Executive Licensing Panel - minutes

Centre 0333 (Harley Street Fertility Clinic)

Interim Inspection Report

Thursday, 16 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Anna Quinn Laura Riley	Head of Intelligence Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Richard Chamberlain	Temporary Committee Clerk
External adviser		
Observers	Catherine Burwood	Senior Governance 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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included an interim inspection report with the Person Responsible (PR) response, and licensing minutes for the last three years:

- 6 October 2017 – Inspection to investigate whistle-blower concerns
- 20 May 2016 – Renewal inspection report
- 29 January 2016 – Progress report
- 30 October 2015 – Inspection report

1.2. The panel noted that the Harley Street Clinic is located in Central London and has held a Treatment (including embryo testing) and Storage licence with the HFEA since July 2014. It provides a full range of fertility services and is registered with the Care Quality Commission (CQC).

1.3. The panel noted that the centre provided 278 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 38 February 2018. In relation to activity this is a small centre.

1.4. The panel noted that in 2017, the centre reported 50 cycles of partner insemination with three clinical pregnancies. This is likely to represent a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that between December 2016 and November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 28%. This represents performance that is likely to be statistically greater than the 10% multiple live birth rate target.

1.6. The clinic was inspected on 16 August 2018.

1.7. This clinic has had a history of engagement with the HFEA's Compliance and Enforcement Policy. The panel noted that in June 2015 the CQC received a complaint from a patient regarding the centre's medicines management procedures and numerous other concerns relating to patient safety. As a result, an unannounced inspection was undertaken the same month by a HFEA inspection team. Whilst the inspection team could not find any evidence to support the whistle blower's allegations, a number of concerns were raised by the unannounced inspection, the most significant of which related to medicines management and sedation practices for surgical procedures at the centre.

1.8. The panel noted that in accordance with the HFEA Compliance and Enforcement Policy, a management review was conducted at which the findings of the unannounced inspection were evaluated. It was considered appropriate to conduct a further, announced, full inspection of all the centre's activities to determine the current level of compliance in all areas. This was carried out in July 2015.

1.9. The panel noted seven major areas of non-compliance were identified on these two inspections. The Person Responsible (PR) and her team engaged fully with the HFEA; information requested, and evidence of actions taken were provided in a comprehensive and timely manner.

1.10. The panel noted that in consideration of the inspection history of this centre, the level of engagement and commitment to achieving compliance demonstrated by the centre team, and because a comprehensive inspection of all licensable activities had been performed in July 2015, a standard licence renewal inspection was not considered necessary. Instead, the February 2016 renewal inspection visit focused on continuing compliance with the recommendations that were made in the previous inspection report. Two major and three 'other' areas of non-compliance were noted. These recommendations were implemented within the required timeframes and the centre's licence was renewed for four years without any conditions.

1.11. On 8 June 2017, concerns about the centre were raised with the CQC anonymously, via their website. To consider the allegations raised, an additional management review and unannounced inspection was conducted in June 2017. At this inspection, the inspection team concluded that there was no evidence to support the allegations, however, recommendations for improvement were made in relation to one critical, two major and one 'other' areas of non-compliance. The panel noted that the PR provided information and evidence that all of the recommendations were fully implemented within the required timescales. However, on this most recent inspection, it was noted that recommendations had not been implemented in relation to medicines management and infection control.

1.12. The panel noted that at the time of the latest inspection on 16 August 2018 there were four areas of critical non-compliance:

- **Multiple births** - the centre's multiple clinical pregnancy rate has been at 26% since October 2014 and is now 28% meaning that the multiple birth target of 10% is likely to be exceeded.
- **Consent to storage of cryopreserved materials** - the centre does not have an active system for managing storage consent expiry. The electronic data system, used by the centre, does not contain data relating to the date of sample storage; the consented storage period or the expiry of the consented storage period. The inspection team are not assured that the centre recognises the gravity of this non-compliance.
- **Medicines management** - examples of non-compliance were as follows: A significant number of entries in the controlled drugs register are illegible. On some pages the strengths and volumes of the drug is not recorded. The carry-over of drugs from one page to another is not recorded or witnessed. The controlled drugs register only contains single patient identifiers (e.g. just the patient's name), which are illegible in the majority of cases.
- **Infection control –** examples included non-compliance in the area of unlocked waste bins accessible to the public, and temporary closures on sharps bins not being in use.

1.13. The panel noted that with regard to multiple births the Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action was required beyond review of HFEA data of the centre's multiple pregnancy rate in January 2019.

1.14. The panel noted that with regard to consent to storage of cryopreserved materials the inspectorate comment that the PR lacks an understanding of her statutory duties under section 17(e) and schedule 3 of the HF&E Act 1990 (as amended). The panel noted that the Executive will have further discussions with the PR outside of this report.

1.15. The panel noted that with regard to medicines management, following teleconference meetings, the Executive confirmed receipt of the independent review of medicines management practices and acknowledges the centre's actions in implementing the recommendations from this review. The Executive would encourage the PR to audit practice regularly, to ensure that corrective actions taken have been effective in achieving and maintaining compliance. Inspectors found that no further action was required beyond audit reports being provided by 17 October 2018.

1.16. The panel noted that with regard to the 'major' areas of non-compliance the Executive was satisfied that remedial actions had been taken with the exception of compliance with HFEA's standard licence conditions by installing emergency call bells in the patient's post procedure recovery area. The Executive was also satisfied that implementation of recommendations in 'other' areas of non-compliance required no further action.

2. Decision

2.1. The panel considered the long history of non-implementation of inspectors' recommendations and in particular, the lack of action in the area of multiple clinical pregnancies, which had increased

since the earlier inspection of the clinic to 28% when the guideline is 10%. The panel were concerned at the apparent lack of awareness from the PR with respect to this.

2.2. Despite reports of historic engagement between the inspection team and the PR, non-compliances which had been identified on earlier inspections remained, with some new ones.

2.3. The panel did not feel it had sufficient evidence that the centre would be able to implement the recommendations without considerable long-term support from the executive.

2.4. The panel were concerned that the centre's website, which provided data about success rates that related to other licenced centres' data and which did not contain any data about the centre's own success rates was concerning due to how misleading this could be to patients.

2.5. The panel did not feel confident in the PR's ability to ensure regulatory compliance in a timely manner and decided to adjourn a decision on the interim inspection, referring it to the Licence Committee to consider. The Licence Committee should be provided with updates about each of the critical non-compliances. evidence that the centre's website was updated with accurate data and information, and evidence about the outcome of an audit of medicines management.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

3 September 2018

Interim Licensing Report

Centre name: Harley Street Fertility Clinic
Centre number: 0333
Date licence issued: 23 July 2016
Licence expiry date: 22 July 2020
Additional conditions applied to this licence: None
Date of inspection: 17 April 2018
Inspectors: Polly Todd and Louise Winstone
Date of Executive Licensing Panel: 16 August 2018

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

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

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

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

Summary for the Executive Licensing Panel

Summary for licensing decision:

Due to the number and serious nature of the non-compliant areas of practice identified in this report, some of which had been identified at previous inspections, and in accordance with section 3.1 of the HFEA's Compliance and enforcement policy, a management review meeting was held on 27 April 2018, to evaluate the findings of this interim inspection report and consider a proportionate course of action. It was considered appropriate to await the PR's response to this report, before considering whether any formal action is necessary. A further management review was held 7 June 2018 to consider the PR's response. Whilst the PR had committed to implementing the recommendations, her responses did not provide satisfactory assurance to the Executive, and it was agreed that a period of focussed support would be provided to the PR to facilitate compliance with the recommended actions, a number of which, were due for completion in the first instance, by 17 July 2018. Of particular concern, was the centre's multiple pregnancy rates and storage consents.

Weekly teleconference meetings took place from 12 June 2018 to 17 July 2018 between the Executive, the PR and members of her team. The PR fully engaged with the process and was successful in completing the required actions within the timeframes specified.

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

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

Critical areas of non-compliance:

- **The PR should take immediate action to reduce the centre's persistently high multiple clinical pregnancy rate, currently at 28%.**
- **The PR must ensure that there is effective written consent in place for all stored gametes and embryos.**
- **The PR must ensure compliance with medicines management regulations and best practice guidance.**
- **The PR must ensure compliance with the requirements of clinical waste regulations.**

Major areas of non-compliance:

- The PR should ensure that all critical points of laboratory and clinical processes are documented.
- The PR should ensure that the quality management system is used effectively to improve the quality and effectiveness of the services provided.
- The PR should ensure that there is a suitable system in place to summon help in the event of an emergency in the recovery area.

‘Other’ areas of non-compliance:

- The PR should ensure that the centre implements guidance from the HFEA regarding patient and donor screening requirements.

The PR has given a commitment to implementing the following recommendations within the prescribed timescales:

Major areas of non-compliance:

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

‘Other’ areas of practice that require improvement:

- The PR should ensure that the information on the centre’s website is compliant with regulatory requirements.

Recommendation:

The Executive recommends continuation of the centre’s licence, but due to the nature and number of non-compliances at this inspection, some of which were noted at previous inspections, the Executive also recommends a further unannounced inspection takes place within twelve months of this inspection, to ensure that compliance has been maintained and corrective actions have been effective.

Information about the centre

The Harley Street Fertility Clinic is located in central London and has held a Treatment (including embryo testing) and Storage licence with the HFEA since July 2014.

The centre provides a full range of fertility services and is registered with the Care Quality Commission (CQC).

The centre provided 278 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2018. In relation to activity levels this is a small centre**.**

In June 2015 the CQC received a complaint from a patient regarding the centre's medicines management procedures and numerous other concerns relating to patient safety. As a result, an unannounced inspection was undertaken the same month by a HFEA inspection team. Whilst the inspection team could not find any evidence to support the whistle blower's allegations, a number of concerns were raised by the unannounced inspection, the most significant of which related to medicines management and sedation practices for surgical procedures at the centre.

In accordance with the HFEA Compliance and enforcement Policy, a management review was conducted at which the findings of the unannounced inspection were evaluated. It was considered appropriate to conduct a further, announced, full inspection of all the centre's activities to determine the current level of compliance in all areas. This was carried out in July 2015.

Seven major areas of non-compliance were identified on these two inspections. The Person Responsible (PR) and her team engaged fully with the HFEA; information requested and evidence of actions taken were provided in a comprehensive and timely manner.

In consideration of the inspection history of this centre, the level of engagement and commitment to achieving compliance demonstrated by the centre team and because a comprehensive inspection of all licensable activities had been performed in July 2015, a standard licence renewal inspection was not considered necessary. Instead, the February 2016 renewal inspection visit focused on continuing compliance with the recommendations that were made in the previous inspection report.

Two major and three 'other' areas of non-compliance were noted. These recommendations were implemented within the required timeframes and the centre's licence was renewed for four years without any conditions.

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 December 2016 to November 2017 show the centre's success rates are in line with national averages.

In 2017, the centre reported 50 cycles of partner insemination with three clinical pregnancies. This is likely to represent a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

Between December 2016 and November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 28%. This represents performance that is likely to be statistically greater than the 10% multiple live birth rate target.

The centre's multiple pregnancy rate has been at 26% since October 2014 and despite reviews of the multiple birth minimisation strategy (MBMS) provided previously to the HFEA by the PR, there has been no improvement in these rates. At this inspection, the PR was unaware of the centre's multiple pregnancy rate and has not reviewed data or audited practice against their elective single embryo transfer (eSET) policy. (See recommendation 1).

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection, but was able to discuss witnessing with staff and review witnessing in patient records. These activities indicated that witnessing procedures are not compliant with HFEA requirements because:

The centre's procedures for witnessing critical points of the clinical and laboratory process are partially compliant because:

- Staff do not record the witnessing of the clear down of workspace between egg collections on the laboratory sheet.
- The witnessing steps performed during an intra uterine insemination are not documented. The PR confirmed that these steps are performed but are not recorded.

(See recommendation 5).

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.

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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 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 $p \leq 0.002$.

On inspection, reports of audits of all stored gametes and embryos 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 not effective because;

- The centre is currently storing three sperm samples and 16 embryos for which the consented storage period has expired. Consent expiry dates for these samples ranges from 11 January 2017 to 24 January 2018.
- The centre does not have an active system for managing storage expiry.
- The electronic system that the centre uses to extract information does not contain the date of storage; the consented period or the date of consent expiry.
- The inspection team are concerned that the centre does not appear to recognise the gravity of this non-compliance.
  (See recommendation 2).

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; consent to treatment; legal parenthood; controlled drugs and consent to storage.

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

- The timeframe for the implementation of corrective actions was not documented on the audits.
- There was no indication on the audits as to whether corrective actions had been implemented or completed.
- On one consent to treatment (WT) form, the audit identified that a signature was missing, but there was no documented corrective action to address this non-conformance.
- It was unclear from reviewing the legal parenthood audit if the audit had considered whether consent had been given before treatment; if counselling was offered and if the consent forms had been completed correctly.
- The centre has not performed an electronic mismatch audit and the witnessing audit does not specify whether if manual and/or electronic witnessing was audited.

- A witnessing SOP provided to the inspection team for review on the day of the inspection, was out of date. It was later found that this SOP had been superseded. (See recommendation 6).

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 content of the centre's website
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding screening requirements

The centre is broadly effective in implementing learning from their audits and or guidance from the HFEA because:

- The centre has not implemented guidance relating to screening for Ebola into its policy or protocols. (See recommendation 9).
- The centre's website is non-compliant with requirements because:
    - The website provides data about success rates that relate to other licensed centres.
    - The website does not contain any data about the centre's own success rates.
    - The success rate data provided on the website is more than three years old (2012).
    - The national rates quoted on the website are from 2011 and not compared like for like. (See recommendation 10).

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 not compliant with guidance because:

- A significant number of entries in the controlled drugs register are illegible (this was a non-compliance at the renewal inspection in February 2016).
- On some pages the strength and volume of the drug is not recorded (this was a non-compliance at the renewal inspection in February 2016 and the unannounced inspection in June 2017).
- The carry-over of drugs from one page to another is not recorded or witnessed.
- The controlled drugs register only contains single patient identifiers (eg. just the patient's name), which are illegible in the majority of cases (this was a non-compliance at the renewal inspection in February 2016).
- The controlled drugs audit does not record corrective actions, or the date by which they should be implemented.
- The quarterly controlled drugs audits lacked scope in that they did not identify issues noted in this report and identified at previous inspections (this was a non-compliance at the renewal inspection in February 2016). (See recommendation 3).

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 not compliant with guidance because:

- Two out of the three clinical waste bins stored outside of the clinic were unlocked and were accessible to the public (this was a non-compliance at the inspection in June 2017).
- Temporary closures on sharps bins were not in use
- Recycling waste was stored in a corridor which led to a fire escape and could impede exit in the event of a fire. (See 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 the following medical devices was reviewed in the course of the inspection, plasticware and media. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not appropriately CE marked:

- Oosafe 4 well dishes;
- Oosafe 60mm round dishes
- Oosafe 5ml tubes
- Vitrification media

Evidence was provided during the inspection to demonstrate that Oosafe are currently seeking CE marked status and the company have confirmed that CE marking as a Class II medical device is expected to be accomplished by September 2018. Similarly, the manufacturer of the vitrification media has also confirmed that they are seeking to achieve CE marking but a time frame has not been provided. (See recommendation 7).

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Patient feedback provided to the centre between February 2018 and March 2018 was reviewed (18 responses). Feedback was positive, with all of the individuals providing written feedback giving compliments about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional.

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 non-compliant with the following HFEA requirement:

- There are no emergency call bells in the patients' post-procedure recovery area, which is situated on the lower ground floor of the centre. Staff are reliant on making a phone call to the nurses' office on the top floor, in the event of a patient emergency. The inspection team are of the view that this places patients at risk as there is no guarantee that anyone would be in the office to take the call. (See recommendation 8).

Compliance with recommendations made at the time of the last inspection

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

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales, however on this inspection, the following recommendations have not yet been implemented:

- The PR should review the centre's procedures to ensure that the management of controlled drugs is compliant with legal requirements and professional best practice.
- The PR should ensure that staff are aware of and comply with requirements to ensure that all clinical waste is traceable and that the clinical waste skip is secure at all times.

On-going monitoring of centre success rates

Since the last renewal inspection in February 2016 the PR has received two risk tool alerts related to multiple pregnancy rates to which there has been no improvement. (See multiple births section of this report and recommendation 1).

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 inspection in February 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, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Three 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. 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, with the exception noted in the QMS section of this report. (See recommendation 6).

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
1. Multiple births The centre's multiple clinical pregnancy rate has been at, 26% since October 2014 and is now 28% meaning that the multiple birth target is likely to be exceeded. The PR was unaware of the centre's multiple pregnancy rate.	The PR should take immediate action to reduce the centre's persistently high multiple clinical pregnancy rate, currently at 28%. The PR should commission an independent review of their multiple birth minimisation strategy including any barriers to its implementation and how the strategy and elective single embryo transfer (eSET) policy is	We shall commission an independent review of the Clinic's multiple birth minimisation strategy, including any barriers to its implementation and how the strategy and eSET policy is embedded into practice, including how this information is communicated to patients.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required. **Executive update following teleconference meetings:** The Executive acknowledges receipt of the independent

The centre has not looked at their data or audited practice against their eSET policy. Considering the ongoing nature of this observation, the risk to patients or children who may be born as a result of treatment and that the centre has not addressed this issue, the compliance has been graded as critical. SLC T2; General Direction 0003	embedded into practice, including how this information is communicated to patients. A formal summary of this review, including actions that will be taken in response to the findings, should be provided to the centre's inspector by 17 September 2018. The inspectorate will continue to closely monitor the centre's multiple pregnancy rate. We must allow sufficient time for the centre to seek advice, implement changes, and for any impact to be shown in the centre's CUSUM plot taking into account a three-month data lag. Therefore, if our data suggest that the centre are making no progress towards meeting the 10% multiple live birth target by 17 January 2019 we will consider whether it is appropriate to take further regulatory action which may entail analysis of the suitability of the centres practices in relation to multiple births.	A formal summary of this review, including actions that will be taken in response to the findings, will be provided to the Clinic's HFEA inspector by 17 September 2018	review of the multiple birth minimisation strategy. The PR has implemented a number of the recommendations from this review and has committed to monitoring the centre's multiple pregnancy rates (MPR) going forward. No further action beyond review of HFEA data of the centre's MPR in January 2019.
2. Consent to storage of cryopreserved materials:	The PR must ensure that there is effective written consent in place for	We have established an action plan to resolve the	The Executive acknowledges the PR's response and

On inspection the following issues were noted: • The consented storage period for three sperm samples and 16 embryo samples had expired. Consent expiry dates for these samples ranges from 11 January 2017 to 24 January 2018. • The centre does not have an active system for managing storage consent expiry. The electronic data system, used by the centre, does not contain data relating to the date of sample storage; the consented storage period or the expiry of the consented storage period. The inspection team are not assured that the centre recognises the gravity of this non-compliance. Schedule 3 HF&E Act 1990 (as amended)	all stored gametes and embryos. The PR must establish an action plan for resolving the cases where sperm and embryos are in storage beyond their consented storage period. A copy of the plan should be provided to the centre's inspector when responding to this report. The PR must provide monthly updates to the centre's inspector on progress with implementing the proposed action plan. It is expected that there will be effective written consent for all stored samples by 17 July 2018. The PR is reminded of the guidance issued by the HFEA in CH (03) 03 (https://portal.hfea.gov.uk/knowledge-base/chairs-letters/756) in relation to the timely disposal of cryopreserved material where there is consent to do so. The PR must ensure that there is an effective system in place to ensure effective management and monitoring of consent expiry dates.	casees where sperm or embryos are in storage beyond the consented period. A copy of the plan is enclosed with this response. We shall provide montly updates to the Clinic's inspector on progress with implementing the proposed action plan. We expect to have effective written consent for all stored samples by 17 July 2018. We appreciate the gravity of this non-compliance and so have assigned responsibilty for ensuring compliance with this duty directly to our laboratory manager.	commitment to implementing this recommendation. However, the Executive is concerned that the action plan submitted with this report indicates that the PR intends to send new consent forms for 'storage renewal' if contact with the patient is made. If the PR takes this action, she will be in breach of the statutory storage regulations. The Executive remains concerned that the PR lacks an understanding of her statutory duties under section 17 (e) and schedule 3 of the HF&E Act 1990 (as amended). The Executive is not assured that the centre has effective systems in place to ensure effective and lawful consent is in place for all stored gametes and embryos. The Executive will have further discussions with the PR outside of this report.

SLC T57; T79. Human fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.			Further action required. **Executive update following teleconference meetings:** The Executive confirms that the centre has taken action to ensure that there is effective written consent in place for all stored samples. No further action required.
3. Medicines management. On inspection the following issues were noted: • A significant number of entries in the controlled drugs register are illegible. • On some pages the strength and volume of the drug is not recorded • The carry-over of drugs from one page to another is not recorded or witnessed. • The controlled drugs register only contains single patient identifiers (eg. just the patient's name), which are illegible in the majority	The PR must ensure compliance with medicines management regulations and best practice guidance. The PR should investigate why non-compliances identified in this report have not been addressed from previous inspections. The PR should commission an independent review of the centre's medicines management practices. A summary report of this review, including staff training requirements and corrective actions taken, should be provided to the centre's inspector by 17 July 2018.	We shall commission an independent review of the Clinic's medicines management practices. We shall provide a summary report of that review to our inspector, including staff training requirements and corrective actions taken, by 17 July 2018.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required **Executive update following teleconference meetings:** The Executive confirms receipt of the independent review of medicines management practices and acknowledges the centre's actions in implementing the recommendations from this review. The Executive would encourage the PR to audit practice regularly, to ensure

of cases. • The controlled drugs audit does not record corrective actions, or the date by which they should be implemented. • The quarterly controlled drugs audits lacked scope in that they did not identify issues noted in this report and identified at previous inspections. **Critical non-compliance with Medicines management practice was noted at the last inspection in June 2017.** SLC T2 DH: Controlled Drugs (Supervision of management and use) Regulation 2013. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. Misuse of Drugs (safe Custody) Regulations 2001.			that corrective actions taken have been effective in achieving and maintaining compliance. No further action required.

NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. NMC (2015) 'Standards for medicines management'.			
4. Infection control: During the inspection, the centre was found to be non-compliant with infection control practices because: • Two out of the three clinical waste bins stored outside of the clinic were unlocked and were accessible to the public. • Temporary closures on sharps bins were not in use • Recycling waste was stored in a corridor which led to a fire escape and could impede exit in the event of a fire. **Infection control non-compliance was noted at the inspection in 2017 so has been escalated to critical in**	The PR must ensure compliance with the requirements of clinical waste regulations. The PR should investigate why non-compliance noted at previous inspections has occurred again. The PR should provide a summary report of this investigation, including staff training requirements (where appropriate) and any corrective actions taken, to the centre's inspector, when responding to this report. Three months after the implementation of any corrective actions, the PR must audit infection control practices including, but not exclusively, those areas of non-compliance identified in this report, to ensure that corrective actions taken have been effective in achieving and maintaining compliance with	We have investigated the non-compliance with regards to clinical waste and have enclosed a summary report of this investigation with this response. We shall audit our infection control practices, with particular regard to the areas of non-compliance identified in this report, to ensure the corrective actions taken have been effective in achieving and maintaining regulatory compliance. We shall provide a summary a report of that audit to our inspector by 16 October 2018.	The Executive acknowledges receipt of the summary report and the PR's response and commitment to implementing this recommendation. No further action beyond submission of the audit summary due by 16 October 2018.

this report. SLC T2 HTM 07-01 Safe Management of Healthcare Waste. Regulatory Reform (fire safety) Order 2005.	regulatory requirements. A summary report of this audit should be provided to the centre's inspector by 16 October 2018. The PR must ensure that recycling waste is appropriately disposed of and that fire exits are kept clear at all times.		

‘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
5. Witnessing. Staff do not record the witnessing of the clear down of workspace between egg collections. The witnessing steps performed during an intra uterine insemination are not documented. The PR confirmed that these steps are performed but are not recorded.	The PR should ensure that all critical points of laboratory and clinical processes are documented. The PR should review the centre’s witnessing practices and ensure corrective actions are implemented to achieve compliance with this recommendation. Three months after the implementation of corrective actions, the PR should audit witnessing checks to ensure that corrective actions implemented have been	We have added the required witnessing to our laboratory paperwork. A copy of the new paperwork is enclosed with this response. We will begin to use this new form by 1 June 2018. Accordingly, we shall perform an audit of the witnessing checks to ensure the above corrective action is effective three months later. We shall provide a summary report of that audit to our inspector by 17 October.	The Executive acknowledges the PR’s response and receipt of the witnessing papers. No further action beyond submission of the audit report due 17 October 2018.

	effective. A summary report of this audit should be provided to the centre's inspector by 17 October 2018.		
6. The Quality Management System. On inspection the following issues were identified: • The timeframe for the implementation of corrective actions was not documented on the audits. • There was no indication on the audits as to whether corrective actions had been implemented or completed. • On one consent to treatment (WT) form, the audit identified that a signature was missing, but there was no documented corrective action to address this non-conformance. • It was unclear from reviewing the legal	The PR should ensure that the quality management system is used effectively to improve the quality and effectiveness of the services provided. The PR should review the centre's auditing practices and ensure they are robust in ensuring that non-compliances are acted upon; corrective and preventative actions are recorded and implemented and effective in achieving improvements in quality standards. The PR should provide a summary report of this review, including corrective actions taken to address this non-compliance, to the centre's inspector by 17 July 2018. Three months after the implementation of corrective	We shall review our auditing practices to ensure they are robust in ensuring that non-compliances are acted upon, corrective and preventative actions are recorded and implemented, and effective in achieving improvements in quality sstandards. We shall provide a summary report of this review to our inspector by 17 July 2018. Three months after implementing corrective actions from the above review, we shall audit our practices to ensure the corrective actions have been effective in achieving compliance. We shall provide a summary report of that audit to our inspector by 17 October 2018. We will review all of our QMS documents to ensure that only	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required. **Executive update following teleconference meetings:** The Executive acknowledges the review of the QMS and actions taken in implementing this recommendation. No further action beyond submission of an audit summary, due by 17 October 2018.

parenthood audit if the audit had considered whether consent had been given before treatment; if counselling was offered and if the consent forms had been completed correctly. • The centre has not performed an electronic mismatch audit and the witnessing audit does not specify whether if manual and/or electronic witnessing was audited. • A witnessing SOP provided to the inspection team for review on the day of the inspection, was out of date. It was later found that this SOP had been superseded. SLC T34; T36	actions, the PR should audit practice to ensure that the actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 17 October 2018. The PR should ensure that only the current versions of documents are in use. The PR should review all QMS documents to ensure that current versions are in use and that there is a process for archiving old documents. A summary report of this review, should be provided to the centre's inspector by 17 October 2018.	current documents are in use. We will perform a mismatch audit at the end of every month and will add this to the quarterly KPIs for regular review. All lab SOPs are currently undergoing review, which will be complete by September 2018. We will ensure that only current versions of all QMS documents are in use and that all staff use the archiving process for storing old versions of documents. We will provide a summary report of this review by 17 October 2018.	
7. CE marking. The following items were not CE marked for Class II medical use: • Oosafe 4 well dishes;	The PR should ensure that only CE marked medical devices are used wherever possible.	We shall ensure a plan is developed and implemented such that CE marked medical devices are used wherever possible.	The Executive acknowledges the PR's response and commitment to implementing this recommendation.

• Oosafe 60mm round dishes • Oosafe 5ml tubes • Vitrification media	We would not recommend precipitous changes that might impact on the quality of treatment, however the PR should ensure that a plan is developed and implemented so that CE marked medical devices are used. This plan should be provided to the centre's inspector by 17 July 2018 and should include the timescales by which products identified in this report will either be replaced with a suitably CE marked alternative, or will obtain CE mark certification. The plan should be fully implemented by 17 April 2019.	We shall provide a copy of that plan to our inspectory by 17 July 2018, including the timescales by which the products identified above will either be replaced with a suitable CE marked alternative, or will obtain CE marking. We will ensure that plan is fully implemented by 17 April 2019	Further action required. **Executive update following teleconference meetings:** The Executive acknowledges receipt of the plan to implement the use of appropriately CE marked products, and the PR's commitment to fully implementing this recommendation. No further action beyond confirmation of full implementation due by 17 April 2019.
8. Compliance with HFEA standard licence conditions. There are no emergency call bells in the patients' post-procedure recovery area. Staff are reliant on making a phone call to a top floor office in the event of an emergency. SLC T9 (b)	The PR should ensure that there is a suitable system in place to summon help in the event of an emergency in the recovery area. The PR should inform the centre's inspector of the measures taken to address this non-compliance.	We have contacted vendors to have a suitable system installed within the Clinic by 17 July 2018.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The Executive awaits confirmation from the PR once a suitable system is in place. Further action required.

	It is expected that a suitable system is in place by 17 July 2018.		**Executive update following teleconference meetings:** The PR has confirmed that a suitable system for summoning help in an emergency, has been installed. No further action.

‘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
9. Implementing guidance from the HFEA. • The centre has not implemented guidance relating to screening for Ebola into its policy or protocols. SLC T50; T52 European Tissues and Cells Directive (EUTCD) 2017. Advisory Committee on Dangerous Pathogens (ACDP) 2017.	The PR should ensure that the centre implements guidance from the HFEA regarding patient and donor screening requirements. The PR should review the centre’s screening policy and procedures and ensure that they are compliant with the requirements for additional screening of patients and donors. The PR should ensure that the information provided to patients about Ebola, accurately reflects current practice guidance. The PR should provide a summary report of the review	The Clinic's current practice with regard to screening for Ebola is to discuss a patient's travel history at their initial consultation so that they can be screened appropriately. To this end: there are specific entries for Zika virus and Ebola virus in the Clinic's patient history template that is used for every new patient consultation. Please find a copy of that template attached for your review. As requested, we shall perform a review of our patient information and Ebola virus screening processes to our inspector by 17 October 2018, including corrective actions	The Executive acknowledges receipt of the revised patient history template and the PR’s commitment to fully implementing this recommendation. No further action beyond submission of audit due 17 October 2018

	including the actions taken to ensure compliance with this recommendation, to the centre's inspector, by 17 October 2018. Three months after the implementation of corrective actions, the PR should audit patient and donor screening to ensure that actions implemented, have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 January 2019.	taken to ensure compliance with this recommendiation. We shall audit our patient and donor screening three months after implementing the above corrective actions to ensure those actions were effective in achieving and maintaining compliance. We shall provide a summary report of this review to our inspector by 17 January 2019.	
10. The centre's website. The following issues were identified on inspection: • The centre's website provides data about success rates that relate to other licenced centres. • The website does not contain any data about the centre's own success rates. • The success rate data provided on the website	The PR should ensure that the information on the centre's website is compliant with regulatory requirements. The PR should audit the centre's website against regulatory requirements and make the necessary corrections. The PR should inform the centre's inspector, when the	We shall ensure our website is fully compliant with regulatory requirements. As a temporary measure, we have removed the non-compliant data from our website and replaced this with a placeholder. We shall inform our inspector once the corrections have been made so that they may be reviewed for compliance. We shall ensure our website is	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond confirmation that the website has been amended.

is more than three years old (2012). • The national rates quoted on the website are from 2011 and not compared like for like. CH (11) 02. Code of Practice 4.12.	required corrections have been made so that a subsequent review for compliance can be undertaken. It is expected that the centre's website will be fully compliant with regulatory requirements by 17 October 2018.	compliant before 17 October 2018.	

Additional information from the Person Responsible