

Licence Committee - minutes

Centre 0067 (St. Mary's Hospital)

Executive Update

Date: Thursday, 14 January 2021

Venue: Teleconference

Attendees: Jonathan Herring (Deputy Chair)
Ruth Wilde
Gudrun Moore

Executive: Dee Knogle – Committee Secretary

Legal Adviser: Alistair Robertson – DAC Beachcroft LLP

Observers: Jane Darragh, Research Manager (Induction)

1. Declaration of interest

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

2. The committee had before it:

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

3. The following papers were considered by the committee:

- Executive update
- Independent review of the centre's success rates for FET (frozen embryo transfer) in women under 40 years old
- Centre's Response to the Independent review of the centre's success rates for FET (frozen embryo transfer) in women under 40 years old
- 2020-05-07 Licence Committee Minutes - Unannounced Targeted Interim Inspection
- The paper set originally considered by Licence Committee on 7 May 2020
 - Cover sheet
 - Unannounced Targeted Interim Inspection Report
 - 2019-12-06 Licensing Officer - Record of consideration - Variation of Licence Holder
 - 2019-11-07 Licence Committee Minutes - Executive Update to Renewal
 - 2019-05-02 Licence Committee Minutes - Renewal

4. Background

- 4.1.** St Mary's Hospital, centre 0067 is located in Manchester. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services.

Current Licence

- 4.2.** The centre's current licence was granted for a period of three years from 1 August 2019 and is due to expire on 31 July 2022.

History of non-compliance:

Renewal Inspection – March 2019

- 4.3.** The centre had a licence renewal inspection on 5 and 6 March 2019. Three critical, seven major and four other areas of non-compliance were identified. Of particular concern were critical areas of non-compliance relating to medicines management, legal parenthood and consent to storage and major areas of non-compliance relating to import and export and surrogacy.
- 4.4.** The PR (Person Responsible) had committed to fully implementing all of the recommendations to address the non-compliances and to providing evidence of action taken, and where required, to audit the effectiveness of those actions within the required timescales.
- 4.5.** The PR had also agreed to a voluntary cessation of treatments with donor sperm for new patients until such time as the HFEA was satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust.
- 4.6.** The Licence Committee considered the report of the renewal inspection at its meeting held on 2 May 2019 and had some concerns about whether the character of the proposed PR was such as is required for the supervision of the licensed activities. On balance, the committee decided that the PR was suitable. However, the committee wanted to see further evidence that the PR would discharge his duties under section 17 of the HFE Act 1990 (as amended).
- 4.7.** The committee granted a three year licence, instead of the standard four and agreed that the Executive should complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance.

Executive Update to Renewal Inspection in March 2019

- 4.8.** At its meeting held on 7 November 2019, the Licence Committee considered the Executive's update on progress at the centre since the renewal inspection carried out in March 2019. The committee noted that most of the required actions to complete the recommendations had been completed and outstanding action in most cases related to audits to verify the effectiveness of corrective action taken by the centre, and these were not yet due to be submitted to the Executive.
- 4.9.** The centre's voluntary cessation of new treatments with donor sperm and embryos created with donor sperm started in March 2019 and ended in August 2019 when the PR had provided evidence to satisfy the Executive of the robustness of the centre's procedures for obtaining effective consent to legal parenthood.
- 4.10.** The PR provided his review of the centre's success rates for FET (frozen embryo transfer) in women under 40 years of age in June and September 2019. The centre's clinical pregnancy rate for FET (frozen embryo transfer) in women under 40 years of age, in the year to 30 June 2019, remained significantly lower than the national average. The PR committed to keep this outcome under review and to monitor the centre's key performance indicators monthly.

- 4.11.** The committee agreed that further action was required to ensure the centre reflects suitable practices.
- 4.12.** The committee was satisfied that, on 11 July 2019, the Executive recommended that imports and exports under General Direction 0006 resume and the centre's Importing Tissue Establishment (ITE) import certificate was renewed in line with the licence. The committee noted that compliance with General Direction 0006 would be reviewed at the targeted interim inspection.

Unannounced Targeted Interim Inspection – January 2020

- 4.13.** An unannounced targeted interim inspection was carried out on 21 January 2020 and a report of this inspection was submitted to the Licence Committee for consideration at its meeting held on 7 May 2020. The committee noted that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, three major and two other areas of non-compliance.
- 4.14.** The clinical pregnancy rate following FET (frozen embryo transfer) in patients aged less than 40 years was below the national average at a statistically significant level. This was noted as a critical area of non-compliance and a recommendation was made requiring the PR to make improvements.
- 4.15.** The committee noted that there was ongoing action for one critical area of non-compliance relating to consent to storage and one major area of non-compliance relating to surrogacy that were identified at the renewal inspection in March 2019. The PR had committed to fully implementing all of the recommendations and to providing further information or audits of practice where applicable.
- 4.16.** The Executive held management review meetings on 28 January 2020 and 4 March 2020, in accordance with the HFEA Compliance and Enforcement Policy and agreed that there was significant improvement in some areas and limited concerns about the safety of patients, gametes and embryos.
- 4.17.** The committee endorsed the Executive's recommendation for the continuation of the centre's treatment and storage licence.
- 4.18.** The committee was concerned that the centre's success rate for FET (frozen embryo transfer) in women under 40 years of age remained lower than the national average at a statistically significant level. The centre was required to commission an independent review to include, but not be limited to, an assessment of the centre's procedures for cryopreservation, storage and thawing of embryos including stimulation and luteal support protocols. A summary report of the findings of the review, including timescales for implementation of corrective action identified, was to be provided to the Executive on completion. The PR was also required to provide the Executive with quarterly updates on the actions taken to address the success rates, with a goal to improving the success rates by 21 July 2020. The centre's independent review was to be submitted to the Licence Committee for consideration.
- 4.19.** The committee also requested that the report of the next inspection is submitted to the Licence Committee for consideration. The committee acknowledged the PR's engagement with the Executive. However, the committee agreed that, if significant improvements are not seen with regards to the full implementation of all of the Executive's recommendations made in the unannounced targeted interim inspection report, and the report of the renewal inspection in March 2019, by the time of the next inspection scheduled late 2020/early 2021, the Executive would cease to be satisfied that the PR is suitable.

- 4.20.** The committee noted that in 2020, the World Health Organisation declared Coronavirus (Covid-19) a world-wide pandemic. In accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic, centres were required to suspend fertility treatments in March 2020. Therefore, the Executive would liaise with the PR to consider appropriate timescales for submissions and full implementation of outstanding recommendations.

5. Consideration of application

Treatments Suspended due to COVID-19 Pandemic

- 5.1.** The committee noted that in response to the COVID-19 pandemic, the centre followed General Direction 0014 and professional body guidance to suspend all non-essential treatments in March 2020. The centre was compliant with the requirements of General Direction 0014 for resuming treatment services in May 2020.

Independent Review of Success Rates - FET (frozen embryo transfer) in women under 40 years of age

- 5.2.** The committee noted that HFEA-held data for the year ending 31 August 2020, showed the centre's clinical pregnancy rates following FET, in women under 40 years old, remained below the national average at a statistically significant level.
- 5.3.** As recommended by the Executive, the PR had commissioned an independent review to find the reasons why the centre's success rates for FET in women under 40 years old were lower than the national average at a statistically significant level. The committee noted that due to the Covid-19 pandemic, it took longer than usual for the external expert to complete the review and a report of the findings was submitted to the Executive on 4 November 2020.
- 5.4.** On 16 December 2020, the PR provided an update on progress with implementing the recommendations made by the external expert. The Executive reported that, of the 18 actions recommended by the external expert, 14 were accepted by the PR and the centre's Clinical Lead, of which six are recorded as complete. Some of the recommendations in progress require significant capital investment and/or additional staffing.
- 5.5.** The Executive also reported that the PR and Clinical Lead do not consider that there is sufficient evidence to implement the expert's recommendation to change the centre's protocol for blastocyst vitrification, or to only proceed to embryo warming if the endometrial thickness is >8mm. The Executive will liaise further with the PR to understand the rationale for this and overall progress in implementing the external expert's recommendations will be followed up at the time of the next inspection in early 2021.
- 5.6.** The Executive acknowledged that the closure of the centre in 2020, due to the Covid-19 pandemic, had impacted on the timescale for improving the centre's clinical pregnancy rates, however expects that the PR will continue to improve the centre's success rates.

Implementation of recommendations

- 5.7.** The PR has provided regular updates on progress with implementing all other recommendations made at the time of the renewal inspection in March 2019 and the unannounced targeted interim inspection in January 2020.

Recommendations

Inspection

- 5.8.** The committee noted that a further targeted interim inspection is scheduled to take place in early 2021 to allow the PR time to fully implement all recommendations and to ensure that changes and improvements in processes have been embedded into the centre's practices, such that the Executive can be satisfied that the PR is suitable.
- 5.9.** The report of this inspection will be submitted to the Licence Committee for consideration.

6. Decision

- 6.1.** The committee noted the Executive update and progress made by the centre.
- 6.2.** The committee was pleased that the centre has taken on board most of the recommendations made by the external expert on review of the centre's practices to improve success rates for FET in women under 40 years old.
- 6.3.** The committee acknowledged that due to the COVID-19 pandemic, there has been some delay in implementing these recommendations, and that a reasonable amount of time should be allowed to see the effectiveness of the centre's actions to increase success rates.
- 6.4.** The committee also acknowledged that it may be difficult to obtain significant capital investment and additional staffing. However, it was agreed that improvements should be made where possible. The committee noted that the Executive will liaise further with the PR to monitor progress.
- 6.5.** Overall, the committee was very pleased with the centre's progress and welcomes the fact that there are ongoing discussions with the Executive to help the centre achieve sustainable compliance.
- 6.6.** The committee looks forward to considering the report of the targeted interim inspection scheduled in early 2021 and expects to see further improvements.

7. Chair's signature

- 7.1.** I confirm this is a true and accurate record of the meeting.

Signature



Name

Jonathan Herring

Date

2 February 2021

Executive update for Licence Committee

14 January 2021

St. Mary's Hospital (0067)

Person Responsible: Mr. Gregory Horne

Executive update and Independent Review of Success Rates (frozen embryo transfer)

1. Background

- 1.1.** Saint Mary's Hospital is located in Manchester and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including storage of gametes and embryos.
- 1.2.** The centre was last inspected on 21 January 2020, which was a targeted inspection focused on reviewing all actions taken by the centre in response to the findings of the renewal inspection in March 2019. The report of the targeted inspection was considered by Licence Committee on 7 May 2020, the minutes of which stated the following.

'Success Rates (frozen embryo transfer) – Independent Review Required

- 3.3.** The committee was concerned that the centre's success rate for FET (frozen embryo transfer) in women under 40 years of age remains lower than the national average at a statistically significant level. The centre is required to commission an independent review to include, but not be limited to, an assessment of the centre's procedures for cryopreservation, storage and thawing of embryos including stimulation and luteal support protocols. A summary report of the findings of the review, including timescales for implementation of corrective action identified, should be provided to the Executive on completion. The PR is also required to provide the Executive with quarterly updates on the actions taken to address the success rates, with a goal to improving the success rates by 21 July 2020. The centre's independent review should be submitted to the Licence Committee for consideration.'
- 1.3.** In 2020 the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19) and in response the centre followed General Direction 0014 and professional body guidance to suspend all non-essential treatments and

was compliant with requirements of General Direction 0014 for resuming treatment services in May 2020.

2. Executive update

- 2.1.** The Person Responsible (PR) has commissioned the independent review as to the reasons why the centre's success rate for FET in women under 40 years old remains lower than the national average at a statistically significant level as recommended by the executive. In view of the Covid-19 pandemic it has taken longer than usual for the external expert to complete this review and the report of the findings was provided to the executive on 4 November 2020. As requested by Licence Committee, a copy of the review is included in this paper set.
- 2.2.** On 16 December 2020, the PR provided an update on progress with implementing the recommendations made by the external expert in her report and a copy of this is also attached with these papers. The executive notes that of the 18 actions recommended by the external expert, 14 have been accepted by the PR and centre's Clinical Lead, of which six are recorded as 'complete'. Some of the recommendations in progress also require significant capital investment and/or additional staffing. The executive also notes the PR and Clinical Lead do not consider that there is sufficient evidence to implement the expert's recommendation to change the centre's protocol for blastocyst vitrification (see 1.1.2) or to only proceed to embryo warming if the endometrial thickness is >8mm (see 4.1.2). The executive will liaise further with the PR to understand the rationale for this and overall progress in implementing the external expert's recommendations will be followed up at the time of the next inspection in early 2021.
- 2.3.** The HFEA's register held data for the year ending 31 August 2020 shows the centre's clinical pregnancy rates following FET in women under 40 years old remains below the national average at a statistically significant level. The executive acknowledges that the closure of the clinic due to the Covid-19 pandemic during 2020 will have impacted on the timescale for improving these clinical pregnancy rates but expects that the PR will continue to work to drive improvements that will raise their success rates to be in line with the national average.
- 2.4.** The PR has provided regular updates on progress with implementing all other recommendations made at the time of the renewal inspection in March 2019 and the targeted inspection in January 2020. A further targeted interim inspection is scheduled to take place in early 2021 to allow the PR time to fully implement all recommendations and to ensure that changes and improvements in processes have been embedded into the centre's practices such that the executive can be satisfied that the PR is suitable. The report of that inspection will be provided to Licence Committee for consideration as requested.