Licence Committee - minutes

Centre 0321 (NewLife Fertility Centre)
Renewal Licence

Thursday, 5 September 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Anita Bharucha (Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Debbie Okutubo - Observer	Committee Secretary Governance Manager
Legal Adviser	Tom Rider	Fieldfisher 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:

- Executive update
- Annex 1 - updated compliance table
- Annex 2 - extract of email from PR and certificate of attendance at consent workshop (received 19 August 2019)
- Importing Tissue Establishment (ITE) certificate
- Minutes of the Executive Licensing Panel - 9 July 2019 – renewal inspection, change of PR and LH

Paper set originally considered by the Executive Licensing Panel on 9 July 2019:

- Inspection report
- Licence renewal application
- Previous licensing minutes for the last three years:
    - Licensing Officer Consideration - 3 October 2018 - Variation - Licence Holder
    - Executive Licensing Panel - 6 October 2017 - Interim/Additional inspection
    - Licensing Officer Consideration - 30 March 2017 - Variation - Licence Holder
    - Executive Licensing Panel - 17 June 2016 – Renewal Inspection
    - Executive Licensing Panel - 17 June 2016 - Variation - Licence Holder

1. Background

1.1. NewLife Fertility Centre, centre 0321 is located in Epsom, Surrey. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2011 and provides a full range of fertility services.

1.2. The centre had a licence renewal inspection on 5 and 6 March 2019.

Executive Licensing Panel (ELP) Decision - 9 July 2019 - Renewal

1.3. The Executive Licensing Panel (ELP) considered the centre's renewal inspection report on 9 July 2019, alongside applications for a change of Person Responsible (PR) and a change of Licence Holder (LH).

1.4. Recommendations were made to address one critical, two major and three other areas of non-compliance

1.5. The panel noted that the previous licence had been issued for three years (rather than the usual four) due to concerns about compliance.

Treatment (including embryo testing) and Storage Licence

1.6. The panel had major concerns regarding the range of non-compliances identified at the renewal inspection. It was particularly concerned about the critical non-compliance relating to legal parenthood and decided to adjourn its decision to renew the centre's licence, and refer the renewal inspection report to the Licence Committee for consideration, requesting that the Executive provides further updates on legal parenthood, medicines management, witnessing, quality management and record keeping.

Importing Tissue Establishment (ITE) Certificate

1.7. The panel also decided that the renewal of the centre's Importing Tissue Establishment (ITE) certificate should be considered by the Licence Committee with the renewal inspection report,.

Change of PR and LH

1.8. The panel agreed to vary the licence to reflect a change of PR and LH with immediate effect.

Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended)

1.9. The panel noted that the centre's licence was due to expire on 2 August 2019 and agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's licence, to allow time for the renewal to be considered by the Licence Committee and for the administration of the outcome of the consideration to be completed within the usual timeframe. These Special Directions came into force on 3 August 2019 and remain in force until a new licence comes into effect, or 2 November 2019, whichever is sooner.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the 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 December 2018, the centre provided 188 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data, for the period 1 October 2017 to 30 September 2018, showed the centre's success rates, were in line with the national averages.

2.5. The committee noted that in 2018, the centre provided 78 cycles of partner insemination with twelve pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

2.6. The committee noted that between 1 October 2017 and 30 September 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 17%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that a renewal inspection was carried out on 5 and 6 March 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. Recommendations were made to address one critical, two major and three other areas of non-compliance:

Critical areas of non compliance:

- The PR should ensure that consent to legal parenthood obtained and documented at the centre is valid.

Major areas of non compliance:

- The PR should ensure that sperm donors are screened in accordance with standard licence conditions and professional body guidelines.
- The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.

Other areas that require improvement:

- The PR should ensure that audits performed by the centre are comprehensive and robust.
- The PR should ensure that any risks associated with deviating from HFEA guidance on witnessing practices are properly assessed and documented.
- The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records.

2.8. The committee noted in particular, the non-compliances relating to staff training in consent to legal parenthood for treatment involving surrogacy, donor screening and in medicines management, particularly related to recording the use of controlled drugs in patients and access to the controlled drugs cabinet. The committee considered the possible impact these non-compliances could have on patients.

2.9. The committee noted that the PR was advised to take immediate action to review the consent to legal parenthood in a surrogacy treatment case noted in the report as a critical non-compliance. Since the inspection visit the PR had committed to fully implement all of the recommendations, and to provide evidence that actions have been taken, and where required, to audit the effectiveness of those actions within the required timescales. However, having reviewed some of the surrogacy documents submitted by the centre which contained some inaccuracies, the inspectorate contacted the centre on 29 March 2019 and was informed by the lead nurse that no action had yet been taken regarding the critical area of non-compliance relating to consent to legal parenthood in a surrogacy treatment. On 1 April 2019 the lead nurse submitted the centre's updated surrogacy information documents and confirmed that they were seeking legal advice.

2.10. The PR stated that they will ensure that staff are suitably trained in consent to legal parenthood and that the centre's documents will be reviewed by a legal adviser. This was discussed further with the PR on 20 June 2019 and it was agreed that until this has been completed the centre will not undertake any further treatments involving surrogacy arrangements.

Management Review Meeting - 23 June 2019

2.11. The committee noted that due to the critical non-compliance relating to legal parenthood identified on inspection, the Executive held a management review meeting, in accordance with the HFEA's Compliance and Enforcement Policy, on 23 June 2019, to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application. The Chief Inspector was in attendance.

2.12. The Executive had concerns about the issues relating to legal parenthood, however considered that the PR had sought legal advice and taken action, including speaking to the parties involved. The PR had already agreed not to undertake any further treatments involving surrogacy arrangements until staff are suitably trained in consent to legal parenthood and the centre's documents have been reviewed by a legal adviser.

Executive Update

2.13. The committee noted that the inspectorate has liaised with the newly appointed PR, Mrs Bhavisha Gloucester-Trotman, appointed in July 2019, regarding action taken to implement the recommendations to address the non-compliances. The new PR had provided requested information in a timely manner and also engaged further with the inspectorate while she was on leave, providing an update on further action taken towards compliance with the recommendations. The Executive considered that the new PR had taken appropriate and timely action.

2.14. The committee noted that some information was due after the deadline date for submission to the Licence Committee and required further review and clarification. This meant that the Executive was unable to provide the Licence Committee with a final assessment of the centre's compliance with all of the recommendations.

Recommendations

Licence

2.15. The inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four years, without additional conditions, subject to the inspectorate's recommendations being implemented within the prescribed timescales.

Inspection

2.16. A three-year licence will allow the centre to be inspected within a year of issue of the new licence, to closely monitor compliance in the areas of concern outlined in the renewal inspection report and assess the leadership of the centre with the new PR in post.

Importing Tissue Establishment (ITE) certificate

2.17. The committee noted that the centre has been issued with an Importing Tissue Establishment (ITE) certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. These certificates are generally synchronised to the centre's HFEA licence. The inspectorate recommends the renewal of the centre's ITE certificate in line with its centre's licence.

Legal Advice

2.18. The Legal Adviser outlined the options available to the committee. Members were invited to consider the following:

- Accept the inspectorate's recommendation to renew the centre's licence for a period of three years, instead of the usual four, without additional conditions, subject to the inspectorate's recommendations being implemented within the prescribed timescales, which would allow the centre to be inspected within a year of issue of the new licence. Also renew the centre's ITE certificate.
- Renew the centre's licence for a period of three years, instead of the usual four with an additional condition, subject to the inspectorate's recommendations being implemented within the prescribed timescales, which would allow the centre to be inspected within a year of issue of the new licence. Also renew the centre's ITE certificate.
- Refuse to renew the centre's licence, which also results in a refusal to renew the ITE certificate.
- Adjourn for further information on the centre's progress on the implementation of the inspectorate's recommendations.

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 in the form required 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) – Mrs Bhavisha Gloucester-Trotman

3.3. The committee was 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. It was further satisfied that the proposed PR will discharge her duties under section 17 of the HF&E Act 1990 (as amended).

3.4. The committee considered that the new PR has only held the post for a short time and that the inspectorate plan to assess the PR's leadership at the interim inspection.

Proposed Licence Holder (LH) – Mr Ahmed Gafar

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

Activities

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

Premises – The Parade, The Pines, Epsom, Surrey, KT18 5DH

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

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

Non-compliances

Legal Parenthood

3.9. The committee was particularly concerned with consent to Legal Parenthood issues and noted that action has been taken to address them.

3.10. The committee noted that the PR has confirmed that staff training in legal parenthood has been provided. The committee decided that following the staff training, their competency in legal parenthood consents should be assessed by the centre and this assessment submitted to the Executive to ensure that the centre is compliant.

3.11. The PR has provided information on how she will ensure that consent to legal parenthood obtained and documented at the centre is valid. The centre has nominated a specialist fertility lawyer to seek advice from should this be required in the future. The committee noted that the process for obtaining consent has changed for all patients since the new PR attended a legal parenthood conference and all consents are now taken in the clinic with a staff member, to prevent patients completing the wrong forms or completing them incorrectly. The committee expects all simple and complex legal parenthood issues to be resolved and not repeated.

3.12. The PR has provided amended IVF/ICSI consent forms and the Executive noted that the incorrect information has been removed. A summary of the review of the centre's documents by their legal adviser and the results of the investigation into why the error in consent forms had not been identified by centre staff was due by 29 August 2019. Further information is awaited regarding the review of the centre's surrogacy documents.

3.13. The PR has confirmed that no new surrogacy treatments are to be provided until the recommendations have been fully implemented.

Donor assessment and screening

3.14. The records of one sperm donor (intended parent in a surrogacy arrangement) indicated that the donor had not been screened in accordance with professional body guidelines as the donor had not had a physical examination. The SOP for screening and assessment of sperm donors did not include the need to perform a physical examination.

3.15. The inspectorate recommended that the PR should ensure that the SOP for the screening and assessment of sperm donors is reviewed and shared with all relevant staff, and ensure that staff are suitably trained to implement this SOP, prior to undertaking donor assessment and screening activities. An ongoing programme to assess staff competence in this area should also be implemented. The PR should also perform an audit of compliance of the screening and assessment of sperm donors recruited by the centre. Where it is identified that donors have not been suitably screened, the PR should seek expert advice, to assess if there have been any risks to those treated with the donor's sperm or to other samples stored with the donor's sperm.

3.16. Since the inspection the centre has processed one person for freezing of sperm prior to potential donation. The centre has confirmed that the donor had a physical examination in line with professional body guidelines.

3.17. The committee noted that further information is awaited on staff training and competency, and any potential risks from the omission to perform a physical examination of sperm donors. This information was due by 29 August 2019 and will be followed up by the inspectorate.

Medicines Management/Quality Management

3.18. The committee noted that the inspectorate reviewed ten patient records and identified issues with medicines management relating to recording the use of controlled drugs in patients and unrestricted access to the controlled drugs cabinet.

3.19. The PR has confirmed that the key to the controlled drugs cabinet is now with a suitable person.

3.20. The inspectorate recommended that the PR should review the methodology of the audit of medicines management to ensure that it includes the legibility of documentation within the controlled drugs register. The PR should also conduct an audit of the documentation in the controlled drug register, three months after the implementation of corrective actions, to see that they have been effective.

3.21. The PR has provided a report of the centre's audit of the documentation in the controlled drugs register and identified further corrective actions to be implemented. The effectiveness of these actions will be assessed when the centre repeats the audit in October 2019.

3.22. The PR has agreed to review the controlled drugs register on a daily basis to ensure the accuracy of each entry and take immediate action where necessary.

Witnessing

3.23. The committee noted that the centre uses an electronic witness system, however the HFEA Code of Practice (CoP) guidance and HFEA model protocols detail critical points at which manual witnessing should still be performed. The centre does not perform double manual witnessing at any of these stages (e.g. insemination, ICSI and disposal) and the risks associated with this had not been assessed.

3.24. The inspectorate recommended that the PR should perform a review of witnessing protocols to ensure compliance with the HFEA CoP and HFEA model protocols. Within three months of the implementation of revised witnessing procedures, the centre should conduct an audit of witnessing practice.

3.25. The PR has provided the findings of the centre's audit of witnessing practice. The audit demonstrates that the centre has implemented the recommendation.

Record Keeping

3.26. The committee noted that the centre does not document who identified the patient/donor in patient records. The inspectorate recommended that the PR should ensure that the identity of the staff member who verifies a patient's identity, is documented in the patient's record. Three months after corrective action has been implemented, the PR should perform a records audit to ensure this action has been effective.

3.27. The PR has provided the findings of the centre's audit which confirms that the identity of the staff member who verifies a patient's identity is documented in the patient records.

Licence

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

3.29. The committee was deeply concerned about the nature and number of non-compliances identified by the inspectorate and noted that since the centre was first licensed in 2011, in consideration of both renewal applications, the inspectorate was unable to recommend a regular four year licence.

3.30. The committee considered the inspectorate's recommendations and the advice from its Legal Adviser. The committee deliberated on which options would be relevant in this case.

3.31. The committee considered the centre's history of non-compliance and that the previous licence had been issued for three years (rather than the usual four) due to concerns about compliance at the last renewal. The committee also considered the issues identified at the renewal inspection.

3.32. The committee noted that since the renewal inspection, the inspectorate considered that the new PR had fully engaged with the HFEA and has demonstrated a commitment to ensure that the centre achieves full compliance. The committee urged the PR to continue along this improved path. The committee noted that action has been taken to address all of the non-compliances within the set timescales, however further information is required to fully implement the recommendations. The PR has provided information in a timely manner, and the inspectorate will complete a final assessment of the centre's compliance with all of the recommendations in due course.

3.33. Carefully weighing all factors in the balance, the committee agreed that a three-year licence, rather than the usual four years, without additional conditions was appropriate, subject to the inspectorate's recommendations being implemented within the prescribed timescales.

Inspection

3.34. The committee endorsed the inspectorate's recommendation to complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance, including leadership. The committee decided that this inspection should also be unannounced. The committee expects the PR to continue to engage with the Executive. It is hoped that not only the PR will have full knowledge and understanding of her role and responsibilities and of the staff working within the team but will have developed systems through which she is able to lead the centre in a compliant manner by the time of the interim inspection.

3.35. The committee requested that the report of the targeted interim inspection is considered by the Licence Committee who expect all of the recommendations to be fully implemented within the timescales with a shift in culture to learning, improving and maintaining good practice.

Importing Tissue Establishment (ITE) Certificate

3.36. The committee also agreed to renew the centre's Importing Tissue Establishment (ITE) certificate in line with the centre's treatment (including embryo testing) and storage licence.

4. Chair's signature

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

Signature

Name

Anita Bharucha

Date

4 October 2019

Licence Committee
5 September 2019

Centre number	0321
Centre name	NewLife Fertility Centre
Person Responsible	Mrs Bhavisha Gloucester-Trotman

Executive update

Background

1. NewLife Fertility Centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2011 and provides a full range of fertility services.

2. The centre had a licence renewal inspection on 5 and 6 March 2019 and the report of that inspection was considered by Executive Licensing Panel (ELP) on 9 July 2019. ELP were asked to consider with the renewal application a change of Person Responsible (PR) and a change of Licence Holder (LH).

3. The minutes of the ELP meeting were provided to the newly appointed PR on 17 July 2019 and recorded the committee's decision.

4. ELP expressed major concerns regarding the range of non-compliances identified at the renewal inspection, particularly noting the critical non-compliance concerning legal parenthood. ELP also noted that the previous licence had been issued for three years (rather than the usual four) because of concerns about compliance at that stage.

5. ELP decided to adjourn renewal of the centre's licence, requesting the matter to be referred to the Licensing Committee for consideration. The panel noted that further updates on legal parenthood, medicines management, witnessing, quality management and record keeping, were due for receipt by 29 August 2019, requesting the inspector to provide the Licensing Committee progress on these non-compliances.

6. ELP also decided that the renewal of the centre's Importing Tissue Establishment (ITE) import certificate should be considered by the Licence Committee, in tandem with the renewal of the centre's licence.

7. ELP agreed to vary the licence with immediate effect to reflect the change of PR to Mrs Bhavisha Gloucester-Trotman and further agreed to vary the licence with immediate effect, to reflect the change of LH to Mr Ahmed Gafar.

8. The centre's inspector has liaised with the newly appointed PR regarding the actions taken towards compliance with the recommendations in the inspection report and at the time of compiling this update has received requested information in a timely manner.

9. Further information is awaited, however the date for submission by the PR, as documented in the renewal inspection report, is 29 August 2019. As the report is for presentation to the Licence Committee on 5 September 2019 papers for presentation are required to be submitted to the licensing secretary by 27 August 2019. Therefore, the centre's inspector is unable to provide the committee with a final assessment of the centre's compliance with all of the recommendations.

10. The PR was on leave at the time of completion of the papers for presentation to committee. She did however engage further with the centre's inspector while on leave regarding compliance with the recommendations, which the centre's inspector acknowledged. The information provided refers to further actions taken towards compliance with the recommendations, however it requires further review and clarification. The executive considers that the PR has taken appropriate and timely action up until the completion of these papers and that the PR can provide an update on her return from leave on 2 September 2019.

11. Annex 1 provides an update on the implementation of the outstanding recommendations. Actions have been taken to address all of the non compliances however further information is required to fully implement the recommendations to address these matters; these actions are within the timescales specified in the report.

12. Annex 2 provides an extract of an email from the PR with information that she requested be brought to the attention of the committee.

13. The centre's licence was due to expire on 2 August 2019 and ELP of 9 July 2019 agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's current licence, to allow time for the renewal to be considered by the Licence Committee and for the administration of the outcome of their consideration to be completed within the usual timeframe. These Special Directions came in to force on 3 August 2019 and remain in force until any new licence comes into effect, or to 2 November 2019, whichever is sooner.

Summary

14. In summary, the PR has addressed the recommendations however further information is required for them to be fully implemented.

15. The centre's inspector considers that the PR has fully engaged with the HFEA and has demonstrated a commitment to ensure that the centre achieves full compliance with the recommendations documented in the inspection report.

16. The centre's inspector will continue to work with the PR to ensure the outstanding recommendations are resolved.

Recommendation

17. The executive confirms that there is no change to the recommendation made by the inspection team in the renewal inspection report - that the centre's treatment (with embryo testing) and storage licence is renewed for a period of three years. The executive also recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

18. The executive recommends that an interim inspection takes place within a year of the licence coming into effect, at which time the inspection team will be able to evaluate the effectiveness of the changes that have been implemented since the time of the renewal inspection.

19. The Licence Committee is invited to make findings in this regard.

Janet Kirkland MacHattie
Clinical Inspector
21 August 2019