Licence Committee - minutes

Centre 0338 (Reproductive Health Group)
Executive Update

Thursday, 11 July 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Eve Piffaretti	Blake Morgan LLP
Specialist Adviser		
Observers	Alistair Robertson	Solicitor (Induction)

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:

- Focused Inspection Report.

- Previous licensing minutes up to the last licence renewal:
    - Licence Committee - November 2018 - Executive Update, Variation - Person Responsible and Licence Holder
    - Licence Committee - September 2018 - Additional inspection / Executive Update
    - Licence Committee - July 2018 - Additional inspection / Executive Update
    - Licence Committee - May 2018 - Executive Update to Interim Inspection
    - Licence Committee - March 2018 - Executive Update to Interim Inspection
    - Licence Committee - January 2018 - Interim Inspection
    - Licensing Officer Consideration - March 2017 - Variation - Licence Holder
    - Executive Licensing Panel (ELP) - January 2016 - Variation - Licence Holder
    - Executive Licensing Panel (ELP) - 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.

1.2. In the 12 months to 28 February 2019 the centre provided 181 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.3. The centre's current licence was granted for a period of four years and is due to expire on 31 March 2020. The licence has been varied to change the Licence Holder (LH) in 2016 and in 2017. Additional variations to the licence are described below.

Unannounced Interim Inspection - November 2017

1.4. An unannounced interim inspection was conducted on 7 November 2017. Recommendations were made in relation to two critical, two major and four other areas of non-compliance. The Licence Committee considered the inspection report and noted in particular the critical non-compliances relating to the import of donor gametes and consent to legal parenthood and the major non-compliance relating to the confidentiality of donors. The committee noted that, since the inspection, the Person Responsible (PR) had started to address the non-compliances and had committed to implementing all of the recommendations within the prescribed timescales.

Legal Parenthood Audit

1.5. 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.

Donor compensation relating to imported eggs from the Ukraine / News Paper Article

1.6. The Licence Committee noted that, prior to the scheduled unannounced interim inspection on 7 November 2017, an article was published in the Warrington Guardian on 5 November, in which a member of the centre's staff had stated that the maximum amount a donor could be reimbursed for expenses was £750 and that this was the same in Ukraine as it is in the UK.

1.7. The committee noted that the HFEA's requirements on donor compensation aim to balance the desire to treat donors fairly with the need to avoid a financial inducement to donate. The fundamental principle is that donation must be altruistic in nature. Donor compensation limits for UK donors are different from those for overseas donors.

1.8. The committee noted that the PR stated that he had not accepted that the imports were not compliant with the requirements of General Direction 0001.

Licence Committee Decision – Variation of Licence to add a Condition - January 2018

1.9. At its meeting on 11 January 2018, the Licence committee considered revoking the centre's licence.

1.10. The Executive reported that, with regard to donor compensation, the PR was unable to comply with his duties under section 17(1)(c), (d) and (e). In circumstances where the Authority is satisfied that the PR has failed to discharge the duty under section 17 and where it is satisfied that the PR has failed to comply with directions given in connection with any licence, it has the power to revoke the licence by section 18(2)(b) and (c).

1.11. The committee considered a revocation of the centre's licence, however on balance, the committee agreed that it would be proportionate to vary the centre's licence with an additional condition prohibiting any further imports of donated gametes from taking place under General Direction 0006 and requiring the PR to make applications to the Authority, for consideration by the Statutory Approval Committee (SAC), for Special Directions in relation to any and all proposed imports of donor gametes in the future.

1.12. The PR was directed to make an application to the Statutory Approvals Committee (SAC) for Special Directions to bulk export the donor eggs and embryos created using those donor eggs back to the Ukraine. The Executive also recommended that, to regularise the status of those embryos and enable their lawful use in the UK, the PR was directed to make a simultaneous application to export those embryos to the Ukraine and re-import them into the UK before any of those embryos could lawfully be used in treatment in the UK (a notional transaction). The Executive had considered the potential impact on patients for whom those embryos had been created. The SAC approved all of these applications at its meeting on 22 March 2018.

1.13. The Licence Committee also endorsed the Executive's recommendation to conduct an inspection, focused on the implementation of the recommendations, particularly in relation to donor compensation and legal parenthood, within one year of the interim inspection report being considered by the Licence Committee.

Focused Inspection – June 2018

1.14. A focused inspection was conducted in June 2018, and the report was considered by the Licence Committee in July 2018. The Executive once 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.

1.15. The committee noted that further evidence relied upon by the Executive in reaching this conclusion, included evidence that suggested that the PR had retrospectively altered a patient's WP (legal parenthood) consent form. In addition, in the view of the Executive, the PR did not ensure that all findings from the centre's audit of consent to legal parenthood undertaken in November 2017 were fully investigated and implemented.

Licence Committee Decision – July 2018

1.16. The committee noted tabled responses from the PR and from lawyers for the centre. It was submitted that it is not necessary, appropriate or proportionate to seek to achieve revocation through statutory enforcement action and that the PR and centre staff were happy to meet with the HFEA Executive to discuss the concerns in the report. The PR was also willing to consider transferring his role to another member of staff.

1.17. The committee adjourned its decision to allow time for the Executive and the PR to further discuss the findings.

Licence Committee Decision – November 2018

1.18. Applications to vary the licence to change the Person Responsible (PR) and Licence Holder (LH) were later submitted and approved by the Licence Committee in November 2018.

2. Consideration

Focused Inspection – 4 April 2019

2.1. A focused inspection was conducted on 4 April 2019 to see whether changes and improvements in processes, as a result of learning from the findings of the inspections in November 2017 and June 2018, had been fully embedded into the centre's current practices. The centre's practices in relation to consent to legal parenthood, surrogacy, import and export of gametes and embryos, and patient complaints were reviewed. In addition, the current PR's overall leadership and oversight of all activities of the centre were considered.

2.2. Further issues relating to consent to legal parenthood were identified. The Executive is extremely concerned that despite having had training in consent to legal parenthood in December 2017, January 2018 and May 2018, provided by two different specialist solicitors, a married surrogate and intended parent had been asked to complete the legal parenthood consent forms which were not applicable to them. Also, the centre's audit of this area of practice did not include a robust review of records, therefore the PR has not ensured that effective audit procedures are in place to ensure on-going compliance with consent taking requirements.

Management Review Meeting – 2 May 2019

2.3. The Executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance. The Executive concluded 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 findings in relation to consent to legal parenthood and surrogacy.

2.4. 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 has not yet been able to demonstrate that she has full oversight of all areas of activity in the centre and noted that she has only been PR for four months, three months after beginning employment at the centre. However, the Executive expects that by the time of the renewal inspection in October 2019, subject to application, the PR will have had sufficient time to fully embed in her role and demonstrate her commitment to fully discharging her duties.

Recommendation

2.5. In consideration of the findings and the centres history of non-compliance, the Executive contacted the PR shortly after the management review meeting on 2 May 2019 to ask her to consider a voluntary cessation of treatments 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 was required to attend a meeting with the HFEA Executive to discuss its concerns.

2.6. The PR was reluctant to voluntarily suspend treatments. However, the Executive reiterated the seriousness of the issues and reasons that it was not assured that the centre's current procedures for obtaining effective consent to legal parenthood were robust. The findings demonstrate that actions taken after previous inspections to ensure compliance had not been effective. The PR was asked to reconsider her position with regard to the voluntary suspension of relevant treatments.

2.7. On 14 May 2019 the PR confirmed that she had instructed the clinical team not to start any new treatments involving donor sperm, embryos created with donor sperm and surrogacy, and that patients currently in the system will continue with their cycles, being reviewed by her prior to treatment.

Meeting – 20 May 2019

2.8. The Executive met with the PR and the centre's Quality Manager on 20 May 2019. 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 considered that the plans were thorough and should, if implemented effectively, address the Executive's concerns regarding the centre's processes for obtaining and checking consent to legal parenthood and for surrogacy arrangements.

Executive Agreement with the PR - on 23 May 2019

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

2.10. 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.

2.11. Further to this, the PR has also requested that treatments with donor sperm could be provided to two specific cases where it would be detrimental to these patients if their treatment was delayed because of their exceptional personal circumstances. The Executive required that the PR and Clinical Director undertake a risk assessment to determine the risk/benefit of proceeding with treatment, that all consents should be checked by the PR, and that these actions should be documented in the patient's records. If the PR did not identify any concerns or risks, then it would be reasonable to provide treatment to these patients on the basis of their specific exceptional circumstances, understanding that they would be compromised by a delay in treatment.

2.12. 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 is fully engaged and committed to attaining compliance and good governance thereby mitigating risks at the centre. However, before the Executive is able to recommend that treatments with donor sperm resume, the PR should 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.

2.13. The Executive noted that the PR has introduced a 'rolling audit' process whereby all records will be audited prior to the provision of treatment. Once treatments resume, the Executive requests that a summary of the findings of these rolling audits is provided monthly to the inspectorate until the scheduled renewal inspection in October 2019, when the effectiveness of the changes implemented in this area of practice will be assessed in detail. In the event that new problems arise before the next inspection the Executive will repeat the recommendation for a suspension of treatments with donor sperm for new patients (including surrogacy cases).

2.14. The committee noted that the Executive recommends the continuation of the centre's current licence.

2.15. The committee noted that, subject to application, a renewal inspection will be carried out at the centre in October 2019, when all areas of practice will be reviewed in detail. In the event that any further problems are identified at that time, the Executive will consider further regulatory action which may include a requirement for a change of PR at the centre.

3. Decision

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

3.2. The 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 has only held the position for four months, three months after beginning employment at the centre and that the Executive expects that by the time of the scheduled renewal inspection in October 2019, when all areas of practice will be reviewed in detail, the PR will have had sufficient time to fully embed in her role and demonstrate her commitment to discharging fully her duties as PR.

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

3.4. The committee noted that there are 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.

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.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

31 July 2019

Report of a focused inspection

Centre name: Reproductive Health Group
Centre number: 0338
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.
Date of inspection: 4 April 2019
Inspectors: Karen Conyers (lead), Janet Kirkland MacHattie and Paula Nolan (HFEA's Clinical Governance Lead).
Date of Licence Committee: 11 July 2019

Purpose of the report

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

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

The HFEA undertook an unannounced interim inspection of the centre in November 2017. Following this, an additional inspection, recommended by the executive and endorsed by the Licence Committee of the HFEA, took place in June 2018. As a result of the findings of that inspection, the HFEA executive recommended that a further focused inspection took place in Spring 2019 to ensure that changes and improvements in processes as a result of learning from findings during the inspections in November 2017 and June 2018 had been fully embedded into the centre's current practices. This is a report of that focused inspection which was announced but undertaken with short notice.

The aim of this report is to provide the Authority's Licence Committee with information on the centre's progress with actions taken in response to findings, so it can decide about the continuation of the centre's licence.

Information about the centre and 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 181 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2019. In relation to activity levels this is a small centre.

The findings of the centre's interim inspection in November 2017 were considered by the HFEA's Licence Committee in January 2018. In the report of that inspection, 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 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. The Licence Committee agreed with the executive's conclusions and 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 the 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 conducted in June 2018, and the report of the additional inspection was considered by the 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 the Licence Committee was invited to make findings in this regard.

In July 2018, the 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.

This meeting took place on 10 September 2018, during which 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. Ms Schnauffer had previously been a PR at centre 0007 between 2014-2017. In addition, the PR at that time also explained the centre's current LH would be leaving her post 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.

Summary for the Licence Committee

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

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

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

Critical area of non-compliance:

- **The PR should ensure that proper consent to legal parenthood is obtained and that effective audit procedures are in place to ensure ongoing compliance with legal parenthood consent taking requirements.**

Major areas of non-compliance:

- The PR should ensure that surrogates and gamete providers in a surrogacy arrangement are suitably assessed, and that this assessment is documented in their records prior to treatment.
- The PR should ensure that there is an effective quality management system (QMS) to continually improve the quality and effectiveness of the service provided in accordance with SLCs and CoP requirements.

'Other' areas 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.
- The PR should ensure that there are suitable arrangements in place to provide clinical cover in the absence of the Clinical Director and for the management of a clinical emergency.
- The PR should ensure that evidence for compliance with General Direction 0006 is robust.
- The PR should ensure that CE marked medical devices are used where possible.

Recommendation to the Licence Committee

The inspection reported on here was focused on reviewing whether changes and improvements in processes as a result of learning from findings during the inspections in November 2017 and June 2018 have been fully embedded into the centre's current practices. The inspection team focused on the centre's practices in relation to consent to legal parenthood, surrogacy, import and export of gametes and embryos, and patient complaints. In addition, the current PR's overall leadership and oversight of all activities of the centre was also considered. Subject to the PR's application, a renewal inspection will be carried out at the centre in October 2019.

The inspection team identified that legal parenthood consent forms had been completed for a surrogate who was married, however it is not possible for the surrogate to nominate a second legal parent as her husband will be the legal parent of any child born as a result of her treatment. No pregnancy resulted from this treatment. The executive is extremely concerned that despite having had training in consent to legal parenthood in December 2017, January 2018 and May 2018 provided by two different specialist solicitors, the married surrogate and intended parent had been asked to complete the legal parenthood consent forms which were not applicable to them. Furthermore, the executive is also concerned that the centre's audit of this area of practice did not include a robust review of records therefore the PR has not ensured that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. This is discussed in detail in the 'Legal parenthood' section below.

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. Of particular concern were the findings in relation to consent to legal parenthood and surrogacy.

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 does have some concern that the PR has not yet been able to demonstrate that she has full oversight of all areas of activity in the centre but notes that she has only been PR for four months, three months after beginning employment at the centre. These concerns are discussed further in the 'Leadership' section below. Subject to the PR's application, the HFEA will be undertaking a renewal inspection in October 2019, and it is expected that the PR will have had sufficient time by then to fully embed in her role, and to be able to demonstrate her commitment to fully discharging her duties as PR.

The issues in relation to consent to legal parenthood were of particular concern as the centre has a history of previous failure in this area which were considered critical non-compliances at the time of the interim inspection in November 2017 and again following the additional inspection in June 2018. 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 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 provided a copy of the draft inspection report and would be required to attend a

meeting with the HFEA executive to discuss its concerns. The executive's decision was communicated to the PR on 2 May 2019 with a meeting arranged for 20 May 2019.

On 3 May 2019, the PR confirmed that she would attend the meeting with the executive on 20 May 2019. The PR also stated that '*I do not accept that there is a lack of robust auditing in place at RHG as you allege*.', and '*In these circumstances, and given the significant impact it would have both on patients and the clinic, I would respectfully suggest that it is not necessary or proportionate for us to be required to cease all treatment using donor sperm and surrogacy.*' Given these statements with no further clarification, the executive concluded that the PR had not agreed to a voluntary cessation of treatments with donor sperm for new patients (including surrogacy cases) as recommended by the HFEA. On 7 May 2019, the executive emailed the PR to reiterate the seriousness of its concerns and the reasons why it was not assured that the centre's current procedures for obtaining effective consent to legal parenthood were robust, and that these findings demonstrate that actions taken after previous inspections to ensure compliance had not been effective. The executive asked the PR to reconsider her position with regard to the voluntary suspension of relevant treatments.

On 10 May 2019, the PR emailed the executive stating '*Please note that my email response on the 3 May did not make any direct refusals but was a request for the HFEA to reconsider the request to suspend all new treatments with donor sperm, embryos created with donor sperm and surrogacy treatments.*' In response, the executive contacted the PR on 13 May 2019 to seek clarification on whether the suspension of treatments with donor sperm for new patients (including surrogacy cases) as recommended by the HFEA had been implemented or not. On 14 May 2019 the PR confirmed that she had '*instructed the clinical team to not start any new treatments involving donor sperm, embryos created with donor sperm and surrogacy.*', and that '*Patients currently in the system will continue with their cycles, being reviewed by me prior to treatment.*'

A copy of the draft inspection report was provided to the PR on 13 May 2019. At that time, the executive recommended continuation of the centre's current licence which is due to expire on 31 March 2020. Subject to the PR's application, the centre is due to have a renewal inspection in October 2019 where all areas of practice will be reviewed in detail. If suitable assurances and appropriate plans were not provided in the PR's response to this report, the executive would consider modifying the report's recommendation to seek a requirement for a change of PR at the centre. The quality of the PR's responses and proposed plans to address the non-compliances and ensure that the centre operates in a compliant manner, would strongly influence the final recommendation made by the inspection team.

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 considered that the plans were thorough and should, if implemented effectively, address the executive's concerns regarding the centre's processes for obtaining and checking consent to legal parenthood and for surrogacy arrangements.

During the meeting, the PR requested that single women were not to be included in this suspension because consent to legal parenthood did not apply to these patients. The executive required further assurance from the PR as to what processes were in place at the centre to check and confirm a patient's marital status. To provide the requested

assurance to the executive, the PR submitted further information about these processes and confirmation that the documentation to be used to establish that patients were single had been checked by the centre's legal advisors 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

Further to this, the PR has also requested that treatments with donor sperm could be provided to two specific cases where it would be detrimental to these patients if their treatment was delayed because of their 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, that all consents should be checked by the PR, and that these actions should be documented in the patient's records. 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 of their specific exceptional circumstances and that they would be compromised by a delay in treatment. The PR confirmed that she would review all documentation, have these checked by a lawyer specialising in fertility law, and advise the executive when the legal advisors had agreed that all consents were correct and appropriate before proceeding with treatment.

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 is fully engaged and committed to attaining compliance and good governance thereby mitigating risks at the centre. However, before the executive is able to recommend that treatments with donor sperm resume the PR should 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.

The executive notes that the PR has introduced a 'rolling audit' process whereby all records will be audited prior to the provision of treatment, therefore once treatments resume, the executive requests that a summary of the findings of these rolling audits is provided monthly to the centre's inspector until the renewal inspection in October 2019 (subject to the PR's application) when the effectiveness of the changes implemented in this area of practice will be assessed in detail. In the event that new problems arise before the next inspection the executive will recommend that a suspension of treatments with donor sperm for new patients (including surrogacy cases) is re-imposed.

On the basis of the discussions held at the meeting and the PR's responses to the report, the executive is assured that the PR will fully discharge her duties and is committed to ensuring that the centre will achieve and maintain compliance with regulatory requirements. Therefore, the executive recommends continuation of the centre's current licence which is due to expire on 31 March 2020. Subject to the PR's application, the centre is due to have a renewal inspection in October 2019 where all areas of practice will be reviewed in detail. At that time, the HFEA would expect to see the evidence of the effectiveness of the changes introduced by the PR, such as by audit of the checking processes and the rolling audit of records. In the event that any further problems are identified at that time, the executive will consider further regulatory action which may include a requirement for a change of PR at the centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 28 February 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

At the time of the inspection the centre had not submitted data relating to partner insemination for 2018 (see recommendation 4). The data was submitted on 18 April 2019. 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.

According to HFEA held register data for the year ending 28 February 2019 the centre reported two multiple pregnancies of the 39 clinical pregnancies for patients who had been provided with IVF, ICSI or FET treatment. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Monitoring of the centre's performance

This inspection was focused on reviewing all actions taken by the centre in response to the findings of the previous inspections in November 2017 and June 2018 and to consider further issues emerging following audits of practice undertaken by the centre since the inspections.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services. The inspection team considered that staffing levels in the clinic on the day of inspection appeared suitable for the activities being carried out.

The current PR was appointed as Laboratory Director at the centre in September 2018 and her application to become PR of the centre was approved in December 2018. The previous PR continues in his role as Clinical Director of the centre.

The PR explained that there has been a large turnover of staff at the centre since summer 2018, across all departments. Therefore, much of the centre's recent focus has been in ensuring that the induction, training and competency assessments for new staff is fully completed. A new Quality Manager has also been in post since November 2018.

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

The inspection team noted that the Clinical Director is currently the only doctor working full-time at the centre. Whilst the centre team could describe a contingency plan in the event of the clinician's absence, the PR seemed to be unsure of the identity of the individuals that could be called upon in the Clinical Director's absence and where they currently worked (see recommendation 5). Other members of staff were also unable to confirm the identity of the doctors assigned to provide cover. The PR informed the inspection team that she is assured that the doctors who would be called in are suitable persons and that their competencies would have been assessed by the Clinical Director (see recommendation 5). The inspection team also noted that the centre does not have a documented process for a clinical emergency such as where to transfer a patient in the event of an emergency (see recommendation 5).

At the time of the inspections in November 2017 and June 2018, one member of the laboratory staff who had been eligible to be registered with HCPC for more than one year had not yet registered, but this action has now been completed. No further action is required.

Legal parenthood

Centre's history

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. However, as part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 the PR 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 previous PR provided this reassurance in writing on 19 November 2015, to the satisfaction of the executive, however, the findings on inspection in November 2017 indicated that he did not have foundation to do so because 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.

Following the interim inspection in November 2017, the PR at the time was asked to undertake an audit of all patients treated with donor sperm, or embryos created with donor sperm in accordance with CE(14)01, from when the centre opened in 2014. This audit was provided on 19 November 2017, but the executive was later informed that it did not include all relevant cycles, so the audit was repeated, and several issues were identified.

On further review the executive considered that these anomalies had not been fully investigated or that corrective actions identified were not appropriate. The executive

remained concerned about the robustness of the centre's audit and reviewed this in detail during the inspection in June 2018. During that inspection (in June 2018) the team identified a further potential anomaly in consent to legal parenthood that had been missed by the centre. Following the inspection, centre staff provided further updates and amendments to the audit report such that the executive was finally able to conclude that in all but one case the anomalies were considered 'near-misses' because the couples had either had a failed cycle, or were able to provide evidence that they were either married or in a civil partnership at the time of treatment. In the one remaining case, the issue is complex, and is being resolved through Court proceedings.

Audit of centre's records

During this inspection, the team reviewed seven records where treatment with donor sperm had recently been provided and where consent to legal parenthood may have been required, and noted that in one case the surrogate had completed a SWP ('Your consent (as a surrogate) nominating an intended parent to be the legal parent) form and an intended parent had completed a SPP ('Your consent to being the legal parent in surrogacy') form. However, the surrogate is married therefore it is not possible for her to nominate a second legal parent as her husband will be the legal parent of any child born as a result of her treatment (see recommendation 1). No pregnancy resulted from this treatment.

After the inspection, the centre provided its current standard operating procedure (SOP) for surrogacy cases, and this correctly states that legal parenthood is not applicable if a surrogate is married or in a civil partnership. The inspection team are concerned why the centre's SOP has not been followed in the case described above (see recommendation 1).

Centre's audit of consent to legal parenthood

During this inspection, the team reviewed the centre's most recent audit of legal parenthood. Although this is a detailed audit reviewing the centre's processes and compliance with relevant requirements in the Code of Practice, it did not include a robust audit of records of consent to legal parenthood. Whilst it is noted that records had been reviewed as part of this audit, it was not clear what had been assessed in each record, for example whether the correct consent form was in place and whether it was correctly completed. The inspection team concluded that this audit did not provide evidence of an assessment of practice in accordance with the Chief Executive's letter CE(14)01 (see recommendation 1).

Given the number and types of issues previously identified at the centre, it is of concern that the centre has not undertaken a robust audit of records since the one requested by the executive following the interim inspection in November 2017. Furthermore, such an audit was not planned. The need for effective audit has been reiterated to the centre in the reports of the inspections carried out in November 2017 and June 2018. The current PR has had previous experience of the HFEA's expectations and requirements in relation to legal parenthood having been PR at another centre between 2014 and 2017, therefore the inspection team expected that a robust audit of records would have been undertaken or planned.

A register of patients undergoing treatment with donor sperm was implemented in July 2018 by the centre and used to ensure that the relevant legal parenthood consents are completed for each couple, where applicable. This register also included details of the couple's marital status. The inspection team noted that there were nine entries on this register, three of which were single women, and it was recorded that consent to legal

parenthood was not applicable for these patients. The register did not include couples undertaking surrogacy treatments or those couples being treated with frozen embryos created with donor sperm. Centre staff explained that this register was being used as the primary source of information from which records for audit would be extracted. However, this list was only implemented in July 2018 and would not include patients seen before that date, or patients treated with frozen embryos created with donor sperm or those involved in surrogacy arrangements (see recommendation 1).

Review of centre's processes

The inspection team reviewed the centre's processes for obtaining and checking consent to legal parenthood. The lead nurse is responsible for seeing patients and obtaining consent to legal parenthood prior to treatment. The nurse explained that she checks the couples marital or civil partnership status (by obtaining copies of certificates) and that the relevant legal parenthood consent forms are correctly completed. She also explained that she re-checks the consent forms with another person prior to completing the centre's electronic records. However, the findings on inspection do not provide the reassurance that these processes are robust as the incorrect legal parenthood consent forms completed by the surrogate and intended parent noted by the inspection team had not been identified by the centre (see recommendation 1).

Conclusion

The inspection team concluded that the centre's processes for obtaining consent to legal parenthood are not compliant with HFEA requirements and that effective audit procedures to ensure ongoing compliance are not in place.

Surrogacy

During the review of consent to legal parenthood records, the inspection team also reviewed two records of a surrogate and the intended parents and noted the following (see recommendation 2):

- In both cases there were potential risk factors in relation to the gamete provider or the surrogate, but in both cases, there was no documentation that these had been risk assessed prior to offering treatment, and the rationale for proceeding with treatment had not been clearly documented. These potential risks were a gamete provider who was adopted (therefore their medical history may not be fully known) and the surrogate had a BMI of 35.
- Whilst a surrogate had told the centre that she had previously had counselling there was no evidence of when this had taken place, and whether it could be considered suitable, such as with a suitably accredited counsellor.
- A surrogate had called the centre with some concerns but there was no evidence in the records that these had been discussed with a clinician and addressed.

Import of donated gametes

The PR confirmed that, in accordance with the additional condition on the centre's licence, the centre has not imported any donor gametes since January 2018. Again, in accordance with the additional condition on the centre's licence, the PR has submitted an application for a Special Direction for the import of donor sperm from a sperm bank in Denmark for a specific patient. The Special Direction was granted by the Statutory Approvals Committee on 25 April 2019.

Prior to the inspection, the centre's inspector noted that the centre's website stated the following:

'*We offer our patients options to access high quality donor eggs here in the UK without the need to travel overseas, or to travel to trusted clinics overseas for their treatment, such as the Pedieos IVF Center in Cyprus.*
Pedieos IVF Center is one of the most experienced IVF clinics in Cyprus and is licensed in the EU and USA (EUTCD and FDA accreditation). The Center has a well established egg donation programme and works with several international clinics. Medical Director Dr Krinos Trokoudes has been a pioneer in the IVF field since 1986.
IVF treatment using egg donation can help women achieve pregnancy where it has been proving very difficult. IVF with donor eggs may be needed for a variety of reasons, whether it be age, ovarian failure or previous medical treatment that have directly affected your fertility.
What is egg donation?
In an IVF cycle with donor eggs, an egg is fertilised using either sperm from your partner or a sperm donor, creating an embryo to be transferred into your womb.
We have frozen donor eggs which are available immediately, so there is no longer a need to go through the stressful process of synchronising your menstrual cycle with a potential donor before your treatment can begin.
Donor eggs are available immediately. The time between choosing to undergo IVF with donor eggs and matching with a suitable egg donor of your choice can be as short as a couple of weeks.
Your medical history will be reviewed, and some health tests undertaken to see if the egg donation process is suitable. If it is, the consultant would then prepare the treatment protocol.
Patients can access our catalogue for the egg bank, where they can find out data of their donors and suggest preferences, with the ultimate match carefully selected by our coordinator.
The IVF process then takes place, whereby donor eggs are fertilised in the laboratory using your partner's or donor's sperm, before the embryo is transferred into the woman's uterine cavity.'

During the inspection, these statements were discussed with the PR, who was not aware that this information was on the centre's website. The PR reiterated that the centre has not, and will not, import donated eggs because of the condition on the centre's licence. Whilst the information did not explicitly state the frozen donor eggs available at the centre are from Cyprus, the way the information is presented leads the reader to infer this. The PR immediately removed this information from the centre's website and there is no longer any reference to treatment in Cyprus, therefore no further action is required.

Import and export of patient gametes

The inspection team reviewed the only import and export undertaken by the centre since the time of the last inspection, which in both cases was the transfer of patient's sperm.

On reviewing the centre's evidence of compliance with General Direction 0006 it was noted that the clinic to which the sperm was to be exported had advised the centre that their national accreditation document was late being issued, which was not unusual in that country, therefore the previous one which had expired 3 months previously would 'suffice'. There was a further delay of 6 months before the export was performed, but given the previous assurances by the clinic abroad, the centre had not re-checked the accreditation status of the clinic prior to export (see recommendation 6). Whilst the inspection team is assured that the centre had reviewed compliance with General Direction 0006 and had checked the accreditation status of the clinic abroad, it is concerned that staff were accepting of the expired certificate, and that they did not re-check the centre's

accreditation status prior to export. During the inspection, centre staff were able to contact the clinic abroad and confirmed that valid accreditation was in place at the time of the export.

Complaints and incidents

In 2019, the HFEA received two serious complaints from patients following treatment at the centre. In view of this, the HFEA's Clinical Governance Lead also attended the inspection to review the centre's handling of complaints and adverse incidents.

During the investigation into one of these complaints, the centre had identified that there should be a change in the processes for monitoring patients prior to insemination to minimise the risk of multiple pregnancy. The centre noted that the relevant SOP would be amended to reflect this change in practice and that this corrective action was completed by March 2019. During the inspection, the team requested a copy of the amended SOP to review the changes, but this was not provided until 7 May 2019 (revision date 17 April 2019) despite two requests since the time of the inspection (see recommendation 3).

Patient feedback

During the inspection visit patients were not 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. At the time of the inspection 46 patients had provided feedback in the last 12 months, giving an average 4.5-star rating to the clinic. The HFEA website also gives the ability for patients to comment on the cost of treatment, and the majority of patients confirmed that they had paid what they expected to. Of the 46 responses, 29 patients also provided written feedback to the HFEA complimenting the staff and service at the clinic.

A member of centre staff also contacts patients seen in the clinic via email inviting them to provide feedback directly to the HFEA, or to the clinic's social media site or electronic survey facility. A member of centre staff collates this information which is circulated to staff in a bi-monthly newsletter. Feedback was comparable to that provided to the HFEA. The centre plans to further develop their processes for collecting and responding to patient feedback.

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.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The current Quality Manager explained that she has begun 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 will be 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. Similar concerns have been raised during the previous inspections at the centre, therefore the inspection team was assured that the Quality Manager had also identified these issues and was taking action to improve the centre's QMS. The inspection team expects to see that these changes will be fully embedded at the time of the renewal inspection in October 2019, where, subject to the PR making an application to renew the centre's licence, this area of practice will be assessed in detail.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements for the following reasons as set out in the relevant sections of the report:

- The centre's audit of legal parenthood did not provide evidence of an assessment of practice in accordance with the Chief Executive's letter CE(14)01. See the 'Legal parenthood' section above.
- The centre had identified that there should be a change in the processes for monitoring patients prior to insemination to minimise the risk of multiple pregnancy. The relevant SOP would be amended to reflect this change in practice and that this corrective action was completed by March 2019, but it was not done until 17 April 2019. See the 'Complaints and incidents' section above

Confidentiality

At the time of the interim inspection in November 2017, centre staff informed the inspector that recipients are shown a photograph of the donor and the inspection team was concerned that the centre was not fulfilling its duty to protect the confidentiality of its donors. No further action was needed at the time of the inspection in June 2018. During the inspection, the current PR reiterated previous assurances provided that photographs of donors are not obtained or used by any staff at the centre.

Equipment and Materials

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

At the time of the interim inspection in November 2017, the centre was using a specimen container that was not CE marked as a medical device. Following that inspection, the centre confirmed that it had obtained an appropriately CE marked specimen container for sperm samples. No further action was needed at the time of the inspection in June 2018.

The CE mark status of the following medical devices was reviewed in the course of the inspection: specimen containers, plastic ware, culture medium, vitrification medium. The centre maintains a stock of a product used to activate sperm which is CE marked as an 'in vitro diagnostic' device, rather than a medical device. This classification means the product is suitable for diagnostic use only. The inspection team noted that this product is very rarely used, but it had been needed during a recent difficult ICSI case when it was used therapeutically as no other processes were successful. Whilst the inspection team recognises that staff were trying to help the couple in this difficult case, the product was being used 'off label' i.e. for a purpose for which it was not appropriately classified. The

centre had not completed a robust risk assessment and had not provided appropriate information to the patient regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use of this item) prior to use in treatment (see recommendation 7).

Prescription of intralipid 'off label'

This area of practice was not reviewed in detail on this inspection, as no further action was needed at the time of the inspection in June 2018.

Premises and facilities

The premises and facilities were not reviewed in detail on this inspection, as no further action was needed at the time of the inspection in June 2018.

Leadership

The inspection team noted that the PR has been at the centre for seven months and has been PR for the last four months. In view of the recent staff turnover, the PR's initial focus since joining the centre has been to ensure that vacant positions have been filled, that new staff have been fully trained and are considered competent, and that she fulfils her duties as Laboratory Director.

The inspection team has some concerns that the PR's oversight within the centre is not yet evident. These concerns arise from the findings on inspection as detailed above. In particular the failings in relation to consent to legal parenthood and that the PR did not seem aware of all the details of the contingency arrangements for the centre and the potentially misleading information on the centre's website.

Given these concerns, the PR was required to attend a meeting with the HFEA executive on 20 May 2019 to discuss the corrective and preventative actions that would be taken to address the non-compliances identified and to ensure the future compliance of this centre. The executive recommended that the PR focuses on her role as PR to ensure that she fully discharges her duties and has comprehensive oversight on all activities at the centre. The PR assured the executive that she did have, and would continue to have, full oversight on the centre's activities and would fully engage with the HFEA to address all of the non-compliances identified at the time of the inspection. The executive expects to see robust evidence of the PR's oversight and ability to fully discharge her duties to ensure compliance of this centre at the time of the renewal inspection in October 2019.

On-going monitoring of centre success rates

Since the last focused inspection in June 2018 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. Legal parenthood During the inspection, the team reviewed two records of a surrogate and intended parents. In one case the surrogate had completed a SWP ('Your consent (as a surrogate) nominating an intended parent to be the legal parent) form and an intended parent had completed a SPP ('Your consent to being the legal parent in surrogacy') form. However, the surrogate	The PR should ensure that proper consent to legal parenthood is obtained and that effective audit procedures are in place to ensure ongoing compliance with legal parenthood consent taking requirements. The PR has been asked to voluntarily suspend the provision of treatments with donor sperm and surrogacy until such time that the	The PR can confirm that a full review of the legal parenthood audit procedures has been undertaken and a system to ensure that compliance with legal parenthood consent taking has been introduced. A patient-by-patient rolling audit, has been implemented with all consents being passed to the PR to approve prior to the patient's treatment being started. QAF061 – Consent to Legal Parenthood rolling audit	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that she has suspended the provision of new treatments with donor sperm, embryos created with donor sperm or surrogacy.

is married therefore it is not possible for her to nominate a second legal parent as her husband will be the legal parent of any child born as a result of her treatment. No pregnancy resulted from this treatment. The inspection team noted that this is not in accordance with the centre's SOP for surrogacy. The inspection team reviewed the centre's most recent audit of legal parenthood. Although this is a detailed audit reviewing the centre's processes and compliance with relevant requirements in the Code of Practice, it did not include a robust audit of records of consent to legal parenthood. Human Fertilisation and Embryology Act 2008 (as amended). Chief Executive's letter CE(14)01 and SLC T36.	executive is satisfied that the centre's processes in this area of practice are robust. The executive will liaise with the PR to determine when such a suspension can be lifted. The PR should provide a summary of immediate actions taken to address the case identified during the inspection when responding to this report. The PR should conduct a root cause analysis into the circumstances which led to the failure of the centre's processes to identify the issue found by the inspection team. A copy of the root cause analysis should be provided to the centre's inspector when responding to this report. On receipt of the information the HFEA executive will liaise with the PR to determine what further actions and/or recommendations are required. The PR should implement further staff training in consent	is in place and captures all patients having treatment with donor sperm, embryos created with donor sperm or surrogacy. The audit is triggered by the sign out of consent packs as described in PAT006 – Consents Packs Issuing and Checking Process (attached). Consent packs are required for all new treatments and FETs. Until further notice, all Consents Packs will be checked by the PR and audited by the QM. The implemented system is a robust system that ensures all patients are captured and checked before treatment. A new Query has been set up on the IDEAS database to filter all patients havingtreatmetn with donor sperm and the list is currently being cross checked against the rolling audit. All data will be reported and available for review by 4th July 2019. The PR can confirm that all treatments with donor sperm, embryos created with donor sperm and surrogacy have	During the meeting with the HFEA executive on 20 May 2019, the PR provided a summary of the immediate actions she had taken to ensure that the centre's processes for obtaining and checking consent to legal parenthood for all relevant patients, including in surrogacy treatments, were robust. These included the introduction of an additional process whereby 'consent packs' which specify which forms are required depending on the treatment and couple's marital status would be used. All consents are to be reviewed and checked by the PR who will confirm whether or not treatment can proceed. In addition, a further process has been introduced to record that a patient is single, so that the centre has confirmation that no legal parenthood consent forms are needed. The PR confirmed that she (seeking legal input as required) would be providing the staff training in consent to

	to legal parenthood including surrogacy arrangements. An action plan on when and by whom this training will be provided should be submitted when responding to this report. The PR should conduct an audit of legal parenthood consent for treatments involving the use of donor sperm or embryos created with donor sperm, since the time of the interim inspection in November 2017 to date. A copy of the audit including the methodology used, should be provided to the centre's inspector by 4 July 2019. The PR should review the centre's processes for taking consent to legal parenthood including surrogates and intended parents to consider why the issues identified during the inspection arose. A summary report of the findings of the review, including corrective actions and timescales for implementation should be provided to the	been suspended. Following a meeting with with senior inspectors it was agreed that single women seeking treatment with donor sperm may continue with treatment following PR approval. The PR can confirm that a root cause analysis has ben completed and is attached to this report for review. The PR can confirm that staff training for consent taking for legal parenthood will be completed by 14th June 2019. Competency assessments will be provided for all staff. The PR can confirm that the audit of legal parenthood consent has been completed has been cross-checked by 2 members of the clinical team. The PR will review this and forward to the centre's inspector by 4th July 2019. The PR can confirm that a review of the the processes for taking consent has been completed and staff training	legal parenthood by 14 June 2019. The PR also presented a summary of the findings of her review of the centre's processes for taking consent to legal parenthood including surrogates and intended parents during the meeting with the HFEA executive on 20 May 2019. Several corrective actions had been identified, some of which had already been implemented. The PR has provided a copy of the centre's root cause analysis into the circumstances which led to the failure of the centre's processes to identify the issue found by the inspection team. The centre identified four 'root causes' which included lack of staff understanding in this area of practice, gaps in training and competency in relation to legal parenthood in surrogacy, and insufficient time to complete consents properly during the consultation appointment. The

	centre's inspector by 4 July 2019. The PR should ensure that this area of practice is audited at least monthly until such time that she has robust evidence that consent to legal parenthood is compliant with requirements.	will be completed by 14th June 2019. The evidence of training will be forwarded to the centre's inspector by 4th July 2019.	centre identified a number of corrective and preventative actions including further staff training and competency assessments to be completed by 14 June 2019. Changes in the centre's processes for assessing surrogacy patients, including considering legal parenthood described in the 'Surrogacy' section below have also been implemented. The executive awaits confirmation that staff training, and competency assessments have been completed, and a summary of the findings of the centre's audit of consent to legal parenthood since the time of the interim inspection in November 2017 to date which is due by 4 July 2019. Once the executive is satisfied that the centre's procedures for obtaining and checking consent to legal parenthood are robust, it will be able to recommend that the provision of new treatments with donor sperm, embryos created with

			donor sperm or surrogacy can resume. The executive notes that the PR has introduced a 'rolling audit' process whereby all records are audited prior to the provision of treatment to prevent any similar issues from arising in the future. The executive requests that once treatments resume, a summary of the findings of these rolling audits is provided monthly to the centre's inspector until the renewal inspection in October 2019. **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
2. Surrogacy On review of two sets of surrogacy records several issues were noted which are set out in the body of the report SLC T46 and SLC T49.	The PR should ensure that surrogates and gamete providers in a surrogacy arrangement are suitably assessed, and that this assessment is documented in their records prior to treatment. The PR should review the two surrogacy cases audited by the inspection team to determine whether the surrogates and gamete providers have been suitably assessed. A summary of the findings of the reviews should	The PR can confirm that a review of the surrogacy assessments has been completed and a new surrogacy assessment form has been put in place (CLF115) and a patient information leaflet has been implemented (PAI082). The PR can confirm that the two surrogacy cases audited had had assessments. Concern had been raised with regards to the BMI of one of the surrogates, however she had reached her appropraiate BMI before treatment	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. During the meeting with the HFEA executive on 20 May 2019, the PR presented a summary of the changes she would be implementing as a result of the findings on inspection, and of her initial review of the centre's processes for assessing surrogates and intended parents. These included revision of the centre's

	be provided when responding to this report. The PR should audit all surrogacy treatments carried out in the centre since the last renewal inspection in October 2015 to determine whether there are any cases where gamete providers in surrogacy arrangements were not suitably assessed. A summary of the findings of the audit should be provided to the centre's inspector by 4 July 2019. If cases are identified where the gamete providers in surrogacy arrangements were not suitably assessed, the PR should seek expert advice to fully assess if there may have been any risks to the surrogates that have undergone treatment with these gametes. The review should also consider whether surrogates affected are to be contacted and advised of possible risks of their treatment. The PR should inform the centre's inspector	commenced. In one surrogacy case the gamete provider/intended parent disclosed that he was apdopted and there is no evidence that the surrogate had been made aware. The new assessment form includes medical history and a requriement to request medical information from the GP. The PR can confirm that a full audit of all surrogacy treatments at RHG since 2015 is underway and will be provided by 4th July 2019. The PR can confirm that the assessments for surrogates and intended parents will be reviewed and the findings will be risk assessed and provided to the centre's inspector by the 4th July 2019. The PR can confirm that a patient-by-patient rolling audit is in place and will be completed for all surrogacy cases once treatment is resumed. The PR will also be	'Surrogacy assessment form', SOP and patient information. In addition, 'consent packs' have been developed to ensure that, where applicable, proper consent to legal parenthood is obtained prior to treatment. The PR has reviewed the two surrogacy cases identified during the inspection and is assured that these patients had been suitably assessed. In order to make the process more robust, the PR has implemented changes to the centre's forms to ensure that the details of the assessments are clearly recorded, and any issues or concerns raised are fully considered, and risk assessments completed and documented before provision of treatment. The executive awaits a summary of the findings of the audit all surrogacy treatments carried out in the centre since the last renewal inspection in October 2015, and of the risk

	of the timeline for completing this risk assessment by 4 July 2019. The PR should review the centre's processes for assessing surrogates and intended parents to ensure that any issues or concerns raised are fully considered, and risk assessments completed and documented before provision of treatment. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 4 July 2019. Once the provision of new surrogacy treatments has resumed, the PR should audit the effectiveness of changes introduced in this area of practice within three months of providing surrogacy treatments.	approving all surrogacy cases prior to commencing treatment.	assessment of cases by 4 July 2019. The executive notes that the PR has introduced a 'rolling audit' process and requests that once treatments resume, a summary of the findings of these rolling audits is provided monthly to the centre's inspector until the renewal inspection in October 2019. **Further action is required.**
3. Complaints and incidents The centre had identified that there should be a change in the processes for monitoring	The PR should ensure that there is an effective QMS to continually improve the quality and effectiveness of the	The PR can confirm that a full review of the QMS is underway.	The executive acknowledges the PR's response and her commitment to fully

patients prior to insemination to minimise the risk of multiple pregnancy. The relevant SOP was to be amended to reflect this change in practice and that this corrective action was completed by March 2019. During the inspection, the team requested a copy of the amended SOP to review the changes, but this was not provided until 7 May 2019 (revision date 17 April 2019) despite two requests since the time of the inspection. SLC T36.	service provided in accordance with SLCs and CoP requirements. The PR should ensure that all corrective actions identified during the reviewed complaint investigation are fully implemented. The PR should review why this corrective action was recorded as being fully implemented when it had not been completed. A summary of the findings of this review should be provided when responding to this report.	The PR can confirm that the complaint/incident was investigated and closed (see attached report RHGIRM002v2). The PR can confirm that the corrective actions were completed, however due to an internal miscommunication the updated documentation was not provided until a later date for which the PR apologises.	implementing this recommendation. The amended SOP has been provided and the executive notes the reason for the delay in providing this to the executive was an internal miscommunication in the centre. The executive notes that the centre's Quality Manager is conducting a full review of the QMS and it is expected that robust systems will be implemented so that similar issues are prevented from happening in the future. This will be assessed at the time of the renewal inspection in October 2019. **No 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
4. Obligations and reporting requirements The centre has not submitted data relating to partner insemination for 2018 within the required timeframe. General Direction 0005. This was noted as an issue at the time of the previous inspection in 2018.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. Soon after the inspection, the PR submitted the data relating to partner insemination carried out in the centre in 2018, therefore no further action is required.	The PR can confirm that the reporting of all licenced treatments will be within the required timeframe.	The executive acknowledges the PR's assurances that all licensed treatment activity will be reported to the Authority within the timeframe required by General Direction 0005. **No further action is required.**
5. Staffing The inspection team was concerned that whilst the centre team could describe a contingency in the event of the Clinical Director's absence, the PR seemed to be unsure of the identity of these individuals and where they currently worked.	The PR should ensure that there are suitable arrangements in place to provide clinical cover in the absence of the Clinical Director and for the management of a clinical emergency.	The PR can confirm that there is appropriate clinical cover from consultants employed by RHG for any period of absence by the Cinical Director. The RHG Consultants are Tahla Shawaf and Hossam Elsheikh. All approparite practicing	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed the identity of the personnel that provide cover in the absence of the Clinical Director. The

Section 17, Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). The centre does not have a documented process for a clinical emergency such as where to transfer a patient in the event of an emergency. SLC T33b.	The PR should ensure that contingency arrangements are clear to all staff, and that these are documented. Confirmation that this has been completed should be provided to the centre's inspector when responding to this report. The PR should confirm the identity of the personnel that are to provide cover in the absence of the Clinical Director and ensure that the identified individuals are suitable and competent to undertake their roles. The PR should confirm when she is suitably assured that proper arrangements are in place to provide cover for the Clinical Director and confirm to the centre's inspector that she has evidence of their competence to undertake the role when responding to this report. The PR should review the centre's processes for managing a clinical emergency to ensure that it includes provision for the	privilages are in place for Dr Shawaf and Dr Elsheikh. The PR can confirm that there is a service level agreement with the Hewitt Fertility Centre for the provisoin of laboratory and clinical services in case of emergency (attached).	PR is assured of the suitability and competency of these persons to carry out their designated tasks. The PR has provided evidence of the contingency arrangements in place at the centre. **No further action is required.**

	transfer of a patient in the event of an emergency. A copy of the SOP should be provided to the centre's inspector when responding to this report.		
6. Import and export The centre had not ensured that the accreditation of a receiving clinic was valid at the time of export. General Direction 0006.	The PR should ensure that the evidence of compliance with General Direction 0006 is robust. The PR should review the centre's processes for assessing compliance with General Direction 0006 to ensure that evidence is reviewed at the time of import or export. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 4 July 2019.	The PR can confirm that the review processes for General Direction 0006 is underway and a summary will be provided by 4th July 2019.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that a review of the centre's processes for assessing compliance with General Direction 0006 is underway and that a summary of the findings of this review will be provided by 4 July 2019. **Further action is required.**
7. Equipment and materials The centre had used a product which is CE marked as an 'in vitro diagnostic' device as a medical device to activate sperm prior to ICSI treatment. Therefore, it has been used	The PR should ensure that CE marked medical devices are used where possible. If the PR considers that there is no CE marked medical device available, or no other	The PR can confirm that immediately following the inspection on the 4th April 2019 the use of this product was terminated.	The executive acknowledges the PR's response and her confirmation that she has discontinued the use of this product in the centre.

'off label' i.e. for a purpose for which it was not appropriately classified. Where a centre is using a product as a medical device for which there is no CE marked alternative available, it is expected that a robust risk assessment would have been undertaken, and that appropriate information is provided to patients regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use of this item) prior to use in treatment. SLC T30, SLC T24, SLC T28, SLC T72 and CoP 26.5.	process using CE marked medical devices can be used to activate sperm for ICSI, then she should ensure that a robust risk assessment and validation has been undertaken prior to use of this product, and that patients are informed that a product that is not appropriately classified as a CE marked medical device is to be used. A copy of the risk assessment and validation for the use of this product in treatment, and patient information should be provided to the centre's inspector by 4 July 2019.		The PR should ensure that if in the future, any product that is not appropriately classified as a CE marked medical device is to be used as one, then a robust risk assessment and validation is undertaken prior to its use, and that patients are informed of any possible risks associated with the use of this item prior to its use in treatment. **No further action is required.**

Reponses from the Person Responsible to this inspection report
The PR would like to thank the inspectors for their support and feedback during the inspection and the subsequent discussions to resolve the issues that were identified. The PR would like to reassure the executives that we are determined to resolve the issues and ensure that they are not repeated in the future.