Licence Committee - minutes

Centre 0338 (Reproductive Health Group)
Renewal Licence

Thursday, 9 January 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Nora Cooke-O'Dowd (Observing - Induction) Victoria Brown (Observing – Induction)	Committee Secretary Head of Research & Intelligence Inspector
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers		

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:

- Renewal inspection report.
- Renewal application form.
- Confirmation of licence type
- Letter from PR to centre's inspector (17 December 2019).
- Previous licensing minutes up to the last licence renewal:
    - Licence Committee - 11 July 2019 - Focused Interim Inspection
    - Licence Committee – 8 November 2018 - Executive Update, Variation - Person Responsible and Licence Holder
    - Licence Committee – 6 September 2018 - Additional inspection / Executive Update
    - Licence Committee – 12 July 2018 - Additional inspection / Executive Update
    - Licence Committee – 3 May 2018 - Executive Update to Interim Inspection
    - Licence Committee – 8 March 2018 - Executive Update to Interim Inspection
    - Licence Committee – 11 January 2018 - Interim Inspection (Additional Condition)
    - Licensing Officer Consideration – 7 March 2017 - Variation - Licence Holder
    - Executive Licensing Panel (ELP) – 15 January 2016 - Variation - Licence Holder
    - Executive Licensing Panel (ELP) – 15 January 2016 - Renewal

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 four years from 1 April 2016 and is due to expire on 31 March 2020. During this time the centre's licence has been varied to reflect a change of Person Responsible (PR) and Licence Holder (LH). An additional condition has also been added to the licence.

History of non-compliance:

1.3. The centre has been subject to inspections focused on the implementation of the recommendations, particularly in relation to donor compensation and legal parenthood.

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:

Critical non-compliances as of November 2017

Import of donor gametes – donor compensation

1.5. The PR 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 in post at the time 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 Person Responsible (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.

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.'

Consent to legal parenthood

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.

1.13. 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.

1.14. 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)

1.15. 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 is the centre's Clinical Director and Lead Clinician.

Inspections:

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

1.17. 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.

Management Review Meeting on 2 May 2019 (April 2019 Inspection)

1.18. 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.

1.19. The Executive 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.

1.20. The Executive also considered the current 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, three months after beginning employment at this centre.

1.21. 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

1.22. 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. 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.

Executive Agreement with the Person Responsible (PR) on 23 May 2019

1.23. The PR requested that single women were not to be included in this suspension of treatments as consent to legal parenthood does not apply to these patients.

1.24. The PR submitted further information about the centre's processes and confirmation that the documentation to be used to establish that patients were single had been checked by the centre's legal advisers who confirmed that it was robust. Following further discussions with the PR, on 23 May 2019 the Executive agreed that if the centre is able to confirm that a patient is single, then treatments with donor sperm (not surrogacy) could be provided to this specific group of patients.

1.25. Further to this, the PR also requested that the centre be allowed to provide treatments with donor sperm, or embryos created with donor sperm, to specific patients where it would be detrimental to them if their treatment was delayed because of exceptional personal circumstances. For these specific cases, 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. If the PR did not identify any concerns or risks, then it would be reasonable to proceed with providing treatment to these patients on the basis that, due to their specific circumstances, they would be compromised by a delay in treatment.

1.26. 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

1.27. 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, 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.

1.28. The committee noted that, at that time, the Executive was assured that the PR would fully discharge her duties and was committed to ensuring that the centre would achieve and maintain compliance with regulatory requirements. Therefore, the committee agreed to the continuation of the centre's licence.

1.29. The committee noted that there were some outstanding actions to be completed to address the non-compliances identified and agreed that the inspectorate should continue to monitor the centre's performance and the PR should continue to engage with the Executive to improve the quality of service provided to patients.

1.30. The committee requested that the Executive should provide an update following the renewal inspection scheduled in October 2019, for consideration by the Licence Committee at a future meeting.

1.31. The Executive has now submitted the report of the renewal inspection carried out in October 2019 for consideration by the Licence Committee.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of a treatment and storage licence, however, the PR has confirmed that the licence application is for a treatment (including embryo testing) and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 31 October 2019, the centre provided 213 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that HFEA-held register data for the year ending 31 July 2019 showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages.

2.5. The committee noted that for the year 2018, the centre reported one cycle of partner insemination with no pregnancy. This represented a clinical pregnancy rate which was in line with the national average.

2.6. The committee noted that HFEA-held register data for the year ending 31 July 2019 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 12%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 8 and 9 October 2019. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there were two critical, five major and one other area of non-compliance identified:

Critical areas of non-compliance:

- The PR should ensure that the donor recruitment, assessment, selection and screening procedures are compliant with all regulatory requirements and professional body guidance.
- The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles.

Major areas of non-compliance:

- The PR should ensure that all medical gases are stored safely and kept secure at all times.
- The PR should ensure that the centre's quality management system (QMS) is effective.
- The PR should ensure that all agreements with third parties meet the requirements of the relevant licence conditions and the guidance set out in the HFEA CoP, and that the ability of all third parties to meet the required standards is evaluated.
- The PR should ensure that she fully discharges her duties under section 17(1) of the HF&E Act 1990 (as amended) and has comprehensive oversight on all activities at the centre.
- The PR should ensure that staff training and assessment of competency in consent to legal parenthood is completed.

Other areas of non-compliance or poor practice:

- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

2.8. The committee noted that since the inspection visit, the PR has committed to fully implementing all of the recommendations within the required timescales. The PR has confirmed the actions taken to date and that she will provide all of the requested evidence and any audits of practice within the required timescales.

Assessment and screening of gamete donors

2.9. 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.

Staff

2.10. The Executive considered that the nursing staff numbers were inadequate for the activities being undertaken. The centre has 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 is concerned that the nurse manager is currently responsible for all of the clinical work (as the two part-time nurses are not yet trained) as well as fulfilling her management duties and additional responsibilities such as being the centre's Safeguarding lead. The nurse manager's appointment diary was reviewed by the inspectorate and it was considered that the number of tasks and appointments designated to her were so high that she would be left with no time during her contracted working hours to undertake other important tasks that she needs to do, for example arranging staff cover which she can only complete by regularly working two hours extra every day. Furthermore, she is not able to train the other nurses, maintain her management responsibilities, and undertake continuous professional development. The inspectorate was concerned that she has to be reactive instead of having time to be proactive and anticipate issues thereby mitigating any potential risks.

Consent to Legal Parenthood

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

2.12. 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.

Management Review Meetings - 18 & 25 November 2019

2.13. The Executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy on 18 November 2019, and a further meeting was held on 25 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.

2.14. The committee noted that the Executive was particularly concerned with the inspection findings in relation to: assessment and screening of donors, the numbers and training of nursing staff, 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.

2.15. The committee noted that the Executive also considered the PR's ability to discharge her duties under section 17(1) of the HF&E Act 1990 (as amended) and concluded that the PR has failed to discharge her duty under section 17(1)(a), (d) and (e). The Executive reached this conclusion as a result of the following non-compliances:

- **Staff** - The PR has not ensured that staff are available in sufficient number and assessed as competent for the tasks they perform. The PR has not taken actions to ensure adequate levels of nursing staff. Training and competence assessments for staff in relation to critical activities such as consent to legal parenthood and donor assessment and screening have not been completed.
- **Assessment and screening of gamete donors** - The PR has not ensured that suitable practices are used in the course of the activities and that the conditions of the licence are complied with. A number of issues were identified in relation to the assessment and screening of gamete donors.
- **Legal Parenthood** - The PR has not acted on recommendations for improvement and has not effectively implemented recommendations in relation to the previous critical non-compliance regarding consent to legal parenthood following the inspections in November 2017, June 2018 and April 2019. Issues identified during the time of the previous PR include an anomaly in consent to legal parenthood affecting a couple who had a live birth, no assessment of practice in accordance with the HFEA Chief Executive's letter CE(14)01, lack of robustness of the audit that was subsequently carried out, retrospective amendment of a consent form (no live birth in that case). Under the current PR, in April 2019, a critical non-compliance was identified due to a further error in the completion of a consent to legal parenthood form, and the centre's audit of legal parenthood did not include a robust audit of records in accordance with the CE(14)01.

Recommendations

Licence

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

2.17. The Executive considered a range of factors such as the ability of the PR to discharge her duties, and 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 in relation to donor screening, staffing levels, 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 is 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.’

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted on an application form and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Ms Karen Schnauffer

3.3. The committee noted that the Executive had considered the PR’s ability to discharge her duties under section 17(1) of the HF&E Act 1990 (as amended) and concluded that the PR had failed to discharge her duty under section 17(1)(a), (d) and (e). However, the committee also noted that the Executive acknowledges the PR’s commitment to fully discharging her duties and the immediate action taken to reduce the number of procedures being performed at the centre.

3.4. The committee noted that the Executive considered whether 10 months had been sufficient time for the PR to be able to ensure compliance in a centre with a history of non-compliance.

3.5. The committee noted that the Executive acknowledged that the PR has previous experience in the role of PR between 2014 and 2017, and that the PR has commissioned an independent review of the leadership and governance of the centre by a peer who is a current PR at another HFEA licensed centre. The date has yet to be arranged. The Executive will liaise with the PR in relation to the outcome of this review.

3.6. The committee is satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities.

3.7. The committee is also satisfied that the proposed PR will discharge her duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Dr Lee Feddy

3.8. The committee was satisfied that the proposed LH is suitable.

Activities

3.9. The committee was satisfied with the suitability of the activities applied for.

Premises – Daresbury Park, Daresbury, Cheshire, WA4 4GE

3.10. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.11. The committee was satisfied that the third-party premises are also suitable.

Assessment and screening of gamete donors

3.12. The committee noted that the PR had arranged for an external expert to review the centre's processes for donor recruitment, assessment and screening and that this review was scheduled to take place on 20 December 2019. The external reviewer would also 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 are further cases where gamete providers were not suitably assessed and screened as donors, including checks to see if travel history was not reviewed. On completion of the audit the PR should identify whether there are further cases where the gamete providers were not suitably assessed and screened as donors. If cases are identified, the PR should 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 should also consider whether recipients affected are to be contacted and advised of possible risks of their treatment. The PR has been advised to inform the inspectorate of the timeline for completing this risk assessment by 9 February 2020.

Staff

3.13. The committee noted the Executive's concerns about staffing levels at the centre and acknowledged that the current arrangement for managing staffing levels is a short term solution.

Consent to Legal Parenthood

3.14. The committee noted that during this renewal inspection no issues were identified in 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.

3.15. The committee noted that 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, the Executive would consider recommending the removal of these conditions.

3.16. The Legal Adviser reminded the committee members that in the absence of satisfactory evidence, as noted by the Executive, it could not be assured that a robust assessment of staff competency was undertaken.

Licence

3.17. The committee had regard to the HFEA Guidance on licensing and considered the duration of licence it should offer.

3.18. The committee considered the content of the inspection report and deliberated on the PR's letter in response to the report in detail.

3.19. 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.

3.20. Carefully weighing all factors in the balance, the committee agreed that a one year treatment (including embryo testing) and storage licence, with the following additional conditions, was appropriate:

- Existing Condition - the condition currently on the centre's licence remains in place:

  '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 addition of the following 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 addition of the following condition:

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

3.21. The committee agreed that there would be no exceptional circumstances in relation to the two new conditions added to the licence.

3.22. The committee noted that this licence offer will become final and come into effect on 1 April 2020 unless the PR chooses to make representations regarding the proposed decision, or submit any other information within 28 days.

Inspection

3.23. The committee noted that the next renewal inspection will be carried out by Autumn 2020, subject to the PR submitting a renewal application. The committee agreed that the PR should have had sufficient time to address the non-compliances noted in the report by the time of the renewal inspection. The committee encouraged the PR to continue to engage with the Executive and fully implement the recommendations within the required timescales.

Importing Tissue Establishment (ITE) import certificate

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

4. Chair's signature

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

Signature

Name

Kate Brian

Date

24 January 2020

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 8 and 9 October 2019.

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Karen Conyers (lead), Janet Kirkland MacHattie, Paul Knaggs and Victoria Brown (HFEA observer).

Date of Licence Committee: 9 January 2020.

Centre name	Reproductive Health Group
Centre number	0338
Licence number	L/0338/2/d
Centre address	Daresbury Park, Daresbury, Cheshire, WA4 4GE, United Kingdom
Person Responsible	Ms Karen Schnauffer
Licence Holder	Dr Lee Feddy
Date licence issued	1 April 2016
Licence expiry date	31 March 2020
Additional conditions applied to this 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.

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
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 current licence has been varied as follows:

- change of Person Responsible (PR) and Licence Holder (LH) in December 2018;
- the addition of a condition in February 2018; and
- change of LH in March 2017.

The centre provided 213 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2019. In relation to activity levels this is a small centre.

The centre has been subject to a high degree of regulatory oversight since November 2017 as discussed in the section 'Recommendation to Licence Committee' below. Prior to the renewal inspection reported on here, inspections of the centre were carried out in November 2017, June 2018 and April 2019.

In November 2017 and June 2018, the executive concluded that the PR at that time had failed to discharge his duty under section 17(1) of the Act. The executive was no longer satisfied that the PR at that time was a suitable person to supervise the licensed activity of the centre. In September 2018, the PR at that time advised the executive that he had appointed Karen Schnauffer as Laboratory Director and that she would be making an application to become the PR of the centre. The application for change of PR was considered by Licence Committee in November 2018, and the centre's licence was varied to reflect a change of PR, which came into effect on 3 December 2018.

In April 2019 a focused inspection was carried out at short notice. During that inspection further 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; noted as critical non-compliances following inspections in November 2017 and June 2018. 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 is 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 this renewal inspection. This area of practice was a focus of this inspection.

Pregnancy outcomes[1]

HFEA held register data for the year ending 31 July 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2018 the centre reported one cycle of partner insemination with no pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 July 2019 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

[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%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has not fully discharged her duty under section 17 of the HF&E Act 1990 (as amended), however with the effective implementation of the recommendations of this report, the executive considers that the PR will be able to fully discharge her duty;
- the premises (including those of relevant third parties) are suitable with the exceptions noted below;
- the centre's practices are suitable with the exceptions noted below;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two critical, five major and one 'other' area of non-compliance or poor practice as follows.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations within the required timescales. The PR has confirmed the actions taken to date and that she will provide all requested evidence and any audits of practice within the required timescales.

Critical areas of non-compliance:

- **The PR should ensure that the donor recruitment, assessment, selection and screening procedures are compliant with all regulatory requirements and professional body guidance.**
- **The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles.**

Major areas of non-compliance:

- The PR should ensure that all medical gases are stored safely and kept secure at all times.
- The PR should ensure that the centre's quality management system (QMS) is effective.
- The PR should ensure that all agreements with third parties meet the requirements of the relevant licence conditions and the guidance set out in the HFEA CoP, and that the ability of all third parties to meet the required standards is evaluated.
- The PR should ensure that she fully discharges her duties under section 17(1) of the HF&E Act 1990 (as amended) and has comprehensive oversight on all activities at the centre.
- The PR should ensure that staff training and assessment of competency in consent to legal parenthood is completed.

‘Other’ area that requires improvement:

- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Licence Committee

The centre has two critical and five major areas of non-compliance.

The inspection team notes that the centre’s success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target.

Following a routine interim inspection in November 2017 a number of significant issues came to light particularly in relation to the compensation of overseas donors and consent to legal parenthood. The executive concluded that the PR of the centre at that time 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 failed to understand the requirements in relation to compensation for overseas donors and ensure that gametes imported from the Ukraine meet the requirements on compensation for overseas donors set out in General Direction 0001. The HFEA’s Licence Committee agreed that although it considered there were 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 that:

- a condition be added to the centre’s licence prohibiting it from conducting any further imports of donated gametes under General Direction 0006 and that the PR must make an application to the Authority, for consideration by the HFEA’s Statutory Approvals Committee, for Special Directions in relation to any and all proposed imports of donor gametes in the future;
- the PR should apply for Special Directions for the return of imported donor eggs to Ukraine; and
- the PR should apply for Special Directions for the simultaneous export and reimport of embryos created with imported donor eggs to Ukraine to allow them to be used in treatment.

Applications for these Special Directions were made by the PR at that time and were considered and approved by the Statutory Approvals Committee on 22 March 2018.

In addition, at its meeting in January 2018, Licence Committee endorsed the executive’s recommendation to conduct an inspection, focused on the centre’s implementation of the recommendations (particularly in relation to donor compensation and legal parenthood) within one year. That inspection was undertaken in June 2018, and the report was considered by Licence Committee in July 2018. The executive again concluded that the PR at that time had failed to discharge his duty under section 17(1)(d) of the Act as he had failed to ensure that suitable practices were used in the course of the clinic’s activities. The executive was no longer satisfied that the PR at that time was a suitable person to supervise the licensed activity of the centre and Licence Committee was invited to make findings in this regard.

In July 2018, Licence Committee decided to adjourn consideration of the additional inspection report and related papers without making any findings, to enable a request from the PR at that time that a meeting take place between himself and the HFEA executive. That meeting took place on 10 September 2018, during which the PR at that time advised the executive that Karen Schnauffer would be making an application to become the PR of

the centre. Karen Schnauffer had previously been a PR at centre 0007 and centre 0344 between 2014 and 2017. In addition, the PR at that time also explained the centre's current LH would be leaving the centre and that an application to change LH would also be submitted to the HFEA in due course. The applications for change of PR and change of LH were considered by Licence Committee in November 2018, and the centre's licence was varied to reflect a change of PR and LH which came into effect on 3 December 2018. The previous PR is the centre's Clinical Director and lead clinician.

In view of the centre's history, the executive also recommended that a focused inspection be carried out in Spring 2019, which was conducted at short notice in April 2019. During that inspection further issues in consent to legal parenthood were identified for a surrogate and the commissioning couple which were of particular concern in view of the centre's history of failure in this area of practice. In addition, the inspection team also had some concerns in relation to assessment of surrogates and intended parents prior to treatment.

In view of these concerns, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance. The meeting on 2 May 2019 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. At this meeting the executive also considered the current PR's ability to discharge her duties under section 17(1) of the Act. 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 but noted that she had only been PR for four months, three months after beginning employment at the centre.

In consideration of the findings on this inspection and the centre's previous failings in relation to legal parenthood, the executive contacted the PR soon after the management review meeting on 2 May 2019 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. The executive also agreed that the PR would be required to attend a meeting with the HFEA executive to discuss its concerns.

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 her continued oversight and governance of all activities in the centre. The executive was satisfied with the PR's assurances of the immediate actions she had taken in response to the inspection findings, of her commitment to fully discharging her duties, and of 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. 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 have been completed, and confirmation that no further issues have been identified in the centre's audits of consent to legal parenthood and surrogacy cases.

Further to this, the PR also requested that the centre be allowed to provide treatments with donor sperm, or embryos created with donor sperm, to specific patients where it would be detrimental to them if their treatment was delayed because of exceptional personal

circumstances. For these specific cases, 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. If the PR did not identify any concerns or risks, then it would be reasonable to proceed with providing treatment to these patients on the basis that, in their specific circumstances, they would be compromised by a delay in treatment. 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 have been provided with treatment since May 2019, and their records were reviewed during the inspection. No issues were identified.

In July 2019, Licence Committee minutes recorded '3.2 The committee had concerns about the centre's history of non-compliance and the suitability of the current PR.' and '3.5 The committee requested that the Executive provides an update following the renewal inspection scheduled in October 2019, for consideration by the Licence Committee at a future meeting.'

Following the meeting in May 2019, the PR and centre's quality manager provided the centre's inspector with reports of the audits of records confirming that no further legal parenthood issues have been identified. The centre's inspector advised the PR that evidence of staff training and competency assessment were awaited before the executive was able to recommend that treatments with donor sperm or embryos created with donor sperm can resume.

On 16 August 2019 the PR provided assessments of competency of obtaining consent to legal parenthood for seven members of staff. These were reviewed by the executive and were not considered as satisfactory evidence of staff competence in this area. On 22 August 2019 the centre's inspector advised the PR that the executive did not consider that these competency assessment documents alone were satisfactory, and also provided specific guidance on what would be expected in a robust assessment of competency which would assure the executive that staff fully understand the requirements in relation to consent to legal parenthood (for example provision of information, offer of counselling, which forms are required, how to complete the forms correctly, when they must be completed, what actions to take if there are any errors, what actions to take if there is a withdrawal of consent etc).

During the inspection reported on here the executive notes that the inspection team has not identified any anomalies in four records of consent to legal parenthood for treatments carried out in 2019 that were audited, and no further issues have been identified in the centre's audits of consent to legal parenthood and surrogacy cases. 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. In addition, the inspection team considered that the nursing staff numbers was inadequate for the activities being undertaken and noted several issues with the centre's processes for assessment and screening of donors.

In view of these concerns the executive held a management review meeting on 18 November 2019 in accordance with the HFEA Compliance and Enforcement Policy, and a further meeting was held on 25 November 2019. The meetings 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. Of particular concern were the inspection findings in relation

to: assessment and screening of donors; the numbers and training of nursing staff; 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.

At these meetings the executive also considered the PR's ability to discharge her duties under section 17(1) of the HF&E Act 1990 (as amended) and concluded that the PR has failed to discharge her duty under section 17(1)(a), (d) and (e). The executive reached this conclusion as a result of the following non-compliances which are described in detail in this report.

- The PR has not ensured that staff are available in sufficient number and assessed as competent for the tasks they perform. The PR has not taken actions to ensure adequate levels of nursing staff. Training and competence assessments for staff in relation to critical activities such as consent to legal parenthood and donor assessment and screening have not been completed.
- The PR has not ensured that suitable practices are used in the course of the activities and that the conditions of the licence are complied with. A number of issues were identified in relation to the assessment and screening of gamete donors.
- The PR has not acted on recommendations for improvement and has not effectively implemented recommendations in relation to the previous critical non-compliance regarding consent to legal parenthood following the inspections in November 2017, June 2018 and April 2019. Issues identified during the time of the previous PR were; an anomaly in consent to legal parenthood affecting a couple who had a live birth, no assessment of practice in accordance with the Chief Executive's letter CE(14)01, lack of robustness of the audit that was subsequently carried out, retrospective amendment of a consent form (no live birth in that case). Under the current PR, in April 2019, a critical non-compliance was identified due to a further error in the completion of a consent to legal parenthood form, and the centre's audit of legal parenthood did not include a robust audit of records in accordance with the CE(14)01.

The management review meeting also considered the HFEA's Guidance on Licensing in order to determine a recommendation as to the renewal of the centre's licence. In reaching a proportionate decision the executive considered a range of factors such as the ability of the PR to discharge her duties, and whether 10 months had been sufficient time for the PR to be able to ensure compliance in a centre with a history of non-compliance. Given the issues noted in relation to donor screening, staffing levels, and the centre's compliance history, 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 would recommend that the centre's Treatment (including embryo testing) and Storage licence is renewed for one year with the following additional conditions.

- The condition currently on the centre's licence remains in place: '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.'
- The addition of the following 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.'

- The addition of the following condition: ‘The centre is prohibited from providing treatments with donor sperm or embryos created with donor sperm for patients, including surrogacy cases.’

Before the executive can consider recommending the removal of any of these conditions, it will require robust evidence that the centre’s processes are compliant with regulatory requirements and professional guidelines as set out in the body of the report; such as standard operating procedures (SOPs) and training and assessments of competency of staff undertaking these activities.

Assuming that the centre wishes to apply to renew its licence, and subject to an application from the PR, a renewal inspection will be carried out by Autumn 2020. By this time the executive would expect that the PR will have had sufficient time to address the non-compliances noted in the report and will be able to provide satisfactory and robust evidence of compliance such that the executive will be able to recommend that the centre’s licence is renewed without additional conditions.

The draft inspection report was provided to the PR on 3 December 2019 and she provided her responses on 17 December 2019, within the required timescale. The executive has reviewed the PR’s responses and acknowledges her commitment to fully implementing all recommendation in the report. The executive makes no change to its recommendation that the centre’s Treatment (including embryo testing) and Storage licence is renewed for one year with the following additional conditions.

- The condition currently on the centre’s licence remains in place: ‘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.’
- The addition of the following 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.’
- The addition of the following condition: ‘The centre is prohibited from providing treatments with donor sperm or embryos created with donor sperm for patients, including surrogacy cases.’

Centre 0338 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Assessment and screening of donors (Guidance note 11)
The centre's procedures for assessing and screening donors are partially compliant with HFEA requirements. 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.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Assessment and screening of donors (Guidance note 11)
The following issues were noted during an audit of records of three egg donors and two sperm donors (see recommendation 1).

- In three records there was no evidence the donor's health and medical history had been provided on a questionnaire (SLC T52a).

- No physical examination had been carried out for one of the sperm donors. The Clinical Director confirmed that this was not part of the routine assessment unless the sperm donor was having a surgical sperm retrieval. This is not in accordance with professional guidelines (T52a and UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019)).

- In two egg donor records there was no result of a repeat test for syphilis at the time of donation (T52b). The Clinical Director confirmed that this test would have been requested however no result was available for the inspectors to review.

  In one of the sperm donor records there was no result available for the testing for Gonorrhea. The Clinical Director again confirmed that this test would have been requested.

  In one sperm donor record, the second page of the donor's travel history declaration (including consideration of Zika and Ebola risk) was not scanned in the electronic record management system. No paper records are kept at the centre.

  In these cases, the inspection team was concerned how the clinical team was able to confirm that all screening tests were negative and the donor's travel history did not indicate any potential risks to the recipients without having all relevant information.

- Recently updated professional guidelines recommend that centres perform nucleic acid amplification technique (NAT) testing in addition to serological testing at or around the time of starting stimulation for an egg donation cycle. For the three egg donor cases, although the centre had performed a NAT test at the appropriate time this was not in addition to serological testing. The inspection team noted that serological testing had been carried out two weeks previously but not at the time the NAT testing had been performed and there was no documentation of the reason for this deviation from professional guidance (CoP 11.23, CoP 11.24 and UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019)).

- The inspection team also noted that HTLV testing had not been undertaken for any of the donors, however the rationale for not performing this (i.e. the donor's history did not indicate it was necessary) had not been documented (SLC T52g and UK

guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019)).

- One sperm donor known to the recipient was older than that specified in professional guidelines but there was no evidence in the patient's medical records of the reasons for using a donor above the recommended age limit (CoP 11.4).

- The inspection team requested the centre's SOP for donor assessment and screening. The SOP provided was not adequate as it did not reflect the centre's practices and did not incorporate recent changes in regulatory requirements and professional guidance (SLC T33b). The Clinical Director informed the inspection team that the SOP provided was not the most recent version and that it had recently been updated however no other document was given to the inspectors during the inspection.

- The inspection team noted that there was no assessment of competencies in relation to this area of practice, see 'Staff' section below.

- The centre's audit of egg donor assessment and screening was not robust as it did not identify the issues noted by the inspection team such as lack of medical questionnaire and lack of evidence of screening results in the records (SLC T36). There was no audit of sperm donor assessment and screening.

During the inspection the Clinical Director explained that it is the centre's practice to screen donors known to recipients ('known donors') differently to those that are not known to the recipients in that a 'single' negative screen is accepted. The inspection team understood that in these cases screening was undertaken when the donor was screened before being accepted as a donor but was not screened again before using the donated gametes in treatment. However, this is not in accordance with SLC requirements where no such distinction is made. The centre is also expected to follow professional guidance for the assessment and screening of donors and if there is any deviation from such guidance it is expected that each case has been risk assessed, and that the rationale for this is fully documented. However, this was not seen in the records, as discussed above. The documents provided during the inspection included a template for a 'waiver' for a recipient to agree to accept a donor who had only 'one' negative screen. During the inspection the Clinical Director informed the inspection team that this 'waiver' was no longer in use. An updated SOP provided by the PR two weeks after the inspection included a statement 'One screen is deemed adequate in 'low risk' women donors provided the couple are aware of the small risk of seroconversion in the next 180 days.' Again, this is not in accordance with SLC T52 and the centre's inspector sought further clarification from the PR.

In view of the concerns noted above, and the potential risks involved in use of donated gametes and embryos which have not been screened in accordance with the requirements, at the end of the inspection the lead inspector asked the PR and Clinical Director to ensure that they complete a review of the centre's processes for recruitment, selection and assessment of donors before undertaking any further donor gamete or embryo procurement or treatments. The PR was asked to ensure that the centre's processes are compliant with all licence conditions and relevant guidance including 'Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)

Donor Selection Criteria Report (2017) Version 2' and 'UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019)). This was reiterated by email immediately after the inspection, on 10 October 2019.

On 21 October 2019 the PR confirmed that 'we have reviewed our egg donation protocol, the patient information, the donor assessment and the screening/rescreening protocol and can confirm they are now in line with the regulatory requirements (HFEA and SaBTO).' On further review, the centre's inspector noted that the revised SOP provided ('Viral screening and management of patients at risk of infectivity' CLP019 v2) did not reference the UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019) and contained the statement regarding the 'one screen' discussed above.

In view of these concerns that if the assessment of donors is not fully compliant with screening requirements and guidance there remains an unacceptable risk to recipients, the centre's inspector again sought the PR's assurance that she will take full responsibility for ensuring that the assessment and screening of donors providing gametes or embryos being used in treatment is fully compliant with requirements. On 11 November 2019 the PR confirmed that '… as PR I will take responsibility for ensuring that the assessment and screening of donors providing gametes or embryos being used in treatment is fully compliant with requirements...'.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are partially compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance with the exceptions noted in the 'Staff' section below.

Medicines management (Guidance Note 25)
The centre's arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines were reviewed during the inspection and the findings are discussed below.

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

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

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

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

Pre-operative assessment and the surgical pathway (Guidance Note 25)

The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country

suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has not yet been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have not been made since the introduction of the ITE import certification scheme on 1 April 2018.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability to;

- identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- identify the donor and recipient of particular gametes or embryos;
- identify any person who has carried out any activity in relation to particular gametes or embryos; and
- identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is partially compliant with HFEA requirements.

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are partially compliant with HFEA requirements.

Satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events

and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Gas cylinders are stored in three different locations within the centre and the inspection team noted the following issues (recommendation 3; SLC T17 and Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management).

- In the 'plant room' although chains were in place, they were not fastened over two of the cylinders and therefore the cylinders were not secure.
- Gases are also stored behind a fenced area outside the building. Whilst the inside of the fenced area had safety signage there was not sufficient safety signage on the outside of the area.
- In another storage area six large, three medium and three small gas cylinders were not secured sufficiently and were at risk of falling over.

Medicines management (Guidance Note 25)
The clinical inspector discussed practices related to controlled drugs and reviewed the controlled drugs register. No issues were identified. The clinical inspector was also able to discuss practices related to more general medicines management with the nurse manager but due to the lack of availability of nursing staff was not able to review evidence in order to complete the evaluation of compliance with guidance. The inspection team did not consider there were any significant concerns in this area of practice, and it will be reviewed at the time of the next inspection.

Prescription of intralipid 'off label'
Due to the lack of availability of nursing staff during the inspection, the inspectors were not able to review the process for administering and monitoring patients during intralipid infusion in detail, therefore it is not possible to conclude whether these are suitable. Based on the brief review of these processes the inspection team did not consider there were any significant concerns in this area of practice, and it will be reviewed at the time of the next inspection.

Quality management system (QMS) (Guidance note 23)
The centre's quality manager began working at the centre in November 2018 and has made progress in undertaking a complete overhaul of the centre's QMS as she considered that the processes that were in place under the previous quality manager were not effective. As part of this overhaul she has been reviewing the auditing processes, including the scope and methodology of audits and the systems for ensuring that corrective actions are appropriate, are recorded accurately, and are completed in a timely manner. The inspection team considered that significant progress has been made and noted the following actions remaining, which the quality manager has also recognised and has an action plan in place to address (see recommendation 4).

- Quality indicators are either not currently in place or are not appropriate for several areas of practice such as counselling, provision of information, donor assessment and screening, consent to storage, traceability of equipment, confidentiality and record keeping (SLC T35). The quality manager is currently undertaking a comprehensive review of the centre's quality indicators against the regulatory requirements and CoP.

- The centre's audit of egg donor assessment and screening is not robust (see section 'Assessment and screening of donors' above) and there was no audit of sperm donor assessment and screening or confidentiality in the last two years (SLC T36).

- Three of the centre's SOPs provided on inspection were not compliant with regulatory requirements and contained incorrect information; 'Viral screening' (see section 'Assessment and screening of donors' above), consent to legal parenthood (see section 'legal parenthood' below) and safeguarding which named the safeguarding lead as a staff member who left in 2018 (SLC T33b).

The centre has not yet undertaken a review of the performance of the QMS to ensure continuous and systematic improvement. The inspection team is assured that this will be undertaken once the overhaul of the QMS is completed therefore no further recommendation is made at this time. This will be followed up at the next inspection.

Third party agreements (Guidance note 24)
During the inspection two of the centre's third party agreements were reviewed and were not compliant with requirements (see recommendation 5; SLC T114d-f and SLC T116).

The centre has not evaluated the ability of all of the centre's third parties to meet the required standards (see recommendation 5; SLC T112). The inspection team noted that the centre's quality manager is aware of this and has plans in place to complete this audit.

During a review of donor records the inspection team noted that a number of blood test results did not appear to be in the records. It was not clear if this reflects a failure of the third party to ensure that it provides the results. The inspection team also noted that the third party agreement with the laboratory undertaking the testing does not document how test results will be relayed (see recommendation 5; SLC T114f).

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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 partially compliant with HFEA guidance regarding leadership.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Person Responsible (Guidance note 1)
The PR has worked at the centre since September 2018 and has been PR since December 2018. At the time of the focused inspection in April 2019, the inspection team considered that the PR's oversight within the centre was not yet evident. Following that inspection, the executive recommended that the PR should focus on her role as PR to ensure that she fully discharges her duties and has comprehensive oversight on all activities at the centre.

The inspection team noted the progress made in overhauling the centre's QMS and that the PR checks every set of records prior to treatment to ensure that all documents are in order. However, the inspection team was concerned that the PR has not been proactive in addressing a number of significant issues as follows.

- The PR has not taken action to address the concerns regarding the nurse manager's workload (see 'Staff' section below).
- The assessment of competency in obtaining consent to legal parenthood has been awaited since the previous inspection in April 2019 and has been discussed with the PR at the meeting attended in May 2019. Detailed guidance on what was expected was provided by the centre's inspector in August 2019, yet no further progress has been made in completing this recommendation.
- The PR has not completed assessment of competencies for critical activities such as donor assessment and screening.
- The PR's audit of donor assessment and screening did not identify the issues noted by the inspection team.
- The centre's counsellor was not aware of the other counsellor employed by the centre (see 'Counselling' section below). The PR has confirmed that they are now to be 'introduced'.
- The PR had not identified the anomalies in the SOPs for consent to legal parenthood and viral screening noted by the inspection team.

Whilst the PR responds to issues raised by the centre's inspector or during an inspection, the inspection team was not assured that the PR has demonstrated that she has comprehensive oversight on all activities at the centre. Overall, the inspection team considered that leadership at the centre is not strong and requires improvement (see recommendation 6; Section 17(1) of the HF&E Act 1990 (as amended) and HFEA document: 'Person Responsible key behaviours and role description').

Staff (Guidance note 2)

The inspection team was not assured that the number of nursing staff is sufficient for the activities undertaken at the centre. (see recommendation 2; SLC T12, SLC T15, CoP 1.7(b)). The centre has 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 have been taken to recruit to this role. The centre's two part-time nurses also cover non-IVF related theatre procedures carried out at the centre and they are therefore not able to learn or progress in the roles for which they were employed. The inspection team was concerned that at present the nurse manager is responsible for all of the clinical work (as the two part-time nurses are not yet trained) as well as fulfilling her management duties and additional responsibilities such as being the centre's Safeguarding lead. The nurse manager's appointment diary was reviewed by the inspector and it was considered that the number of tasks and appointments designated to her are so high that she is left with no time during her contracted working hours to undertake other important tasks that she needs to do, for example arranging staff cover which she can only complete by regularly working two hours extra every day. Furthermore, she is not able to train the other nurses, maintain her management responsibilities, and undertake continuous professional development. The inspection team was concerned that she has to be reactive instead of having time to be proactive and anticipate issues thereby mitigating any potential risks

The inspection team noted the following (see recommendation 2, SLC T12 and SLC T15).

- There was an unrealistic expectation on the capacity of the nurse manager to perform all the roles allocated to her (including training of new staff) without consideration of the time required to undertake these roles.
- There was no documented assessment of competency of several critical activities undertaken by staff at the centre; consent to legal parenthood, donor recruitment, selection, assessment and screening and confidentiality and privacy. The inspection team considered this was because of lack of time to undertake these assessments.
- Staff have been allocated lead roles for which they have not received training (e.g. infection control).
- There was no robust system in place to cover nursing staff sickness and absence.
- The inspection team was not clear if staff have been made aware of the provision in the HF&E Act 1990 (as amended) that anyone who has a conscientious objection to participating in a particular activity done in the centre must not be obliged to do so.
- There was no evidence that staff had been able to undertake continuing professional development.

In view of these concerns the centre's inspector sought the PR's assurance that she will monitor activity and staff workloads to ensure that patients and staff are safe at all times. On 11 November 2019 the PR provided the following confirmation: 'I will monitor activity and staff workloads to ensure that patients and staff are safe at all times.'.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
It is important that the centre's patients and staff are protected from harm where possible. The centre's procedures are compliant with safeguarding guidance with the exceptions noted elsewhere in this report.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

No patients were available to speak to the inspectors.

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Fifty-four patients have provided feedback in the last 12 months, giving an average 4.5-star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to, however it was noted that some individuals commented that there was a lack of clarity on costs of their treatments. Several patients provided individual comments to the HFEA complimenting the staff at the clinic. There were also several negative comments regarding the waiting times for appointments and poor communication at the centre. This feedback is similar to that in the centre's own patient surveys and the centre's communication lead who manages the patient feedback processes advised the inspection team that several actions had already been taken to address this. The inspection team urges the PR to continue to monitor patient feedback to ensure the actions taken are effective.

The centre seeks patient feedback via an electronic platform called 'Doctify' and patients are given a device to complete the survey whilst in the clinic. This system has been in use since 3 September 2019 and since that time 150 reviews have been submitted with an overall rating of 4.75 (out of 5) stars for the clinic and 4.84 stars out of 111 reviews for the Clinical Director. Prior to the implementation of this system the centre was encouraging patients to submit feedback via the HFEA's 'Choose a Fertility Clinic' page and were monitoring the star ratings published by the HFEA. No other active surveys were in use as they had suspended previous survey formats as they considered they were too complicated for the patients and did not provide useful feedback to the centre.

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.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg sharing arrangements
Surrogacy
Complaints

Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are not compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act as noted in the section 'Staff' above.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Patient support (Guidance note 3)
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.

Counselling (Guidance note 3)
It is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood. The centre's counselling procedures are compliant with HFEA requirements with the exceptions noted below.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
It is important that the centre's procedures for egg and sperm sharing arrangements ensure that:

- care is taken when selecting egg and sperm providers donating for benefits in kind
- egg and sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

The inspection team was informed by the centre's Clinical Director that the centre does not provide treatments involving egg sharing therefore this area of practice was not reviewed. However, in response to the draft report the PR has informed the executive that the centre does provide treatments involving egg sharing. This area of practice will be reviewed at the time of the next inspection.

Surrogacy (Guidance note 14)
The PR informed the inspection team that the centre would no longer be undertaking treatments involving surrogacy. No surrogacy treatments had been provided since the time of the last inspection in April 2019, therefore this area of practice was not reviewed during the inspection.

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Counselling (Guidance note 3)
The centre's audit of counselling documented the number and type of sessions provided but does not include any assessment of the effectiveness of the service (see recommendation 4; SLC T36).

One of the centre's quality indicators states: '100% of counsellors BICA accredited', however this has not been met (see recommendation 4; SLC T35).

The inspection team spoke to the centre's counsellor who was present during the inspection. She is a registered member of the British Association for Counselling and Psychotherapy (BACP) and has completed the British Infertility Counselling Association (BICA) Foundation course. She is working towards accreditation with BICA which she hopes to complete in 2020. Later in the inspection the PR informed the inspection team that there is another counsellor employed by the centre who is BICA accredited and can provide telephone counselling sessions (as she lives away) but has not done any recently. The inspection team was concerned that the counsellor they spoke to in the centre was not aware of the other counsellor, although she thought that there may be one that they could call on if she was unable to see patients. Shortly after the inspection the PR confirmed that the counsellors are to be 'introduced'.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
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 for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information or counselling is not offered prior to both parties giving consent, there may be doubt as to the effectiveness of the consent and 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.

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 are no anomalies; that procedures for obtaining consent to legal parenthood are robust; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR at the time provided this reassurance in writing on 19 November 2015.

At the time of the interim inspection in 2017 the centre's procedures for taking consent to legal parenthood were reviewed. The inspection team identified an anomaly in consent to legal parenthood, and the centre had not undertaken any audit of records in accordance with CE(14)01. These findings are detailed in the report of that inspection.

Since that time, two further focused inspections have been carried out at the centre; in June 2018 and April 2019. During each of these a critical non-compliance in consent to legal parenthood was identified and are detailed in the reports of those inspections. As a result, in May 2019, the executive recommended that the current PR 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. This cessation of treatments remained in place at the time of this renewal inspection as the executive was not satisfied with the evidence of staff competency assessments that had been provided by the PR in August 2019. This area of practice was reviewed in detail during this inspection.

The inspection team discussed the centre's legal parenthood consenting procedures with the nurse manager who is responsible for taking these consents and reviewed the results of recent legal parenthood consenting audits. In view of the cessation of treatments currently in force, only four sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were available to be audited by the inspection team. No anomalies were

identified in the records. However, the inspection team was not able to determine whether the centre's processes used to collect legal parenthood consent are compliant with HFEA requirements as discussed below.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The HFEA's Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born as a result of it. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA, so that the HFEA holds an accurate record of patients' consent and only releases patient identifying information to researchers with a patient's consent.

The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

What the centre could do better

Legal parenthood (Guidance note 6)
Following the cessation of treatments with donor sperm for new patients (including surrogacy cases), the PR provided training in consent to legal parenthood and undertook assessment of competency of staff, evidence of which was provided to the centre's inspector on 16 August 2019. The assessment of competency comprised of a record of the slides used during the training provided by the PR and the member of staff's answers to six questions in response to what consent to legal parenthood forms should be completed in various scenarios. The executive did not consider that these documents alone provided satisfactory evidence of competencies in the provision of information regarding legal parenthood and correct completion of consent. On 22 August 2019 the centre's inspector provided the PR with detailed guidance on what was expected in a robust training and competency assessment and reiterated that these were needed before the executive could consider recommending that the cessation of treatments can be lifted. The guidance provided by the centre's inspector included examples of what would be expected in a robust assessment of competency which would assure the executive that staff fully understand the requirements in relation to consent to legal parenthood; provision of information, offer of counselling, which forms are required, how to complete the forms correctly, when they must be completed, what actions to take if there are any errors, what actions to take if there is a withdrawal of consent etc.

During the inspection the PR informed the inspection team that no further actions have been taken in relation to the assessments of competency (see recommendation 7; SLC T12). Therefore, the cessation of treatments with donor sperm or embryos created with donor sperm for new patients (including surrogacy cases) remains in place. Shortly after the inspection the PR informed the centre's inspector that an external legal team who are specialists in this area of practice is to provide training to staff at the centre.

The inspection team reviewed the centre's SOP for consent to legal parenthood provided during the inspection and noted that WT ('Women's consent to treatment and storage form (IVF and ICSI)') form was listed as a relevant consent form rather than the

WP (‘Your consent to your partner being the legal parent’). In addition, the SOP did not specify what actions to take if there is a withdrawal of consent to legal parenthood (see recommendation 7; SLC T33b, SLC T64 and SLC T65). Whilst the use of the WT form was not mentioned further in the SOP the inspection team was concerned that this error had not been identified by the PR or other staff who would have reviewed this document, particularly in light of the centre’s previous failures in this area of practice.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)

The centre’s procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained with the exceptions noted in the section 'Assessment and screening of donors' above.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

It is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors. The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register (see recommendation 8; General Direction 0005 and SLC T41).

- A sample of the centre's data submissions of licensed activity was requested by the inspection team. All 50 IVF and nine DI treatments in the sample provided by the PR and reviewed post inspection had been reported to the HFEA. However, the inspection team noted that the data on the first spreadsheet provided by the PR had materially different dates to those recorded on the Register, but the particulars were in all other respects the same. The centre submits this information to the HFEA via an electronic third party data submission system and the PR has reported this error to the supplier of their data submission system.

- 31% (16/50) IVF and 33% (3/9) DI treatments in our sample had been reported to the HFEA outside the period required by General Direction 0005.

Section 3: Monitoring of the centre's performance

Following the focused inspection in April 2019, recommendations for improvement were made in relation to one critical, two major and four 'other' areas of non-compliance or poor practice.

The PR provided information and evidence that all of the recommendations were fully implemented except the provision of assessments of competency in relation to consent to legal parenthood.

On-going monitoring of centre success rates

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

Areas of practice requiring action

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, General 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 carried out.

Critical area 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of 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
1. Donor assessment selection and screening A number of issues with donor selection and screening were noted by the inspection team. These are described in the body of the report. On 11 November 2019 the PR confirmed that '… as PR I will take responsibility for ensuring that the assessment and screening of donors providing gametes or embryos being	The PR should ensure that the donor recruitment, assessment, selection and screening procedures are compliant with all regulatory requirements and professional body guidance. The executive recommends that the centre is prohibited from undertaking any further activity in relation to donor recruitment, assessment and screening.	The PR can confirm that the donor recruitment, assessment, selection and screening procedures were reviewed and implemented in line with the professional guidelines and submitted to the centre's inspector for her assurance on the 7th November 2019. The centre's inspector replied on the 11th November that she was '… only seeking your confirmation and assurance that as PR you	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. On 21 October 2019 the PR provided the centre's revised SOP ('Viral screening and management of patients at risk of infectivity' CLP019 v2). The executive had concerns with this document, most notably that it included the

used in treatment is fully compliant with requirements...'. SLC T52a, SLC T52g, SLC T33b, SLC T36, CoP 11.4, CoP 11.23 and CoP 11.24. UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019).	The PR should commission a review by an external expert to assess the centre's processes for donor recruitment, assessment and screening. The HFEA expects that this person will be independent of the centre and will have a degree of knowledge and expertise in the requirements for assessment and screening of donors. The PR should advise the HFEA of the person she has commissioned before the review is conducted. It is expected that this review will include, but not be limited to, ensuring that the centre's SOP is compliant with regulatory requirements and professional body guidance, 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 are further cases where gamete providers were not suitably assessed and screened as donors, including if travel	will take full responsibility for ensuring that the assessment and screening of donors providing gametes or embryos being used in treatment is fully compliant with requirements…' The requested assurance was provided in a statement by the PR as requested on the 11th November 2019. The PR can confirm that an independent external expert has agreed to review the centre's processes for donor recruitment, assessment and screening on 20/12/19. The executive was made aware of the name of the individual separately to this report on 17th december 2019. The PR can confirm that the timeframe for the review of all egg donor treatments will be provided to the centre's inspector by the 9th February 2020.	statement: 'one screen is deemed adequate in low risk women' and it did not reference the 2019 UK professional guidelines. On 7 November 2019 the PR provided three documents in relation to donor screening ('Egg donor assessment proforma', 'Gamete and embryo donor self-assessment form' and 'Supplementary guidance v1 Gamete and embryo donor self-assessment form'). However, the PR has not provided any further updates or information in relation to the executive's concerns about the centre's *SOPs* for donor recruitment, assessment and screening, therefore the executive does not have sufficient assurance that this area of practice will be compliant with regulatory requirements. In view of this and the significant risk to recipients of donated gametes or embryos, the executive continues to

	history has not been reviewed), and that robust staff training and competency assessments are undertaken. As no activities will be provided at the centre, the PR should consider including how best to demonstrate staff competence in this area. When responding to this report, the PR should provide an action plan and timescales for the commissioning and completion of this external review. A summary report of the findings of the review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector upon completion. On receipt of the findings of the review the HFEA executive will be able to consider whether it is able to recommend that the condition prohibiting treatments with donated gametes or embryos can be removed.		recommend the addition of a condition to the centre's licence whereby the centre is prohibited from undertaking any further activity in relation to donor recruitment, assessment and screening Once the executive is assured that the centre's processes for donor assessment, recruitment and screening are compliant with regulatory requirements it will be able to consider recommending that the condition prohibiting any further activity in relation to donor recruitment, assessment and screening can be removed. The PR has arranged for an external expert to review the centre's processes for donor recruitment, assessment and screening which is scheduled to take place on 20 December 2019. The PR has confirmed (in an accompanying letter) that the external reviewer will also undertake a full audit of gamete and/or embryo donor records since the time of the

	The PR should review the cases identified during the inspection and fully assess the risks to recipients who have had treatment with these donated gametes. Once the audit of all gamete and/or embryo donation treatments carried out in the centre since the last renewal inspection in October 2015 has been carried out the PR should identify whether there are further cases where the gamete providers were not suitably assessed and screened as donors. If cases are identified the PR should seek expert advice to fully assess if there may have been any risks to the recipients that have undergone treatment with these gametes and/or embryos. The review should also consider whether recipients affected are to be contacted and advised of possible risks of their treatment. The PR should inform the centre's inspector of the timeline for completing this risk assessment by 9 February 2020.		last renewal inspection in October 2015 (to determine whether there are further cases where gamete providers were not suitably assessed and screened as donors, including if travel history has not been reviewed Once the audit has been carried out the PR should identify whether there are further cases where the gamete providers were not suitably assessed and screened as donors. If cases are identified the PR should seek expert advice to fully assess if there may have been any risks to the recipients that have undergone treatment with these gametes and/or embryos. The review should also consider whether recipients affected are to be contacted and advised of possible risks of their treatment. The PR should inform the centre's inspector of the timeline for completing this risk assessment by 9 February 2020.

			The PR has confirmed that she will provide a review of the cases identified during the inspection and fully assess the risks to recipients who have had treatment with these donated gametes by 9 February 2020. **Further action is required.**
2. Staff The inspection team had several concerns in relation to the number and training of nursing staff as described in the body of the report. Because these staffing concerns also relate to non-IVF procedures that come under the remit of the CQC, the executive will contact the CQC to inform them of our findings. On 11 November 2019 the PR provided the following confirmation: 'I will monitor activity and staff workloads to ensure that patients and staff are safe at all times.'.	The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles. The PR should review the workload of the centre's nurse manager and take actions to address the concerns noted by the inspection team. It is expected that the PR reduces or rearranges all activities in the centre, including non-IVF theatre procedures, until such time as there are sufficient trained nursing staff at the centre to cover IVF activities. A summary of the PR's action plan should be provided to the	The PR can confirm that replacement staff for the vacant posts has been advertised. A fertility nurse position became vacant on 25th July 2019 however at the time there were two full time Consultant Gynaecologists, a nurse manager, two part-time nurses and a HCA in post which provided sufficient cover for the workload. One of the consultant posts became vacant on 3rd September 2019 and at the time of the inspection (8th October) the vacancy had not yet been successfully filled. In addition the centre's full-time ODP unexpectantly went off on sick	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of her review of the centre's staffing levels and the actions taken since the time of the inspection. In an accompanying letter the PR also confirmed that: 'We have advertised for replacement nursing and theatre staff, we continue to use agency theatre staff and have emergency contingency arrangements with local licenced centres if required. We have also reduced the

HF&E Act 1990 (as amended), SLC T12 and SLC T15.	centre's inspector when responding to this report. The PR should review the centre's staffing levels and processes for assessment, and re-assessment, of competencies. The review should include, but not be limited to, consideration of the issues identified by the inspection team. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's when responding to this report.	leave on the 13th September resulting in additional work for all clinical staff while a replacement was appointed. Since the inspection the nurse manager's workload has been reviewed and weekly planning meetings are scheduled to identify staffing requriements internally and from agency, a dedicated diary has been allocated to allow her to manage her workload more efficiently. The post of fertility nurse has been advertised. The PR can confirm that competencies of clinical staff were assessed prior to the inspection with the exception of the external legal parenthood training from a specialist lawyer which due to his availability of the specialist was scheduled for 3rd December 2019.	number of theatre procedures to predominantly egg collections with the majority of gynae procedures now being performed at another hospital.' The executive is assured that the PR has taken immediate action to reduce the number of procedures not related to HFEA licenced activity taking place at the centre. The PR states that '…competencies of clinical staff were assessed prior to the inspection…'. However, assessments of competency in relation to donor assessment and screening were not provided during or since the time of the inspection. The executive expects that the PR will undertake assessments of competency of staff performing these activities once the external review of the centre's practices in relation to the assessment and screening of donors (male and female) has been completed. Examples of these should be

			provided to the centre's inspector upon completion. **Further action is required.**

Major area of non-compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a 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
- 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
3. Safety and suitability of premises and facilities The inspection team noted the following issues with storage of gases. • In the 'plant room' although chains were in place, they were not fastened over two of the cylinders therefore the cylinders were not secure. • Gases are also stored behind a fenced area outside the building. Whilst the inside of the fenced area had safety signage there was not	The PR should ensure that all medical gases are stored safely and kept secure at all times. When responding to the report, the PR should provide an update on immediate actions that have been taken to address this issue identified by the inspection team. The PR should undertake a review to identify the factors that have led to this non-compliance. A summary of the findings of the review including corrective actions	The PR can confirm that all medical gases are stored safely and secured at all times. The PR and the clinical team have reviewed the storage of medical gases. One medical gas has now been decommissioned which has provided additional space in the gas store. Additional chains/straps have been sourced and the introduction of additional checks. These checks are signed by the member of staff to confirm that the cylinders are appropriately secure. If at any time any cylinders are found to be free-	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided an update on the immediate actions taken and has confirmed that medical gases are stored safely and kept secure at all times, and that safety signage has been fitted. **No further action is required.**

sufficient safety signage on the outside of the area. • In another storage area six large, three medium and three small gas cylinders were not secured sufficiently and were at risk of falling over. SLC T17 and Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management.	and the timescales for implementation should be provided to the centre's inspector when responding to this report.	standing and not secure, they are to be immediately secured and the PR is to be informed. The PR can confirm that staff who take receipt of the gases during delivery have been reminded that cylinders are to be secured at all times. The PR can confirm that the safety signage for the gas stores has been sourced and fitted.	
4. QMS The following issues were noted in relation to the QMS. • Quality indicators are either not currently in place or are not appropriate for several areas of practice such as counselling, provision of information, donor assessment and screening, consent to storage, traceability of equipment, confidentiality and record keeping.	The PR should ensure that the centre's QMS is effective. The PR should ensure that the issues noted on inspection are addressed and a summary report of the actions taken are provided to the centre's inspector by 9 February 2020. The PR should provide a summary of an audit of effectiveness of the counselling service by 9 February 2020.	The PR can confirm that the overhaul and introduction of the new QMS will continue and be completed by 9 May 2020. The Quality Indicators for the centre are being reviewed including effectiveness of counselling, provision of information, donor assessment and screening, traceability of equipment, confidentiality and record keeping.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of the actions taken and confirms that the overhaul of the QMS will be completed by 9 May 2020. The PR states that the 'Viral screening' SOP (CLP068) was reviewed and re-issued on 17 October 2019. The executive notes that this is a different

• The centre's audit of egg donor assessment and screening is not robust and there was no audit of sperm donor assessment and screening or confidentiality in the last two years. • Three of the centre's SOPs provided on inspection were not compliant with regulatory requirements and contained incorrect information; 'Viral screening', consent to legal parenthood and safeguarding. • The centre's audit of counselling documented the number and type of sessions provided but does not include any assessment of the effectiveness of the service. • The inspection team noted that one of the centre's quality indicator states:' 100%	Actions in relation to the donor assessment and screening and consent to legal parenthood will be followed up as part of the recommended actions elsewhere in the report. The PR should ensure that the overhaul of the QMS already underway is completed by 9 May 2020.	The egg donor assessment, sperm donor screening and confidentiality audits are on the centre's audit schedule. The Viral screening SOP (CLP068) was reviewed and reissued on 17th October in line with regulatory requirements. The 'typo' mentioned previously in the consent to legal parenthood SOP (CLP066) was corrected immediately and the SOP reissued. The name of the employee who was no longer in post was removed from the safeguarding SOP immediately and the SOP was reissued. The quality indicator now state that the centre's counsellors are BICA accredited or working towards BICA accreditation. The PR will provide a summary report of actions taken by 9th February 2020. The PR can confirm that a summary of the audit for	reference number to the SOP provided to the centre's inspector on 21 October 2019 (CLP019) and has not seen this document. The PR has confirmed that she will provide a summary report of the actions taken and an audit of effectiveness of the counselling service by 9 February 2020. **Further action is required.**

of counsellors BICA accredited', however this has not been met. SLC T35, SLC T36 and SLC T33b.		'effectiveness of counselling' will be provided to the centre's inspector by the 9th February 2020.	
5. Third party agreements During the inspection two of the centre's third party agreements were reviewed and were not compliant with requirements. The centre has not evaluated the ability of all third parties to meet the required standards. The inspection team noted that the centre's quality manager is aware of this and has plans in place to complete this audit. During a review of donor records the inspection team noted that a number of blood test results did not appear to be in the records. It was not clear if this reflects a failure of the third party to ensure that it provides the results. The inspection team also noted that the third party agreement	The PR should ensure that all agreements with third parties meet the requirements of the relevant licence conditions and the guidance set out in the HFEA CoP, and that the ability of all third parties to meet the required standards is evaluated. A plan for the completion of this action should be provided to the centre's inspector when responding to this report. It is expected that this action will be completed by 9 May 2020. The PR should investigate why the issue noted by the inspection team (results of screening tests are not in the patient's records) has occurred. As part of this investigation the PR should review if this issue impacts more widely than the cases	The PR can confirm that the Third Party Agreements are under review to ensure they meet licence conditions and HFEA CoP and that all third parties meet the required standards by 9th May 2020. The TPA audit is on the centre's audit schedule. The issue with the apparent missing screening results will be investigated and a summary provided to the centre's inspector by 9th February 2020.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that she will ensure that all agreements with third parties meet the requirements of the relevant licence conditions and the guidance set out in the HFEA CoP, and that the ability of all third parties to meet the required standards is evaluated by 9 May 2020. The PR has also confirmed that she will provide a summary of the findings of her investigation into the issues noted in relation to the third party laboratory undertaking testing by 9 February 2020. **Further action is required.**

with the laboratory undertaking the testing does not document how test results will be relayed. SLC T114d, SLC T114e, SLC T114f and SLC T116.	identified by the inspection team. A summary of the findings of the investigation including whether any further issues have been identified and corrective actions with timescales for implementation should be provided to the centre's inspector by 9 February 2020.		
6. Person Responsible The inspection team had several concerns in relation to the PR's oversight and leadership of the centre as described in the body of the report. Section 17(1) of the HF&E Act 1990 (as amended). HFEA document: 'Person Responsible key behaviours and role description.'	The PR should ensure that she fully discharges her duties under section 17(1) of the HF&E Act 1990 (as amended) and has comprehensive oversight on all activities at the centre. The PR should commission an independent review of the leadership and governance of the centre by a peer who is a current or recent PR of a HFEA licensed centre. When responding to this report, the PR should provide an action plan and timescales for the commissioning and completion of this external review.	The PR is fully aware of the HFEA's guidance document 'Person Responsible key behaviours and role description' having had considerable experience as a PR in two previous centres at the same time (Centre 0007 August 2014-April 2017 & Centre 0344 May 2015-April 2017). The executive is fully aware the PR joined the centre while there were a number of historical issues outstanding and the PR has dedicated the first 10 months in this role working to ensure that these issues are fully addressed and compliant. A new QMS has been introduced and although	The executive acknowledges the PR's commitment to fully discharging her duties and the immediate action taken to reduce the number of procedures being performed at the centre. The PR confirms that she is fully aware of the HFEA's guidance document 'Person Responsible key behaviours and role description.' The executive has acknowledged that the PR has previous experience in this role between 2014 and 2017. Furthermore, when making the recommendations set out in the report, the executive has also considered whether

	The PR should review the HFEA's guidance document 'Person Responsible key behaviours and role description.' to consider how best to address the inspection team's concerns regarding the lack of oversight and leadership at the centre. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report.	time has not enabled everything to be completed, as yet, the executive has recognised the huge amount of work that has been achieved since the short notice inspection in April 2019 and that the outstanding areas have been identified and are scheduled to be completed. The PR is fully committed to resolving all historical issues The PR can also confirm that an independent peer review from a colleague who is currently a PR has been arranged. The inspector was made aware of the name of the individual separately to this report on 17th December 2019.	10 months had been sufficient time for the PR to be able to ensure compliance in a centre with a history of non-compliance. The PR has commissioned an independent review of the leadership and governance of the centre by a peer who is a current PR of a HFEA licensed centre. The date has yet to be arranged and the executive will liaise with the PR in relation to the outcome of this review. **Further action is required.**
7. Consent to legal parenthood The assessments of competency for staff obtaining consent to legal parenthood are not satisfactory. The centre's SOP for consent to legal parenthood lists the WT form as a relevant consent form and does not specify	The PR should ensure that staff training and assessment of competency in obtaining consent to legal parenthood is completed. The executive recommends that the centre is prohibited from providing treatments with donor sperm or embryos created with donor sperm for	The PR is satisfied that staff have fulfilled the legal parenthood training and competency requirements in accordance with licenced conditions. All staff who take/check consents completed internal training in August 2019. The training took place individually (or in group of two) as a presentation	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR states that she has provided training to staff in consent to legal parenthood by means of a presentation with a supporting training

what actions to take if there is a withdrawal of consent to legal parenthood. SLC T12, SLC T33b, SLC T64 and SLC T65.	patients, including surrogacy cases. When responding to this report, the PR should indicate when robust assessments of competency of staff undertaking consent to legal parenthood will be completed. Examples of these should be provided to the centre's inspector upon completion. The PR should review the centre's SOP for consent to legal parenthood to ensure that there are no inaccuracies and that it includes all aspects of this activity. A copy of the revised SOP should be provided to the centre's inspector when responding to this report. On receipt of the above information the executive will be able to consider whether it is able to recommend that the condition prohibiting treatments with donor sperm or embryos created with donor sperm can be removed.	provided by the PR with a supporting training logbook. The presentation/logbook provided information about the HFEA responsibilities, requirements of consents, donor treatments including legal implications, information about treatment using donor gametes, single and married/civil partnership status, surrogacy arrangements and legal parenthood consents. This was followed by a competency assessment of six different legal parenthood scenarios that staff had to complete separately and return to the PR. The pass rate was set at 100%. One member of staff had made corrections to one scenario prior to returning the logbook to the PR and had explained the reason for doing so which the PR accepted. In May 2019 the PR had also introduced a system whereby all consents were passed to her for approval and the QM monitored the consents by a rolling audit of completed consents, no errors have been	logbook followed by a competency assessment which consisted of the staff member's responses to six different legal parenthood scenarios. Copies of the responses to the questions were provided to the centre's inspector on 16 August 2019 but the training logbook described has not been provided during or since the time of the inspection. As acknowledged by the PR, the centre's inspector did not consider that these documents alone (staff responses to six scenarios) provided satisfactory evidence of competencies in information giving and taking consent to legal parenthood. For example, they did not include ensuring an offer of counselling was made or what actions should be taken if there is a withdrawal of consent. The PR has not provided any further clarification or information in response to the inspector's feedback in August 2019

		found (this information has been shared with the executive on two separate occasions). The PR was satisfied that the training provided and the ongoing accuracy of the centre's consents was sufficient to ensure that the staff were suitably competent. The completed logbooks were sent to provide reassurance and evidence of training and competency to the executive by the PR on the 16th August. The executive replied on the 22nd August stating that 'If I have interpreted this correctly, these documents record the staff member's answers to 6 questions relating to legal parenthood scenarios' and the training was rejected as 'these documents alone do not provide satisfactory evidence of competencies in information giving and taking consent to legal parenthood'. The training logbooks were reviewed by the PR and additional information of the requirements to fulfil competency were added to	during or since the time of the inspection. The PR has confirmed that training in consent to legal parenthood was provided by an expert in fertility law on 3 December 2019. No other information has been provided to the executive. In view of this and the potential risk to patients the executive continues to recommend the addition of a condition to the centre's licence whereby the centre is prohibited from undertaking treatments with donor sperm or embryos created with donor sperm for patients, including surrogacy cases. The executive awaits the PR's confirmation of when robust assessments of competency of staff undertaking consent to legal parenthood will be completed. Examples of these should be provided to the centre's inspector upon completion. On receipt of the above information the

		the training and assessment logbook and they were reissued. A HFEA consent competency logbook was developed, passed to a specialist lawyer and then issued to staff taking consent. Formal legal training was arranged with an expert in fertility law for 3rd December 2019 – this training was mandatory for all staff involved in taking or checking consents. The PR can confirm that there was a typo in the 'related documents' section at the beginning of the SOP which was corrected as soon as the error was highlighted. There was no further reference to this consent in the entire document or referenced in the protocol for taking legal parenthood consents. The PR deems this minor typo to be no different to the wrong inspector initials being added to the HFEA inspection agenda that was provided for our inspection in October.	executive will be able to consider whether it is able to recommend that the condition prohibiting treatments with donor sperm or embryos created with donor sperm for patients, including surrogacy cases can be removed. The PR has confirmed that there was a typographical error in the SOP which has been corrected. The inspection team also noted that the SOP does not describe actions to take if there is a withdrawal of consent to legal parenthood. The PR should ensure that this is included in the centre's SOP and provide a copy to the centre's inspector by 9 February 2020. **Further action is required.**

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates 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
8. Obligations and reporting requirements The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register. • A sample of the centre's data submissions of licensed activity was requested by the inspection team. All 50 IVF and nine DI treatments in the sample provided by the PR and reviewed post inspection had been reported to the HFEA. However, the inspection team noted that the data on the first spreadsheet provided	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the centre's systems and processes used for licensed treatment data submission to identify and address the issues identified, including the apparent inaccuracies in the submitted data. The PR should also investigate why the data initially provided had different dates to those recorded on the Register and whether this is likely to impact all data submissions by the centre. A summary of the findings of the review including corrective actions	The PR can confirm that the inaccuracy with the data request by the registry team was due to formatting when copying from one spreadsheet to another and not the electronic third party data submission system – 4/9 of the dates submitted were from a period before the centre had opened. Once the inaccuracy had been highlighted the dates were checked from the database and added to the registry spreadsheet. The executive received a copy of the centre's full activity for the requested period, no inaccuracies with any other data were highlighted to the PR. The PR would like to apologise for the inaccuracy with the initial data submitted	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of the findings of her review of the centre's systems and processes used for licensed treatment data submission and why the data initially provided had different dates to those recorded on the Register. The PR concludes that this was as a result of copying data from one spreadsheet to another and does not impact data submissions by the centre. The audit of the effectiveness of changes introduced in this

by the PR had materially different dates to those recorded on the Register, but the particulars were in all other respects the same. The centre submits this information to the HFEA via an electronic third party data submission system and the PR has reported this error to the supplier of their data submission system. • 31% (16/50) IVF and 33% (3/9) DI treatments in our sample had been reported to the HFEA outside the period required by General Direction 0005. General Direction 0005 and SLC T41.	and the timescales for implementation should be provided to the centre's inspector by 9 February 2020. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings of the audit should be provided to the centre's inspector by 9 August 2020.	and will ensure any future requests for data will be double checked. The EDI lead has been working and continues to work closely with the HFEA registry department and the electronic third party data submission system to resolve any issues that arise. A number of errors have been identified as a result of issues with both the HFEA server and the third party supplier, these are reviewed and corrected with the assistance of the HFEA registry team and the third party supplier as and when required. The PR can confirm that a review of the data submission will be completed and that the EDI audit has already been included in the centre's audit schedule and will be provided to the executive by 9th February 2020.	area of practice is awaited. The PR has indicated that this will be provided by 9 February 2020. **Further action is required.**

Reponses from the Person Responsible to this inspection report