Executive Licensing Panel - minutes

Centre 0329 (Wales Fertility Institute, Neath)

Executive Update

Monday 2 November 2020

HFEA, Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Dina Halai Yvonne Akinmodun	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Background

1.1. The panel noted that Wales Fertility Institute, Neath has held a licence with the HFEA since 2013 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos and embryo testing.

1.2. The panel noted that the centre had a licence renewal inspection on 19 and 20 February 2019; at the time of the inspection, there was one major area of non-compliance concerning treatment success rates, alongside three 'other' areas of non-compliance regarding multiple births, traceability and obligations and reporting requirements.

1.3. The report of the renewal report was considered by Executive Licensing Panel (ELP) on 21 May 2019 and they particularly noted that the centre's treatment success rates, for FET in women under 40 years old, was lower than average at a statistically significant level, requesting a progress update on this specific area of practice by the close of 2020.

1.4. The panel noted that the centre's inspector has liaised with the Person Responsible (PR) regarding the actions taken towards compliance with the recommendations in the inspection report, and at the time of compiling the updated presented, has received requested information in a timely manner.

1.5. The panel noted that since the renewal inspection, the PR has fully implemented all of the recommendations and has not received any risk tool alerts for pregnancy success rates for FET. Success rates for this group of patients have remained within the national average.

1.6. The panel also noted the update provided regarding the implementation of outstanding actions, in relation to all the non-compliances identified at the renewal inspection.

2. Consideration of Progress Update

2.1. The panel considered the papers, which included an executive update, update on recommendations made at the renewal inspection and licensing minutes for the last five years. years.

2.2. The panel noted the confirmation, from the executive, that there is no change to the recommendation that the centre's treatment (with embryo testing) and storage licence is renewed for a period of four years. The executive also confirms that there is no change to the recommendation to the renewal of the centre's ITE import certificate in line with the centre's licence.

3. Decision

3.1 The panel noted the executive update provided, in relation to the non-compliances identified at the centre's renewal inspection, particularly in relation to the finding that the treatment success rates, for FET in women under 40 years old, was lower than average at a statistically significant level.

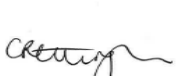
3.2 The panel noted that the PR had fully implemented the recommendations in relation to treatment success rates, for FET in women under 40 years old; success rates have remained at the national average.

3.3 The panel endorsed the executive's recommendation that the centre's treatment (including embryo testing) and storage licence and ITE certificate should be continued, noting the renewals were agreed at the 21 May 2019 ELP meeting.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

6 November 2020

Executive update for Executive Licensing Panel

2 November 2020

Wales Fertility Institute Neath (centre 0329)

Person Responsible: Paul Knaggs

Executive update

1. Background

1.1. Wales Fertility Institute Neath has held a licence with the HFEA since 2013 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos and embryo testing.

1.2. The centre had a licence renewal inspection on 19 and 20 February 2019 and the report of that inspection was considered by Executive Licensing Panel (ELP) on 21 May 2019.

1.3. At the time of the inspection, there was one major area of non-compliance concerning treatment success rates, alongside three 'other' areas of non-compliance regarding multiple births, traceability and obligations and reporting requirements.

1.4. The panel noted the centre's treatment success rates for FET in women under 40 years old was lower than average at a statistically significant level and, requested a progress update on this specific area of practice by the close of 2020.

1.5. The centre's inspector has liaised with the 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.

1.6. Since the inspection visit, the Person Responsible (PR) has fully implemented all of the recommendations and has not received any risk tool alerts for pregnancy success rates for FET. Success rates for this group of patients have remained within the national average.

1.7. Appendix 1 provides an update on the implementation of the outstanding recommendations.

2. Recommendation

2.1. 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 four years. The executive also confirms that there is no change to the recommendation to the renewal of the centre's ITE import certificate in line with the centre's licence.

2.2. The ELP is invited to make findings in this regard.

Nicola Lawrence

Clinical Inspector

3 October 2020

Appendix 1

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
1. **Treatment success rates:** The centre's clinical pregnancy rate for FET in women under 40 years old, is lower than the national average at a statistically significant level. SLC T2	The PR should seek to improve the clinical pregnancy rate for women under 40 years old undergoing FET cycles. The PR should conduct a review of clinical and laboratory practices and procedures that could have an impact on the success rates for FET in patients under 40 years old. A report of the review with proposed corrective actions, with timescales for implementation, should be	I acknowledge that the FET results are below the HFEAs national average per cycle started figures. A review of clinical and lab processes will be undertaken together with an evaluation of the MBMP. Additionally the PR will ask the HFEA to provide national data based on per embryo transfer results as that is a more meaningful statistic by which to measure laboratory and clinical outcomes whilst accounting for	The executive acknowledges the PR's response and commitment to improve the centre's success rates. Further action is required. **Update 2 October 2020:** The PR provided a review immediately after the inspection. Since the inspection, the centre's success rates for FET in women under 40 have been consistently within the national

	provided to the centre's inspector by 19 May 2019. The PR should thereafter continue to monitor success rates generally and for FET in the <40 years age group and should take further actions if problems recur. The centre's inspector will also continue to monitor success rates via the monitoring system.	the transfer of muliple embryos. The report will be sent to the HFEA before 19th May 2019	average. No risk tool alerts have been issued. No further action was 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
2. Multiple births: The centre keeps a summary log of cases in which multiple embryos have been transferred, but it was not clear which cases met the criteria for elective single embryo transfer set out in the multiple births minimisation strategy. A clear explanation of the reasons for transferring more than one embryo in a case where eSET criteria were met, was not recorded appropriately in either the log or in a set of notes audited on inspection. General Direction 0003.	The PR should ensure that: • the log of multiple embryo transfers includes information about whether a case meets elective single embryo transfer criteria; • in cases where multiple embryos have been transferred to a patient who meets the criteria for elective single embryo transfer, a clear explanation of the reasons for transferring more than one embryo is documented in the summary log and the patient's notes. The PR should confirm the actions taken to address this non-compliance when responding to this report.	The current recording system has been changed to incorporate a separate column in the treatment spreadsheet to enable clinicians to enter the reasons for a double embryo transfer in eSET eligible patients. Clinicians have been reminded to type a clear rationale at the time of embryo transfer. The audti will be provided to the HFEA following change of practise within the agreed timescale	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of an audit report due 19 August 2019. **Update 2 October 2020:** Recommendation fully implemented within prescribed timescale.

	Within three months of the implementation of the change in practice, the PR should conduct an audit to ensure that the corrective actions have been effective in achieving and maintaining compliance. A summary report of this audit should be submitted to the centre's inspector by 19 August 2019.		
3. Traceability: One of ten batches of consumables audited had not been recorded accurately as being in use on the centre's traceability database. SLC T99b.	The PR should ensure that all relevant data relating to anything coming into contact with gametes or embryos is traceable. The PR should review the centre's traceability processes to ensure they are compliant with regulatory requirements. A summary report of this review, including corrective actions taken, should be provided to the centre's inspector by 19 May 2019. Within three months of the implementation of corrective actions, the PR should assess	The traceability system operated at WFI is generally reliable with the outstanding record being caused due to an extraordinary transfer of consumables between labs. WFI operate a quarterly audit of all lab consumables, which would normally highlight any anomalies. This frequency will be increased to montly to monitor compliance. If after 3 months of no anomalies being reported, audits will revert to quaterly. The HFEA will be provided with the next 3 months audit	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of an audit report due 19 August 2019. **Update 2 October 2020:** Recommendation fully implemented within prescribed timescale.

	the impact of those actions in a second audit. A summary report of the findings of the audit should be provided to the centre's inspector by 19 August 2019.		
4.Obligations and reporting requirements: 5% (1/20) of the DI treatments reviewed had not been reported to the HFEA in accordance with General Direction 0005. 87% (102/117) of the IVF and 89% (17/19) of the DI treatments reviewed had been reported to the HFEA outside the period required by General Direction 0005. General Direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the systems and processes used to submit licensed treatment data to the register, to identify and address the reasons for delayed data submission. A summary of the findings of the review including corrective actions with timescales for implementation, should be provided to the centre's inspector by 19 May 2019. The PR should audit the effectiveness of the actions taken within six months. A summary report of the audit findings should be provided to	All DI treatments are now entered on EDI at the time of treatment. Between December 2017 and November 2018 the centres EDI system was largely unavailable and it was only with significant input from both the HFEA and NHS IT teams that this issue was resolved in July 2018. It was agreed with the HFEA that a 4 month period would be agreed to ensure the backlog of data could be submitted. These problems may have contributed to the reported late submission of data. Currently data submission now forms part of the quarterly data quality audit and audits will be submitted in line with required timescale.	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of an audit report due 19 August 2019. **Update 2 October 2020:** Recommendation fully implemented within prescribed timescale.

	the centre's inspector by 19 August 2019.	Additionally WFI is pursuing the implementation of the Meditex clinic management software system in order to optimise data collection analysis and submission	