Licence Committee - minutes

Centre 0153 (Homerton Fertility Centre)
Executive update following licence renewal

Thursday, 2 May 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 Jennifer Rogerson Amanda Evans	Committee Secretary Research Manager (Staff Induction) Research Manager (Staff Induction)
Legal Adviser	Sarah Ellson	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:

- Further Executive Update
- Licence Committee Minutes – Renewal - 6 September 2018.
- Executive Licensing Panel (ELP) Minutes - Renewal - 12 July 2018
- Full paperset originally considered by Executive Licensing Panel (ELP) - 12 July 2018.

    - Licence Renewal Inspection Report - 6 March 2018
    - Licence Renewal Application
    - Executive Licensing Panel (ELP) Minutes - Interim - 29 July 2016.
    - Executive Licensing Panel (ELP) Minutes – Renewal - 13 June 2014.

1. Background

1.1. Homerton Fertility Centre, centre 0153, is located in London. The centre has held a licence with the HFEA since 1995 and provides a full range of fertility services.

Renewal inspection findings

1.2. A renewal inspection was carried out on 6 and 7 March 2018 and the inspectorate identified eight major areas of non-compliance regarding pregnancy success rates, traceability, the Quality Management System (QMS), consent to storage, witnessing, medicines management, imports and exports and CE marking. There were also eight 'other' areas of non-compliance concerning pre-operative assessment and the surgical pathway, equipment and materials, staff, disclosure of information held on the HFEA register for use in research, screening of patients, record keeping and document control and obligations and reporting requirements.

Licensing Decision - Renewal Application

1.3. The centre's renewal inspection report was submitted to the Executive Licensing Panel (ELP) for consideration, however the panel decided to refer it to the Licence Committee due to concerns regarding the number and extent of non-compliances identified at the renewal inspection, impacting on high quality of care and safety of patients.

1.4. The Licence Committee considered the renewal application along with an Executive update at its meeting on 6 September 2018. The committee was particularly concerned about the length of time taken to investigate the low success rates for IVF treatments involving fresh embryos in women under 38 years at the centre, and the lack of data on the reasons for this. The committee was also concerned by the PR's lack of response regarding the latest request for information relating to imports and exports.

1.5. The Licence Committee had regard to its Guidance on licensing, and carefully considered the duration of licence it should grant. The committee agreed that a three-year licence was appropriate, with no additional conditions, subject to the implementation of the recommendations set out in the renewal inspection report. The committee requested an update on information regarding success rates for IVF treatments involving fresh embryos in women under 38 years and information on imports and exports.

1.6. The Licence Committee also agreed that an inspection should take place within the first year of licence renewal.

2. Consideration of application

Executive Update

Pregnancy Success Rates – Major area of non-compliance

2.1. The centre's success rates for IVF treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level. Success rates in this group of women was also identified as an area of concern at the previous inspection.

2.2. The PR commissioned an independent review for October 2018. A summary report of the review, including a number of recommendations, was received. Some of the recommendations have already been implemented and the PR has provided the inspectorate with an action plan for the implementation of the outstanding recommendations.

2.3. The committee noted that the PR has committed to keeping the success rates for these patients under close review and the Executive will also continue to review the centre's success rates on a regular basis.

Imports & Exports - General Directions 0006 - Major area of non-compliance

2.4. The committee noted that the centre could not provide evidence of compliance with all of the requirements of General Direction 0006 (Schedule 4, 1e) for one of two gamete import/export cases reviewed. This area was identified for improvement at the previous licence renewal inspection.

2.5. The committee noted that the PR has now provided the required audit report and the Executive is assured that the centre's procedures for import and export are now compliant with the requirements.

3. Decision

3.1. The committee noted the Executive update and progress made on the implementation of the recommendations to address two major areas of non-compliance regarding success rates for IVF treatments involving fresh embryos in women under 38 years and information on imports and exports.

4. Chair's Signature

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

Signature

Name

Kate Brian

Date

30 May 2019

Executive summary for Licence Committee

2 May 2019

Centre number	**0153**
Centre name	**Homerton Fertility Centre**
Person Responsible	**Mr Anil Gudi**

Further Executive update for Licence Committee.

Background

1. The Homerton Fertility Centre was granted a 'Treatment and Storage' licence by a Licence Committee (LC) on 6 September 2018.

2. The licence was issued for a period of three years (rather than the standard four) due to:

- the history and recurrence of non-compliances;
- concerns about the Person Responsible's (PR) lack of response to a request for information relating to the import and export of gametes and embryos;
- concerns about the length of time taken by the PR to investigate the low success rates for IVF treatments involving fresh embryos in women under 38 years.

3. The LC requested that they be provided with an update as soon as the outstanding information regarding imports and exports and success rates for IVF treatments involving fresh embryos in women under 38 years was available.

The table in Annex A outlines what actions the PR has taken to address these non-compliances.

Julie Katsaros
Clinical Inspector

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Imports and Exports The centre could not provide evidence that they had complied with all the requirements of General Direction 0006 (Schedule 4, 1e) for one of two gamete import/export cases reviewed. General Direction 0006. This was an area for improvement identified at the previous licence renewal inspection.	The PR should review the centre's procedures for import and export of gametes and/or embryos to ensure that evidence required, demonstrating compliance with General Direction 0006 is obtained before gametes and/or embryos are imported or exported. A summary of the review and any changes implemented as a result should be provided to the centre's inspector by 6 July 2018. The PR should audit the records relating to imports and exports of gametes or embryos six months after the implementation of corrective	Consent forms CN57 (for sperm) and CN58 (for embryos) have been amended to include the requirement of General Direction 0006 (Schedule 4, 1e)- stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom.	**Update following ELP consideration 12 July 2018:** The PR was given two further deadlines to provide the evidence required to demonstrate compliance with this recommendation. The PR has not responded within the given time frame. Further action required. **Update following LC consideration 6 September 2018:** The PR has provided the required audit report. The Executive is assured that the centre's procedures for

	actions against compliance with General Direction 0006 and forward a summary of the audit to the centre's inspector by 6 January 2019.		import and export are now compliant with requirements No further action required.
2. Pregnancy success rates The centre's success rates for IVF treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level. Success rates in this group of women was identified as an area of concern at the previous inspection. SLC T2.	The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old. The PR should commission an independent review of all clinical and laboratory practices and procedures that can have an impact on the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years. The review should include an action plan for addressing the success rates, a schedule for implementation and review of any corrective actions identified. The PR should provide the centres' inspector with a plan	We freeze a significant proportion of embryos of our under 38 years and the frozen embryo sucsses rates are higher than the national average We will be planning an external review on all clinical and laboratory practices and procedures that will have an impact on syucess rates and will aim to have one in July 2018. A full summary and actions will be provided to the HFEA after the review before the 6th of January 2016 and will review and implement the recommendations We have already contacted 2 senior specialists to arrange a date for a review	**Update following ELP consideration 12 July 2018:** The PR has commissioned an independent review for October 2018. The Executive awaits a summary report of the review by 6 January 2019. **Update following LC consideration on 6 September 2018:** A summary report of the review has been received which makes a number of recommendations. Some of the recommendations have already been implemented by the PR who has provided the centre's inspector with an action plan for the implementation of the

	for commissioning an independent review by 6 July 2018. A summary of the independent review and action plan for the implementation of any recommendations to address the success rates should be provided to the centre's inspector by 6 January 2019.		outstanding recommendations. The PR has committed to keeping the success rates for these patients under close review. The executive will also continue to review the centre's success rates on a regular basis.