Licence Committee - minutes

Centre 0338 (Reproductive Health Group)
Targeted Interim Inspection

Thursday, 2 September 2021

HFEA, 2nd floor, 2 Redman Place, London E20 1JQ (Teleconference)

Committee members	Jonathan Herring Anita Bharucha Ruth Wilde Gudrun Moore Ermal Kirby	(Chair) (Deputy Chair)
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers	Neil Ward (Induction)	Mills & Reeve LLP

Declarations of interest:

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

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

Papers enclosed:

- Targeted Interim Inspection Report
- Licensing minutes from the last three years:
    - 2021/04/06 Licensing Officer Record of Consideration - Variation of Licence Holder
    - 2020/10/15 Representations - Licence Committee Decision
    - 2020/09/22 Executive Licensing Panel Minutes - Special Directions to permit continuation of licence
    - 2020/02/25 Executive Licensing Panel Minutes - Special Directions to permit continuation of licence
    - 2020/01/09 Licence Committee Minutes - Renewal Inspection
    - 2019/07/11 Licence Committee Minutes - Executive update
    - 2018/11/08 Licence Committee Minutes - Executive update, Variation of Person Responsible (PR) & Licence Holder (LH)
    - 2018/09/06 Licence Committee Minutes - Additional Inspection and Executive update

1. Background

1.1. Reproductive Health Group, centre 0338 is located in Warrington. The centre has held a treatment and storage licence with the HFEA since April 2014 and provides a full range of fertility services including embryo testing.

Current Licence

1.2. The centre's current licence was granted for a period of three years from 16 October 2020 and is due to expire on 15 October 2023. In the last three years the centre's licence has been varied to change the Person Responsible (PR) once and Licence Holder (LH) twice. The centre's current licence has been varied without application to reflect European Union (EU) Exit requirements. The centre also has one additional condition added to the licence.

History of non-compliance:

1.3. The centre has been subject to inspections focused on the implementation of recommendations.

Unannounced Interim Inspection on 7 November 2017

1.4. An unannounced interim inspection was carried out on 7 November 2017 and recommendations were made in relation to two critical, two major and four other areas of non-compliance. The Executive had concerns about the serious nature of the critical areas of non-compliance:

Import of donor gametes – donor compensation - Critical area of non-compliance

1.5. The PR in post at the time of the inspection had failed to understand the requirements in relation to compensation for overseas donors and ensure that gametes imported from Ukraine met the requirements on compensation for overseas donors set out in General Direction 0001. Donor compensation limits for UK donors are different from those for overseas donors. The PR stated that he had not accepted that the imports were not compliant with the requirements of General Direction 0001.

1.6. The Executive concluded that the PR had failed to discharge his duty under section 17(1)(c), (d) and (e) of the HF&E Act 1990 (as amended), ('the Act'), because he had failed to understand the requirements.

1.7. The PR had failed to ensure that the import of donor gametes was compliant with General Direction 0001 and General Direction 0006.

1.8. The HFEA Licence Committee agreed that although it considered there were sufficient grounds to revoke the centre's licence, a variation of the centre's licence with the addition of a condition would be a proportionate response and endorsed the Executive's recommendations, including the addition of the following condition:

'The centre is prohibited from conducting any further imports of donated gametes under General Direction 0006 and the Person Responsible is required to make an application to the Authority, for consideration by the Statutory Approvals Committee, for Special Directions in relation to any and all proposed imports of donor gametes in the future.'

Consent to legal parenthood - Critical area of non-compliance

1.9. 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. The PR is responsible for ensuring that effective consent to legal parenthood is obtained.

1.10. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre was not licensed until April 2014 and was therefore not required to respond to this request. This centre has been inspected since 2014 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

1.11. Shortly after the renewal inspection in 2015, the PR at the time was asked to undertake an audit to review all cases where treatment with donor sperm had been provided to ensure that:

- there were no anomalies;
- procedures for obtaining consent to legal parenthood were robust;
- there were effective methods for assessing the on-going competence of staff to take this consent; and
- effective audit procedures were in place to ensure on-going compliance with consent taking requirements.

1.12. In October 2015 the PR confirmed that he had conducted an audit of consent to legal parenthood, that there were effective methods for assessing the on-going competence of staff to take this consent and that effective audit procedures were in place to ensure on-going compliance with consent taking requirements. However, the findings on inspection indicated that this was not the case. The PR was asked to undertake an audit of all patients that had treatment with donor sperm, or embryos created with donor sperm in accordance with CE(14)01, from the start of activity at the centre in 2014. Further anomalies were identified during the inspection process in November 2017, June 2018 and April 2019.

Licence Variation – Change of Person Responsible (PR) & Licence Holder (LH)

1.13. The centre's licence was varied to reflect a change of PR and LH which came into effect on 3 December 2018. Karen Schnauffer, the new PR, had previously been a PR at two HFEA licensed centres, centre 0007 and centre 0344 between 2014 and 2017. The previous PR was the centre's Clinical Director and Lead Clinician.

Focused Inspections - June 2018 and April 2019

1.14. Since the unannounced interim inspection in November 2017 further focused inspections were carried out in June 2018 and April 2019.

1.15. During a short notice inspection in April 2019 further issues in respect of consent to legal parenthood were identified for a surrogate and the commissioning couple. This was of particular concern in light of the centre's previous failures in this area of practice. The inspectorate also had some concerns in relation to assessment of surrogates and intended parents prior to treatment.

1.16. The Executive held a management review meeting on 2 May 2019 in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance and found that the non-compliances identified on inspection were significant and reflected direct and indirect risks to patients, and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. The Executive also considered the PR's ability to discharge her duties under section 17(1) of the Act 1990 (as amended). The Executive had some concerns that the PR had not yet been able to demonstrate that she had full oversight of all areas of activity in the centre and acknowledged that she had only been PR for four months, having taken up that role three months after beginning employment at the centre.

1.17. In consideration of the findings on this inspection and the centre's previous failings in relation to legal parenthood, the Executive contacted the PR to ask her to consider a voluntary cessation of treatments with donor sperm, or embryos created with donor sperm, for new patients (including surrogacy cases) until such time the HFEA is satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust.

HFEA Executive Meeting with the Person Responsible (PR) on 20 May 2019

1.18. The Executive met with the PR and the centre's Quality Manager on 20 May 2019. During this meeting the PR provided evidence of a number of actions that she had already taken and would be taking, to review processes, ensure training and competence of staff and ensure oversight and governance of all activities in the centre. The Executive was satisfied with the PR's assurances as to the immediate actions she had taken in response to the inspection findings, of her commitment to fully discharging her duties, and the proposed plans to address the non-compliances identified. The Executive considered that these demonstrated that the PR was fully engaged and committed to attaining compliance and good governance in order to mitigate risks at the centre.

1.19. However, before the Executive was able to recommend that treatments with donor sperm resume the PR was to provide evidence that staff training and competency assessments had been completed, and confirmation that no further issues had been identified in the centre's audits of consent to legal parenthood and surrogacy cases.

1.20. Following further discussions with the PR, on 23 May 2019 the Executive agreed that if the centre was able to confirm that a patient is single, treatments with donor sperm (not surrogacy) could be provided to this specific group of patients. The Executive also agreed that, if there were no concerns or risks, treatment could be provided to patients on the basis that, due to their specific circumstances, they would be compromised by a delay in treatment. The Executive required that the PR and Clinical Director undertake a risk assessment to determine the risk/benefit of proceeding with treatment and that all consents should be checked by the PR. The PR confirmed that she would review all documentation and have these checked by a lawyer specialising in fertility law to ensure that all consents were correct and appropriate before proceeding with treatment. Two patients had been provided with treatment since May 2019, and their records were reviewed during the inspection. No issues were identified.

Licence Committee Decision in July 2019 – Executive Update

1.21. At its meeting held in July 2019, the Licence Committee had concerns about the centre's history of non-compliance and the suitability of the current PR. However the committee noted that the PR had only held the position for four months, having taken up that role three months after beginning employment at the centre, and that the Executive expected that by the time of the scheduled renewal inspection in October 2019, when all areas of practice would be reviewed in detail, the PR would have had sufficient time to fully embed in her role and demonstrate her commitment to discharging fully her duties as PR.

1.22. The committee agreed to the continuation of the centre's licence and agreed that the inspectorate should continue to monitor the centre's performance, noting that there were some outstanding actions. The committee requested an update following the renewal inspection scheduled in October 2019.

Renewal Inspection - 8 and 9 October 2019

Considered by the Licence Committee on 9 January 2020

1.23. The renewal inspection took place on 8 and 9 October 2019. At the time of the renewal inspection there were two critical non-compliances relating to donor recruitment, assessment, selection and screening procedures, and the availability of suitably trained and competent staff in sufficient number to undertake their roles. There were five major non-compliances relating to storage of gases, Quality Management System (QMS), third party agreements, PR requirement to fully discharge their duties, staff training and assessment of competency in consent to legal parenthood and one other area of non-compliance relating to reporting of all licensed treatment activity within the timeframe required by General Direction 0005.

1.24. Following the inspection, the PR had confirmed actions taken and committed to fully implementing all of the recommendations within the required timescales, and to provide all of the requested evidence and any audits of practice within the required timescales.

Assessment and screening of gamete donors

1.25. The Executive noted several issues with the centre's processes for assessment and screening of donors, including issues relating to medical history, physical examinations, missing test results, no recorded travel history, exceeded age of sperm donor. The centre's SOP for this area of practice was inadequate and there was no assessment of staff competencies. The centre's audit of egg donor assessment and screening was not robust and there was no audit of sperm donor assessment and screening.

1.26. The PR had arranged for an external expert to review the centre's processes for donor recruitment, assessment and screening, and to undertake a full audit of gamete and/or embryo donor records since the time of the last renewal inspection in October 2015, to determine whether there were further cases where gamete providers were not suitably assessed and screened as donors, including travel history checks.

1.27. On completion of the audit the PR was required to identify whether there were further cases where the gamete providers were not suitably assessed and screened as donors. If cases are identified, the PR would need to seek expert advice to fully assess whether there may have been any risks to the recipients that have undergone treatment with these gametes and/or embryos. The review would also consider whether recipients affected are to be contacted and advised of possible risks of their treatment.

1.28. The review was scheduled to take place on 20 December 2019. The PR was advised to inform the Executive of the timeline for completing this risk assessment by 9 February 2020.

Staff

1.29. The Executive considered that the nursing staff numbers were inadequate for the activities being undertaken. The centre had one full-time senior nurse manager and two part-time fertility nurses. A full-time trained fertility nurse left the centre in the summer and no actions had been taken to recruit to this role. The centre's two part-time nurses also covered non-IVF related theatre procedures carried out at the centre and they were therefore not able to learn or progress in the roles for which they were employed. The inspectorate was concerned that the nurse manager was responsible for all of the clinical work (as the two part-time nurses were not trained) as well as fulfilling her management duties and additional responsibilities such as being the centre's Safeguarding lead. The inspectorate was concerned that she had to be reactive instead of having time to be proactive and anticipate issues thereby mitigating any potential risks.

Consent to Legal Parenthood

1.30. During the inspection no anomalies were identified in the four records of consent to legal parenthood, for treatments carried out in 2019, that were audited, and no further issues were identified in the centre's audits of consent to legal parenthood and surrogacy cases.

1.31. However, the inspection team was concerned that no further action had been taken to undertake a robust assessment of competency for staff taking consent to legal parenthood despite the specific guidance provided in August 2019.

1.32. The PR had provided information on staff competency assessments in August 2019, however, the Executive reported that the information provided was not satisfactory evidence of the assessment of competencies of staff obtaining consent to legal parenthood, therefore the voluntary cessation of treatments with donor sperm, or embryos created with donor sperm, for new patients (including surrogacy cases) was still in place at the time of this renewal inspection. The Executive had provided the PR with some guidance on the type of evidence required. The committee noted that once the centre has provided robust evidence that the centre's processes are compliant with regulatory requirements and professional guidelines, such as standard operating procedures (SOPs) and training and assessments of competency of staff undertaking these activities, then the Executive would be satisfied that it would be safe to continue treatments with donor sperm or embryos created with donor sperm.

1.33. The Executive held management review meetings in accordance with the HFEA Compliance and Enforcement Policy in November 2019. The Executive found that the non-compliances seen on inspection were significant and reflected direct and indirect risks to patients, and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements.

1.34. The Executive was particularly concerned with the inspection findings in relation to assessment and screening of donors, the numbers of nursing staff and their training, the assessment of competency of staff undertaking various activities such as donor screening, and the lack of implementation of previous recommendations in relation to the assessment of competency of staff taking consent to legal parenthood.

1.35. The Executive considered the HFEA Guidance on Licensing in order to make a recommendation for the licence renewal period.

1.36. The Executive concluded that the PR had failed to discharge her duties under Section 17(1)(a), (d) and (e) of the HF&E Act 1990 (as amended). The Executive reached this conclusion as a result of the non-compliances relating to staff, assessment and screening of gamete donors and Legal Parenthood. The Executive considered whether 10 months had been sufficient time for the PR to ensure compliance in a centre with a history of non-compliance. Given the issues noted and the centre's history of non-compliance, the Executive was concerned that there remained an ongoing direct risk to patients, particularly recipients of donated gametes and/or embryos. Therefore, the Executive concluded that it was proportionate to recommend that the centre's treatment (including embryo testing) and storage licence was renewed for a period of one year with the following additional conditions:

- Existing Condition – remains on the licence

  'The centre is prohibited from conducting any further imports of donated gametes under General Direction 0006 and the Person Responsible is required to make an application to the Authority, for consideration by the Statutory Approvals Committee, for Special Directions in relation to any and all proposed imports of donor gametes in the future.'

- New Condition

  'The centre is prohibited from undertaking any activities in relation to the recruitment, assessment, selection or screening of gamete or embryo donors, whether known to the recipient or not.'

- New Condition

  'The centre is prohibited from providing treatments with donor sperm or embryos created with donor sperm for patients, including surrogacy cases.'

1.37. The committee noted the PR's commitment to fully discharge her duties and the immediate action taken to reduce the number of procedures being performed at the centre. The committee noted that the PR had previous experience in the role of PR between 2014 and 2017, and that the PR had commissioned an independent review of the leadership and governance of the centre by a peer, a PR at another HFEA licensed centre.

1.38. The committee considered the number and nature of non-compliances identified and the impact on the quality of service provided by the centre. The committee noted that the non-compliances seen on inspection were significant and reflected direct and indirect risks to patients, and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. Carefully weighing all factors in the balance, the committee endorsed the Executive's recommendations to offer the centre a one year treatment (including embryo testing) and storage licence, with the three additional conditions mentioned above.

1.39. The committee noted that the centre had not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

Representations considered by the Representations Committee on 7 and 8 October 2020

1.40. The PR made representations against the Licence Committee's decision made on 9 January 2020, to renew the centre's licence for a period of one year with three additional conditions. On 7 and 8 October 2020 the Licence Committee (referred to as the Representations Committee in this instance) heard the centre's case and considered the renewal application and supporting information presented and agreed to offer the centre a new licence for a period of three years with the following additional condition:

'The centre is prohibited from conducting any further imports of donated gametes under General Direction 0006 and the Person Responsible is required to make an application to the Authority, for consideration by the Statutory Approvals Committee, for Special Directions in relation to any and all proposed imports of donor gametes in the future.'

1.41. The PR accepted the new licence offer and the licence came into force on 16 October 2020.

Change in Ownership

1.42. In October 2020, there was a change of ownership of the centre following a merger with the IVF Life Group which also has clinics in Spain and Germany.

Licence Variation Application to change the Person Responsible (PR)

1.43. On 21 August 2021 the PR applied for a change of PR at the centre. The Licence Committee considered this application together with the report of the targeted interim inspection carried out on 23 June 2021. A record of the decision to change the PR will be documented in separate minutes.

2. Consideration of application

Targeted Interim Inspection – June 2021

Application

2.1. The committee noted that the Executive conducted a desk-based assessment with a risk-based approach for this centre. Given the centre's history of non-compliance, the Executive decided to carry out an on-site targeted interim inspection on 23 June 2021 to review areas of concern previously identified at the licence renewal inspection in October 2019, to ensure that action had been taken and was effective, particularly in the area of staffing, donor recruitment assessment and screening, consent to legal parenthood, the quality management system (QMS), surgical procedures and patient experience.

2.2. The Executive has monitored the centre's performance and given consideration to the centre's self-assessment and progress in implementing the recommendations.

2.3. This interim inspection report represents an evaluation of the centre's performance based on the following areas:

- Quality of care defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- Patient safety which is a fundamental and essential attribute to quality healthcare.
- Patient experience, understanding what matters to patients and improving the patient experience.

Inspection Process

2.4. The committee noted that in the 12 months to 31 May 2021 the centre provided 192 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre. The COVID-19 pandemic and suspension of fertility treatments across the United Kingdom would have had an impact on treatment numbers during 2020.

2.5. The committee noted that HFEA-held register data for the year ending 28 February 2021 showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages.

2.6. The committee noted that for the year 2020 the centre reported two cycles of partner insemination with no clinical pregnancies. This represented a clinical pregnancy rate which is comparable to the national average.

2.7. The committee noted that HFEA-held register data for the year ending 28 February 2021 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 2%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

2.8. The committee noted that at the time of inspection, there were four major areas of non-compliance identified.

Major area of non-compliance:

- The PR should ensure that practices regarding fire safety and waste management are compliant with regulatory requirements and best practice guidance.
- The PR should ensure that the assessments of competency of staff for the roles they undertake are properly completed and documented and that all appropriate pre-employment checks are undertaken.
- The PR should ensure that the centre's Quality Management System (QMS) and processes for auditing, recording audit findings and corrective actions are effective and compliant with HFEA requirements.
- The PR should ensure that medicines management practices are compliant with regulatory and best practice guidance.

2.9. The committee noted that since the on-site inspection the PR has confirmed that the recommendation relating to fire safety and waste management has been fully implemented. The PR has committed to fully implementing all of the remaining recommendations, and to provide further information or audits of practice where required.

Staffing

2.10. The committee noted that having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Nurse Manger's Role

2.11. The nurse manager has recently been promoted to clinic manager which includes responsibility for management of the nursing, theatre, and administration teams in addition to her clinical duties. The nurse manager is also currently one of the key staff members responsible for obtaining consent to legal parenthood and assessment and screening of donors. The nurse manager has a role in supervising clinicians whilst they embed into the centre's activities and will also be the responsible individual for the Care Quality Commission (CQC). The Executive noted that this is the same nurse manager whose workload was of concern at the time of the renewal inspection in October 2019.

Staffing & Activity Levels

2.12. At the time of the inspection there was only one other registered nurse at the centre who is still completing some aspects of her training. The Executive considered that staffing levels in the centre appeared suitable for the activities being carried out, however the Executive is concerned that this would not be the case should activity levels increase, given the additional duties required of the most experienced nurse who has also taken on the substantial role of clinic manager. The committee noted that the Executive acknowledged the PR's assurances that activity levels are closely monitored to ensure that patients and staff are safe at all times, and that all clinical staff have been appropriately screened.

Staff Competency Assessments

2.13. The committee noted that new clinicians have joined the centre since February 2021. The Executive had concerns following the review of a sample of the records for some of the centre's newer staff members. The PR's assessments of competency in donor recruitment, assessment and screening for one of the clinicians that joined the centre in February 2021 was reviewed and the template used was dated June 2021, however the date of completion of the assessment was March 2021. The PR acknowledged that a mistake had been made and explained how this occurred. There was no evidence of competency assessment for the provision of information or assessment of the welfare of the child for one of the new clinicians that joined the centre in February 2021, or for the management of controlled drugs for the staff undertaking this activity.

2.14. The committee noted that the PR has confirmed that she is in the process of completing the assessments of competencies noted as outstanding by the Executive and has confirmed that only staff who have been assessed as competent carry out these activities. The PR informed the Executive that the newly appointed clinicians are working within the fertility sector and she is assured that they are experienced IVF specialists.

Pre-employment Screening

2.15. The Executive was also concerned that there was no robust system in place which detailed the requirements for pre-employment screening for all clinical staff relevant to their specific area of practice. The committee noted that the PR had promptly taken action to address this area of concern.

Further Action Required

2.16. The committee noted that further action is required. The Executive awaits confirmation that the assessments of competency have been completed and a summary report of the root cause analysis to identify why the centre's processes for pre-employment checks did not include ensuring that appropriate screening was in place. These should be provided to the Executive by 23 September 2021.

Quality Management System (QMS)

2.17. The committee noted that 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.

2.18. During the Desk Based Assessment and on-site inspection, the effectiveness of the centre's QMS was assessed by discussing the processes with the quality manager (who joined the centre in January 2020) and reviewing the procedures for auditing and acting on audit findings. The Executive also reviewed the reports of the audits for medicines management, infection control, legal parenthood, witnessing and consent to storage. The centre's procedures for auditing and acting on the findings of audits were partially compliant with requirements.

2.19. Some areas of practice were documented as achieved by the auditor even though they had identified some non-compliances and issues. The audits did not record all findings or consistently document appropriate corrective and preventative actions including dates for implementation and closure.

2.20. There were inaccuracies in the centre's audit schedule including entries with the same identification code, audit record codes did not match the audit report and timing for audits to be completed.

2.21. The embryo biopsy procedures audit had not been conducted within the last 2 years.

2.22. There was no record of witnessing for the administration of a drug and the witnessing audit was poorly constructed.

2.23. There was insufficient detail in the centre's Peri-operative, instrument and needle count SOP. It did not provide sufficient detail of the processes to record the number of swabs used during a procedure.

2.24. No further action had been noted following the audit of consent to storage (May 2021) which identified that there was a discrepancy in the periods of storage recorded by the male and female gamete provider, and repeat findings in the more recent audit indicates that if actions had been taken, they had not been effective.

2.25. In one record, the patient's partner had completed a new consent form 'Your consent to being the legal parent' (PP form) between their treatments in December 2020 and January 2021 but the centre's audit recorded the date of the previous consent form, not the most recent form that was in the patient's records.

2.26. The centre has ensured compliance with guidance issued by the HFEA such as implementing the new WPT form and taking action to ensure compliance of the success rates page of the centre's website. However, the centre is partially effective in implementing learning from their audits and has not ensured compliance with guidance regarding medicines management.

2.27. The centre's quality indicators for several of the HFEA regulatory requirements such as consent, welfare of the child assessments, witnessing, are not clearly documented, however the Executive notes that these are considered to be 100% compliant.

Further Action Required

2.28. The committee noted that further action is required. The centre's processes have been revised to ensure all audit findings are clearly documented, that suitable corrective actions are identified, and that the individuals responsible for implementation within specified timescales are defined.

2.29. The Executive awaits the summary report of the findings of the review of all audits conducted within the last two years, due by 23 September 2021.

Medicines management

2.30. It is important that centres follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. A review of the controlled drugs (CD) register identified some issues and the centre was found to be partially compliant.

Information

2.31. Information was not clearly documented and in several cases the dosage of the CD administered was illegible and the time of administration was not recorded.

2.32. The carry-over of the amount of CD from one page to another was not consistently signed by the clinical practitioner undertaking the carry-over.

2.33. The recording of alterations in the CD register were not compliant with regulatory requirements.

CD Supplier

2.34. In several entries, it was not clearly documented where the drugs came from including the details of the supplier and the serial number of the requisition used to purchase the drugs, or the formulation and strength of the received drugs.

Drug Classification Schedules

2.35. Two drugs of different drug classification schedules due to be destroyed, were recorded on the same page of the CD register rather than on separate pages in accordance with their classification and regulatory requirements. Staff stated that these entries were duplicate entries and the destruction of each drug had been correctly recorded on the relevant CD page.

Witnessing

2.36. Staff stated that the disposal of partly used CDs in theatre by the anaesthetist is not consistently visually witnessed. The Executive was concerned that the witness is signing the CD register despite not visually witnessing the disposal of the CD at all times, which is not compliant with regulatory requirements and professional guidance.

Disposal of CDs

2.37. A denaturing kit (a safety device to render CDs and other waste drugs unusable) appeared to be in use in the theatre area. However, the theatre practitioner asked did not know whether unused and/or partly used CD ampoules were consistently disposed of in this kit or were sometimes disposed onto the sharps bin without an absorbent medium, which is not in line with professional guidance.

Standard Operating Procedures (SOP)

2.38. The local SOP did not detail how unused and/or party used CDs should be disposed of, which is not in line with professional guidance.

Further Action Required

2.39. The committee noted that further action is required. The PR is required to review practices and procedures relating to medicines management, including, but not exclusively, the issues identified in this report. A summary report of the findings of the review, including any staff training needs and corrective actions identified with timescales for implementation should be provided to the Executive by 23 September 2021.

2.40. The PR confirmed that a review of practices and procedures relating to medicines management has begun and a summary report will be provided to the Executive.

2.41. Three months after the implementation of corrective actions the PR is required to audit medicines management practice and procedures to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the Executive by 23 December 2021.

Premises

2.42. The committee noted that the centre had not conducted a fire drill since September 2019, which is not in accordance with 'Fire safety in the workplace' requirements to conduct these at least annually. The committee also noted that the outdoor compound where clinical waste is stored awaiting collection was only secured with a latch which was not locked.

No Further Action Required

2.43. The committee noted that no further action is required.

2.44. The PR has confirmed that a fire drill took place on 22 July 2021 and no issues were identified.

2.45. Immediately after the inspection the PR provided evidence that the waste compound has been secured by a padlock.

Donor recruitment assessment and screening

2.46. At the time of the licence renewal inspection in October 2019 the centre's procedures for assessing and screening donors were not compliant with HFEA requirements, and there were no records of assessment of competencies for staff undertaking these activities.

Review & Audit by an External Expert, and assessments of competency – July 2020

2.47. Following the inspection, the Executive recommended that the PR should commission a review by an external expert to assess the centre's processes for donor recruitment, assessment and screening.

2.48. A full audit of gamete and/or embryo donor records since the time of the last renewal inspection in October 2015 was undertaken. The PR was required to fully assess the risks to recipients who had treatment with donated gametes in the cases identified during the inspection, and if any further cases were identified following the audit by the external expert.

2.49. In July 2020, the PR provided evidence that the review and audit by an external expert, and assessments of competency for the centre's clinical director and nurse manager, had been completed. The PR confirmed that issues identified had been addressed and all recommended actions had been completed.

Audit by an External Expert – April 2021

2.50. Following the renewal of the centre's licence in October 2020, the Executive required the PR to provide an audit of all donor activities, including recruitment, assessment and screening of donors, by an external expert with knowledge and expertise in this area, within six months. This audit was provided in April 2021 and no issues were identified.

2.51. During the inspection, the records of one egg donor were reviewed in detail to assess compliance with HFEA requirements and professional body guidance and no issues were identified.

2.52. The Executive concluded that the centre's processes for donor recruitment, assessment and screening are compliant with HFEA requirements, with the exception of staffing.

Consent to Legal Parenthood
Treatments resumed using donor sperm and embryos created with donor sperm

2.53. Following the centre's licence renewal inspection in October 2019, the PR had not undertaken robust assessments of competency for staff obtaining consent to legal parenthood, therefore the Executive remained concerned about compliance in this area and was unable to recommend that the centre resumes treatments with donor sperm and embryos created with donor sperm, for new patients (including surrogacy cases).

2.54. Following further communication and oversight by the Executive, and the decision to grant the renewal licence made by the Licence Committee in October 2020, a recommendation was made for the centre to resume treatments. The PR was required to provide monthly audits of all treatments with donor sperm in circumstances where consent to legal parenthood was required. Following some initial concerns with the details in the first two audits provided by the PR, the PR has since provided robust audits of all treatments from 15 October 2020 to 8 June 2021 in circumstances where consent to legal parenthood was required. No anomalies or issues were noted.

2.55. During the inspection, a sample of five sets of these records were also audited by the inspectorate and no anomalies were identified. However, the inspectorate noted that in one record, the patient's partner had completed a new consent form 'Your consent to being the legal parent' (PP form) between their treatments in December 2020 and January 2021 but the centre's audit recorded the date of the previous consent form, not the most recent form that was in the patient's records.

2.56. To provide assurance of the continued compliance, and effectiveness of the centre's legal parenthood consenting procedures, the Executive discussed these procedures with staff and reviewed the centre's assessments of competency of staff undertaking this activity. The committee noted that the Executive is satisfied that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements, with exceptions in the QMS.

Recommendations

Licence

2.57. The Executive noted the effectiveness of actions taken to address previous non-compliances and the centre's low multiple pregnancy rate. The Executive also noted that the centre provides a good level of patient support.

2.58. The committee noted that the Executive recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

3. Decision

3.1. The committee had regard to its decision tree.

3.2. The committee noted that patient safety is an essential requirement for the provision of good healthcare and had serious concerns about the issues raised in the targeted interim inspection report.

3.3. The committee noted the centre's progress to date and that there are still some long-standing issues and improvements to be made in the best interest of patients.

3.4. The committee was disappointed to note that the centre was not compliant with the basic requirement of 'Fire safety in the workplace' legislation to conduct a fire drill at least once a year, considering the risk this could pose to patients and staff.

3.5. The committee also had concerns that the centre had not completed an audit of embryo biopsy procedures within the last two years.

3.6. The committee discussed the Executive's concerns about the centre's peri-operative, instrument and needle count SOP, which has insufficient detail of the processes to record the number of swabs used during a procedure, noting that there had been an adverse incident relating to a retained swab reported by the centre less than two years ago, in December 2019. The committee also deliberated on concerns raised about the management of controlled drugs, including record keeping and witnessing, amongst other non-compliances.

3.7. The committee welcomes the new PR, Mrs Caroline Watkins, and notes her willingness to take on the role. The committee hopes that she will prioritise resolving the workload issues, in particular the nurse manager's role, and make and sustain the required improvements as soon as possible. The committee urges the new PR to work closely with the Executive to achieve and maintain compliance.

3.8. The committee strongly recommends that an inspection is carried out within the next 12 months to monitor the PR's progress with the Executive's support and ensure that all changes have been embedded into the centre's practices.

3.9. The committee endorsed the Executive's recommendation for the continuation of the centre's treatment (including embryo testing) and storage licence.

4. Chair's signature

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

Signature

Name

Jonathan Herring

Date

16 September 2021

Targeted Interim Report

Centre name: Reproductive Health Group
Centre number: 0338
Date licence issued: 16 October 2020
Licence expiry date: 15 October 2023
Additional conditions of licence: a) The centre is prohibited from conducting any further imports of donated gametes under General Direction 0006 and the Person Responsible is required to make an application to the Authority, for consideration by the Statutory Approvals Committee, for Special Directions in relation to any and all proposed imports of donor gametes in the future.
Date of inspection: 23 June 2021
Inspectors: Karen Conyers (lead) and Sandrine Oakes
Date of Licence Committee: 2 September 2021

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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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 (SLCs).

This is a report of a targeted interim inspection, to follow up on areas of concern identified at the time of the centre's licence renewal inspection in October 2019.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk-based assessment (DBA) and the use of virtual technology where available and appropriate. A risk-based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

For this centre, the DBA/RBA process was carried out. Given the centre's history of non-compliance the executive considered that an on-site visit was indicated so as to enable a review of areas of concern previously identified, and to ensure that actions taken to address these had been effective.

We also took into account the centre's own assessment of its service, our on-going monitoring of the centre's performance and the current foci for interim inspections.

- **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.

The aim is to provide the Authority's Licence Committee with information on which to make a decision about the continuation of the licence.

Summary for the Licence Committee

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the effectiveness of actions taken to address previous non-compliances and the centre's low multiple pregnancy rate.

The provides a good level of patient support.

The Licence Committee is asked to note that this report makes recommendations for improvement in relation to four major areas of non compliance or poor practice.

Since the inspection visit, the PR has confirmed that the following recommendation has been fully implemented.

Major area of non compliance

- The PR should ensure that practices regarding fire safety and waste management are compliant with regulatory requirements and best practice guidance.

Since the inspection visit, the PR has given a commitment to fully implement all of the remaining recommendations and to provide further information or audits of practice where applicable.

Major areas of non compliance

- The PR should ensure that the assessments of competency of staff for the roles they undertake are properly completed and documented and that all appropriate pre-employment checks are undertaken.
- The PR should ensure that the centre's Quality Management System (QMS) and processes for auditing, recording audit findings and corrective actions are effective and compliant with HFEA requirements.
- The PR should ensure that medicines management practices are compliant with regulatory and best practice guidance.

Information about the centre

Reproductive Health Group is located in Warrington and has held a treatment and storage licence with the HFEA since April 2014. The centre provides a full range of fertility services including embryo testing.

The centre provided 192 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2021. In relation to activity levels this is a small centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers during 2020.

The current licence has been varied to reflect the following changes:

- 6 April 2021 - change of Licence Holder
- 4 March 2021 - All centres: Variation of all licences without application (European Union (EU) Exit requirements.'

The centre followed professional body guidance to suspend all non-essential treatments in response to the Covid-19 pandemic and is compliant with GD0014 Version 2 for resuming treatment services.

The centre has been subject to a high degree of regulatory oversight since November 2017. Prior to the interim inspection reported on here, inspections of the centre were carried out in November 2017, June 2018, April 2019, and October 2019. Critical non compliances were noted at each inspection in relation to: import of eggs provided by donors who were not compensated in accordance with General Direction 0001 (November 2017); consent to legal parenthood (November 2017, June 2018, April 2019); staffing (October 2019); donor recruitment, assessment and screening (October 2019).

As a result of the executive's concerns in relation to import of donor gametes, an additional condition was added to the centre's licence by Licence Committee in January 2018 and remains on the centre's current licence.

Following the inspection in April 2019 issues in consent to legal parenthood were identified which were of particular concern given the centre's history of previous failure in this area of practice. In view of these findings, the executive contacted the Person Responsible (PR) on 2 May 2019 to ask her to consider a voluntary cessation of treatments with donor sperm and embryos created with donor sperm, for new patients (including surrogacy cases) until such time the HFEA was satisfied that the centre's procedures for obtaining effective consent to legal parenthood were robust. The PR had not provided satisfactory evidence of the assessment of competencies of staff obtaining consent to legal parenthood, therefore the voluntary cessation was still in place at the time of the renewal inspection in October 2019.

Following the renewal inspection in October 2019, the executive was further concerned that nursing staff numbers were inadequate for the activities being undertaken, there were several issues with the centre's processes for assessment and screening of donors and no further action had been taken to undertake a robust assessment of competency for staff taking consent to legal parenthood despite the specific guidance provided in August 2019. As a result, the executive recommended the centre's licence be renewed for one year with three additional conditions, which was endorsed by a Licence Committee in January 2020.

The PR of the centre made legal representations against that decision, and these were considered by Licence Committee in October 2020. The committee recommended that the centre's licence was renewed for three years, and that the additional condition on the centre's previous licence was to remain on the new licence.

In October 2020, there was a change in ownership of the centre following a merger with the 'IVF Life Group' which also has clinics in Spain and Germany, and new clinicians have joined the centre since February 2021.

This is a report of a targeted inspection to follow up on the issues identified at the centre during previous inspections particularly in these areas: staffing, donor recruitment assessment and screening, consent to legal parenthood, the quality management system (QMS), surgical procedures, patient experience.

On 21 August 2021 the PR applied for a change of PR at the centre and the Licence Committee is asked to consider that application together with this report.

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]

HFEA held register data for the year ending 28 February 2021 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages

For the year 2020 the centre reported two cycles of partner insemination with no clinical pregnancies. This represents 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.

HFEA held register data for the year ending 28 February 2021 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out. The PR and centre staff confirmed that patients attending for

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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.

The inspection team noted that the Nurse Manager has been recently promoted to Clinic Manager which includes responsibility for management of the nursing, theatre, and administration teams in addition to her clinical duties. The Nurse Manager is also currently one of the key staff members responsible for obtaining consent to legal parenthood and assessment and screening of donors. The Nurse Manager has a role in supervising clinicians whilst they embed into the centre's activities, and will also be the Responsible Individual for the Care Quality Commission (CQC). At the time of the inspection there was only one other registered nurse at the centre who is still completing some aspects of her training.

Whilst the nurse staffing levels are adequate for the current activity levels, the inspection team is concerned that this would not be the case should activity levels increase, given the additional duties on the most experienced nurse who is now also taken on the substantial role of Clinic Manager. Furthermore, the inspection team noted that this is the same Nurse Manager whose workload was of concern at the time of the renewal inspection in October 2019.

The inspection team reviewed a sample of the records for some of the centre's newer staff members and noted the following issues (see recommendation 1).

- The inspection team reviewed the records of the PR's assessments of competency in donor recruitment, assessment and screening for one of the clinicians that joined the centre in February 2021. The template for this competency assessment was dated June 2021 but the date of completion of the assessment was March 2021. The PR explained that she had recently updated the competency template and the clinician had completed the new version, but the PR had signed it with the date of the previous assessment she had done with the clinician. The PR immediately acknowledged that this was incorrect and that it should have been dated at the time of completion rather than backdated.

- There was no evidence of competency assessment for the provision of information or assessment of the welfare of the child for one of the new clinicians that joined the centre in February 2021, or for the management of controlled drugs for the staff undertaking this activity. Whilst the PR informed the inspection team that the newly appointed clinicians are working within the fertility sector and therefore, she is assured that they are experienced IVF specialists, the inspection team considered that the records of competency should be on file in the centre.

- To ensure staff and patients are protected from acquiring infections in the course of providing treatment, it is important that effective infection control policies (including pre-employment screening) are in place. The inspection team noted that there were some records of pre-employment screening and vaccination status for clinical staff therefore mitigating any direct risks to staff and/or patients. However, the inspection team was concerned that there was no robust system in place which detailed the requirements for pre-employment screening for all clinical staff relevant to their specific area of practice and prior to employment. Furthermore, the inspection team

considered that the records of screening when conducted at another hospital and or clinic should be on file in the centre.
The PR acted promptly on the feedback provided by the inspection team and organised further screening for the relevant staff and provided a draft document detailing the new pre-employment screening process soon after the inspection.

Donor recruitment assessment and screening

It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. At the time of the licence renewal inspection in October 2019 the centre's procedures for assessing and screening donors were not compliant with HFEA requirements, and there were no records of assessment of competencies for staff undertaking these activities.

Following that inspection, the executive recommended that the PR should commission a review by an external expert to assess the centre's processes for donor recruitment, assessment and screening. This review was to include, but not be limited to, ensuring that the centre's standard operating procedure (SOP) was compliant with regulatory requirements and professional body guidance, and that a full audit of gamete and/or embryo donor records since the time of the last renewal inspection in October 2015 was undertaken. The PR was required to fully assess the risks to recipients who have had treatment with donated gametes in the cases identified during the inspection, and if any further cases were identified following the audit by the external expert.

In July 2020, the PR provided evidence that the review and audit by an external expert and assessments of competency for the centre's Clinical Director and Nurse Manager had been completed. The PR confirmed that issue identified had been addressed and all recommended actions had been completed.

Following the renewal of the centre's licence in October 2020, the executive required the PR to provide an audit of all donor activities including recruitment, assessment and screening of donors by an external expert with knowledge and expertise in this area within six months. This audit was provided in April 2021 and no issues were identified.

During the inspection, the records of one egg donor were reviewed in detail to assess compliance with HFEA requirements and professional body guidance and no issues were identified.

These activities enabled the inspection team to conclude that the centre's processes for donor recruitment, assessment and screening are compliant with HFEA requirements, with the exception noted in the 'Staffing' section above.

Consent to 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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre was not licensed until April 2014 and was therefore not required to respond to this request. This centre has been inspected since 2014 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

At the time of the centre's inspections in November 2017, June 2018, April 2019, and October 2019 various issues were noted in relation to consent to legal parenthood. Following the inspection in April 2019 issues in consent to legal parenthood were identified which were of particular concern given the centre's history of previous failure in this area of practice. In view of these findings, the executive contacted the PR on 2 May 2019 to ask her to consider a voluntary cessation of treatments with donor sperm and embryos created with donor sperm, for new patients (including surrogacy cases) until such time the HFEA was satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust. The PR has not provided satisfactory evidence of the assessment of competencies of staff obtaining consent to legal parenthood therefore the voluntary cessation was still in place at the time of the licence renewal inspection in October 2019 when this area of practice was reviewed in detail.

Following the centre's licence renewal inspection in October 2019, the executive remained concerned that the PR had not undertaken robust assessments of competency for staff obtaining consent to legal parenthood and was not able to recommend the lifting of this voluntary suspension of treatments. Following further communication with the centre's inspector, oversight by the executive, and the decision to grant the licence made by the Licence Committee in October 2020, the HFEA was able to recommend that these treatments could resume. The PR was required to provide monthly audits of all treatments with donor sperm in circumstances where consent to legal parenthood was required. Following some initial concerns with the details in the first two audits provided by the PR, the PR has since provided robust audits of all treatments from 15 October 2020 to 8 June 2021 in circumstances where consent to legal parenthood was required. No anomalies or issues were noted.

During the inspection, a sample of five sets of these records were also audited by the inspection team and no anomalies were identified. However, the inspection team noted that in one record, the patient's partner had completed a new consent form 'Your consent to being the legal parent' (PP form) between their treatments in December 2020 and January 2021 but the centre's audit recorded the date of the previous consent form, not the most current form that was in the patient's records. There was no change in the content or consent wishes made in the more recent PP form, but the inspection team was concerned that the auditor had not noted or recorded the date of the most recent consent form that the patient had completed.

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 centre's assessments of competency of staff undertaking this activity. The inspection team noted that the PR had updated the competency assessments in June 2021 to incorporate the new HFEA consent form effective from 1 June 2021 'Your consent to providing eggs or embryos created with your eggs for your partner's treatment'

(WPT form), and the requirements for consent to legal parenthood in shared motherhood scenarios.

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 exceptions noted in the 'QMS' section below.

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.

During the DBA and on-site inspection, the effectiveness of the centre's QMS was assessed by discussing the processes with the Quality Manager (who joined the centre in January 2020) and reviewing of the procedures for auditing and acting on audit findings. The inspection team also reviewed the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because the following issues were identified (see recommendation 2).

- In the centre's most recent audit of medicines management conducted by an external auditor, some areas of practice were documented as 'achieved' by the auditor even though they had identified some non-compliances and issues. One of these findings was that there was no record of witnessing for the administration of a drug which the inspection team considered to be a significant non-conformance. The inspection team was concerned that no further discussion or review of the audit findings appeared to have taken place within the centre. Furthermore, the centre's summary report of the same audit did not record all the findings and did not consistently document appropriate corrective and preventative actions (CAPA) including dates for implementation and closure.

- The centre's recent audit of consent to storage (May 2021) identified that there was a discrepancy in the periods of storage recorded by the male and female gamete provider, but no further actions had been noted such as to review or address this finding. The inspection team noted that no embryos had been stored for this couple therefore there was no immediate impact however this could be an issue if embryos were stored in the future. The inspection team also noted that in a previous audit (February 2020), a similar discrepancy was noted, and the report indicated actions to obtain new consent forms with a reminder for staff but it was not clear if this was recorded as a formal corrective action, and whether this had been carried out. Furthermore, the repeat finding in the more recent audit indicates that if actions had been taken, they had not been effective.

- There is no record of the timescales for implementation of corrective actions documented in audit reports or the log of CAPAs. The log records the closure date

for actions but without a timescale for implementation the centre cannot easily monitor the effectiveness of the QMS.

- As discussed in the 'Consent to legal parenthood' section above, the centre's audit of consent to legal parenthood recorded the date of the previous PP form which had been superseded by a newer form completed prior to the treatment that was included in the audit.

- The centre has not completed an audit of embryo biopsy procedures within the last two years, and the centre's audit of witnessing was a set of checklists without any audit report with audit scope, methodology, findings etc.

- The centre's quality indicators for several of the HFEA regulatory requirements such as consent, welfare of the child assessments, witnessing, are not clearly documented, however the inspection team notes that these are considered to be 100% compliant.

- The inspection team noted some inaccuracies in the centre's audit schedule; there were two entries with the same identification code QAF020, some of audit record codes did not match that on the audit report, some of the audits were incorrectly recorded as requiring re-audit every 5 years but these should have been either a rolling audit (completed on an ongoing basis) or every two years to meet the HFEA requirements for auditing.

- The centre's 'Peri-operative, instrument and needle count' SOP does not provide sufficient detail of the processes to record the number of swabs used during a procedure, which is of concern as there had been an adverse incident relating to a retained swab reported by the centre in December 2019.

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:

- counselling
- consent
- screening of donors
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood

The centre has ensured compliance with guidance issued by the HFEA such as implementing the new WPT form and taking action to ensure compliance of the success rates page of the centre's website. However, the centre is partially effective in implementing learning from their audits (as discussed above) and has not ensured compliance with guidance regarding medicines management as discussed in the section 'Medicines management' below.

Surgical procedures

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 DBA and on-site 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 for the following reasons (see recommendation 3). Other issues were also identified in relation to medicines management and are described in the 'Staffing' and 'QMS' sections of this report.

The following issues were identified during the review of photographic evidence of several pages of the controlled drugs (CD) register which were provided by the centre for the DBA.

- The carry-over of amount of CD from one page to another is not consistently signed by the clinical practitioner undertaking the carry-over and/or witnessed by a second person.

- In several entries, the dosage of the CD administered was illegible.

- In several entries, the time of the administration of the CD was not recorded.

- In several entries, when recording the receipt of CDs, the following were not clearly documented; where the drugs have been received from (i.e., whether from a pharmacy and the details of the supplier), the serial number of the requisition used to purchase the drugs, the formulation and strength of the received drugs.

- Alterations in the CD register are not recorded by way of an asterisk and footnote, which is not compliant with regulatory requirements.

- In one entry, the receipt of CD from pharmacy was recorded on the same line/entry as the supply and administration of CD to a patient which is not in accordance with best practice.

On the day of the inspection the following issues were noted.

- Two CDs due to be destroyed were of different drug classification schedules (Temazepam schedule 4 and Tramadol schedule 3 respectively) but were recorded on the same page of the CD register rather than on separate pages, in accordance with their classification and regulatory requirements. Staff stated that these entries were duplicate entries and the destruction of each drug had been correctly recorded on the relevant CD page.

- Staff stated that the disposal of partly used CDs in theatre by the anaesthetist is not consistently visually witnessed. The inspection team was concerned that the witness is signing the CD register despite not visually witnessing the disposal of the CD at all times, which is not compliant with regulatory requirements and professional guidance.

- The inspection team noted that a denaturing kit (a safety device to render CDs and other waste drugs unusable) appeared to be in use in the theatre area. However, the inspection team was concerned that the theatre practitioner asked did not know whether unused and/or partly used CD ampoules were consistently disposed of in this kit or were sometimes disposed onto the sharps bin without an absorbent medium, which is not in line with professional guidance.
  Furthermore, the inspection team noted that the local standard operating procedure (SOP) did not detailed how unused and/or party used CDs should be disposed of, which is not in line with professional guidance.

Prescription of intralipid 'off label'

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

Infection Control

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

During the DBA and inspection, we reviewed infection control practices and found them to be compliant with guidance with the exception noted in the 'Staffing' section above.

Pre-operative assessment and the surgical pathway

It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

During the DBA and on-site inspection, the clinic's processes for pre-operative assessment and management of the surgical pathway were reviewed and found to be compliant with professional body guidance with the exception noted in the 'QMS' section above.

Patient experience

Patient support

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

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

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Thirty-seven patients have provided feedback in the last 12 months, giving an average four-star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

Several patients provided individual comments to the HFEA complimenting the care they received at the clinic. However, there were also several negative comments mainly regarding costs and billing which were discussed during the inspection. The PR confirmed that actions have already been taken to address similar feedback they had received from patients and there is now clearer pricing on the website stating what is and is not included in the prices quoted. The PR was also aware of the recently released guidance from the Consumer and Markets Authority (CMA) and Advertising Standards Authority (ASA) in relation to the content of websites. The inspection team urge the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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

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 the following issues were identified.

- The centre has not conducted a fire drill since September 2019, which is not in accordance with 'Fire safety in the workplace' requirements to conduct these at least annually (see recommendation 4).

  The inspection team noted that a fire risk assessment had been undertaken within the previous year, weekly fire alarm testing with environmental walks are being conducted and fire emergency procedure instructions were seen throughout the centre, mitigating the risks to staff and patients.

- The outdoor compound where clinical waste is stored awaiting collection was only secured with a latch which was not locked (see recommendation 4).

  The inspection team noted that the waste was in a rigid locked receptacle but was concerned that access was not sufficiently secure, and that clinical waste was not being managed in accordance with guidance for the safe management of healthcare waste storage in a fenced locked compound.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in October 2019 recommendations for improvement were made in relation to two critical, five major and one 'other' area of non-compliance or poor practice.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented. The effectiveness of these actions was assessed during this targeted inspection and some issues remain to be addressed in relation to the centre's QMS.

On-going monitoring of centre success rates

Since the last renewal inspection in October 2019 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. There are currently no significant data submission issues at this clinic.

Leadership

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

The centre is compliant with HFEA guidance regarding effective leadership.

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	Executive review
None identified.		The PR acknowledges that no critical areas of non compliance were identified.	

‘Major’ areas 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	Executive review
1. Staffing The following issues were noted in relation to staffing as described in the body of the report. • The template for the assessment of competency for donor recruitment, assessment and screening was dated June 2021 but the date of completion of the assessment was March 2021. • There was no evidence of competency	The PR should ensure that the assessments of competency of staff for the roles they undertake are properly completed and documented and that all appropriate pre-employment checks are undertaken. The PR should continuously monitor activity levels and staff workloads and take any necessary preventative actions to ensure that patients and staff are safe at all times. When responding to this report the PR should confirm that all	The PR can comfirm that the competency logbooks for staff will be appropraitely completed and assessed. The donor recruitment, assessment and screening competemncies have been redone by two of the consultants, and the nurse manager and PR have also completed this. The competency for the clinical director is being assessed by and external expert. The PR can confirm that the pre-empoyment policy has been reviewed to ensure that the approparite pre-	The executive acknowledges the PR’s response and her commitment to fully implementing this recommendation. The executive also acknowledges the PR’s assurances that activity levels are closely monitored to ensure that patients and staff are safe at all times, and that all clinical staff have been appropriately screened. The executive has been provided with updated copies of the competencies of donor

assessment for the provision of information or assessment of the welfare of the child for one of the new clinicians at the centre, or for the management of controlled drugs for the relevant undertaking this activity. • There was no robust system in place which detailed the requirements for pre-employment screening for all clinical staff relevant to their specific area of practice and prior to employment. SLC T12. CoP 2.2, 25.19 and 25.20. Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance.	current staff have been appropriately screened. The PR should ensure that actions are taken to address the issues noted by the inspection team and provide an update on progress when responding to this report. It is expected that these issues will be fully addressed by 23 September 2021. The PR should undertake a root cause analysis to identify why the centre's processes for pre-employment checks did not include ensuring that appropriate screening was in place. A summary report of the findings of the root cause analysis including any corrective actions identified and timescales for implementation and a copy of the centre's recruitment policy that details pre-employment screening requirements should be provided to the centre's inspector by 23 September 2021.	employment checks are taken as discussed during the inspection. The documentation has also been updated to reflect this. The PR can confirm that activity levels are closely monitored to ensure that there are appropriate numbers of staff present to ensure that staff and patients are safe. A schedulling policy has also been introduced. The PR can confirm that all clinical staff have been appropratiely screened.	recruitment, assessment and screening addressing the issue noted during the inspection. The PR has confirmed that she is in the process of completing the assessments of competencies noted as outstanding by the inspection team and has confirmed that only staff who have been assessed as competent carry out these activities. The executive awaits confirmation that the assessments of competency have been completed and a summary report of the root cause analysis to identify why the centre's processes for pre-employment checks did not include ensuring that appropriate screening was in place. These should be provided to the centre's inspector by 23 September 2021. Further action is required.
2. QMS	The PR should ensure that the	The PR has met with the QM	The executive acknowledges

A number of issues with the centre's QMS were noted by the inspection team. These are described in the body of the report. SLC T32, SLC T35 and SLC T36.	centre's QMS and processes for auditing, recording audit findings and corrective actions are effective and compliant with HFEA requirements. The PR should review the inspection findings to consider why these issues identified by the inspection team have arisen. A summary report of the findings of the review including any corrective actions identified and timescales for implementation should be provided to the centre's inspector when responding to this report. The PR should review all audits conducted within the last two years to ensure that audit findings have been accurately recorded, and that appropriate corrective actions have been identified and fully implemented. A summary of the findings of this review should be provided to the centre's inspector by 23 September 2021.	to review the issue as to why the audit reports were not completed in full. The QMS has been completely overhauled from scratch over the last two years, including successfully gaining ISO:9001, and this unfortunately appears to have been missed where no non-conformances had arisen. This has now been rectified and all audits have a summary reports completed to identify actions, timeframes and corrective actions. The PR will review all audits conducted over the last two years to ensure that they have been correctly recorded and actioned which will be provided to the inspector by 23rd September 2021.	the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary report of the review of the inspection findings and the immediate actions taken to address these. The centre's processes have been revised to ensure all audit findings are clearly documented, that suitable corrective actions are identified, and that the individuals responsible for implementation within specified timescales are defined. The summary report of the findings of the review of all audits conducted within the last two years due by 23 September 2021 is awaited. Further action is required.
3. Medicines management	The PR should ensure that	The PR can confirm that a	The executive acknowledges

A number of issues with medicines management were noted by the inspection team. These are described in the body of the report. SLC T2. Department of Health (DH) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007); section 4.7.1.3. Misuse of Drugs (safe Custody) Regulations (2001) 19 (a). The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice, a guide for departments of anaesthesia, critical care and pain management' (2006); Chapter 7 (record keeping): Para 3 (f). DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary	medicines management practices are compliant with regulatory and best practice guidance. The PR should review practices and procedures relating to medicines management, including, but not exclusively, the issues identified in this report. A summary report of the findings of the review, including any staff training needs and corrective actions identified with timescales for implementation should be provided to the centre's inspector by 23 September 2021. Three months after the implementation of corrective actions the PR should audit medicines management practice and procedures to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 23 December 2021.	review of practices and procedures relating to medicines management has begun to ensure that regulatory and best practice guidelines are compliant and a summary report will be provided to the centre's inspector by 23rd September. A follow up review will then be provided after 3 months (23rd December 2021).	the PR's response and her commitment to fully implementing this recommendation. The summary report of the findings of the PR's review due by 23 September 2021, and that of the audit of medicines management practices due by 23 December 2021 is awaited. Further action is required.

care (England)' (2007); section 4.11.1.2. DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007); section 4.11.1.2. DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007); section 4.7.2.1. Misuse of Drugs (safe Custody) Regulations (2001) 20 (c). DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007); sections 4.7.2.1 & 4.11.1.2. Misuse of Drugs (safe Custody) Regulations (2001) 19(b). Misuse of Drugs (safe Custody) Regulations (2001) 27 (3).			

The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' (2019) (section 'recommendation 4' and page 8).			
4. Premises The centre has not conducted a fire drill since September 2019, which is not in accordance with 'Fire safety in the workplace' requirements to conduct these at least annually. Regulatory Reform (Fire Safety) Order (2005) (section 15.1 (a)) Home Office (2021) https://www.gov.uk/workplace-fire-safety-your-responsibilities/fire-safety-equipment-drills-and-training The outdoor compound where clinical waste is stored awaiting collection was only secured with a latch which was not locked.	The PR should ensure that practices regarding fire safety and waste management are compliant with regulatory requirements and best practice guidance. The PR should confirm that a fire drill has been completed when responding to this report. Immediately after the inspection the PR provided evidence that the waste compound has been secured by a padlock therefore no further actions is required in relation to this issue.	The PR can confirm that a fire drill took place on 22nd July 2021. There were no corrective and preventative actions identified following the drill and the next drill is being scheduled for January 2022.	The executive acknowledges the PR's confirmation that a fire drill took place on 22 July 2021 and no issues were identified. No further action is required.

SLC T17. Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste (2013) (point 5).			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas 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	Executive review
None identified.		The PR acknowledges that there were no 'other' areas of non compliance identified.	

Additional information from the Person Responsible