**No further actions beyond the submission of the summary report of the follow-up audit due by 20 February 2020.**

‘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
None			