# Licence Committee - minutes

## Centre 0067 (St. Mary's Hospital)

## Executive Update

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| Date: | Thursday, 8 July 2021 |
| Venue: | Teleconference |
| Attendees: | Jonathan Herring (Chair)<br>Anita Bharucha (Deputy Chair)<br>Ruth Wilde<br>Gudrun Moore<br>Ermal Kirby<br>Alison Marsden |
| Executive: | Dee Knoyle - Committee Secretary |
| Legal Adviser: | Darryn Hale – DAC Beachcroft LLP |
| Observers: | Julia Chain - HFEA Chair (Induction)<br>India Hickey - HFEA Research Officer (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:

Papers enclosed:

- Executive Update
- Person Responsible's response
- Minutes of the Licence Committee meeting held on 4 March 2021 at which the centre's targeted inspection report was considered
- Meeting Papers considered by the Licence Committee on 4 March 2021
    - Targeted Interim Inspection Report
    - Licensing minutes up to the last licence renewal
        - 2021-01-14 Licence Committee Minutes - Executive Update
        - 2020-05-07 Licence Committee Minutes - Unannounced Targeted Interim Inspection
        - 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. The committee noted that in relation to activity levels this is a large centre.

### 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 – 5 & 6 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 and had also agreed to a voluntary cessation of treatments with donor sperm for new patients.

**4.5.** The Licence Committee considered the report of the renewal inspection at its meeting held on 2 May 2019 and granted a three year licence, instead of the standard four. The committee 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 Licence Committee on 7 November 2019

**4.6.** 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 action to address the recommendations had been completed. The outstanding action in most cases related to audits to verify the effectiveness of corrective action and these were not yet due to be submitted. Imports and exports under General Direction 0006 had resumed and the centre's Importing Tissue Establishment (ITE) import certificate was renewed. 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.

**4.7.** However, 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 area under review and to monitor the centre's key performance indicators monthly. The committee agreed that further action was required to ensure the centre reflects suitable practices.

### Unannounced Targeted Interim Inspection – January 2020

**4.8.** 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 one critical, three major and two other areas of non-compliance were identified. 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 upgraded to a critical area of non-compliance from a major non-compliance identified at the renewal inspection in March 2019 and a recommendation was made requiring the PR to make improvements. 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. At its meeting on 7 May 2020, the committee discussed patient information and agreed that the centre should be transparent about its practices, in particular those relating to FET (frozen embryo transfer) success rates in women

under 40 years of age. The committee also noted that there was ongoing action for one critical and one major area of non-compliance. The committee endorsed the Executive's recommendation for the continuation of the centre's treatment and storage licence.

### Executive Update to Licence Committee on 14 January 2021

**4.9.** 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.

**4.10.** 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.

**4.11.** The PR had commissioned an independent review to find the reasons for this and a report of the findings was submitted to the Executive on 4 November 2020. There were 18 actions recommended by the external expert who carried out the independent review, of which 14 were accepted by the PR and the centre's Clinical Lead and six were recorded as complete.

**4.12.** Some of the recommendations in progress required significant capital investment and/or additional staffing.

**4.13.** The PR and Clinical Lead did not consider that there was 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 planned to liaise further with the PR to understand the rationale for this. Overall progress in implementing the external expert's recommendations would be followed up at the time of the next inspection in early 2021.

**4.14.** The PR had 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.

### Targeted Interim Inspection – 19 January 2021

**4.15.** The Licence Committee considered the centre's targeted interim inspection report at its meeting held on 4 March 2021. The committee noted that in view of the ongoing Covid-19 pandemic, the targeted interim inspection was conducted at short notice using videoconferencing technology, rather than an on-site inspection.

**4.16.** The committee noted that the purpose of the targeted interim inspection was to review the centre's progress with the implementation of the recommendations and to ensure that changes and improvements in processes had been embedded into the centre's practices, such that the Executive could be satisfied that the PR is suitable.

**4.17.** The committee noted that at the time of the targeted interim inspection in January 2021, there were no areas of non-compliance or poor practice identified. The Executive reported that the PR continued to address one critical non-compliance identified at the time of the renewal inspection in March 2019, to ensure that there is effective consent in place for all gametes and embryos in storage at the centre. The Executive noted the effectiveness of actions taken by the PR and his senior team to address previous areas of non-compliance or poor practice and reported that the centre is well led and provides a good level of patient support.

**4.18.** The committee noted that HFEA-held register data for the year ending 30 September 2020, showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages with one exception, clinical pregnancy rates following FET (frozen embryo transfer) in patients aged less than 40 years remained lower than average at a statistically significant level.

**4.19.** The committee noted that the Executive had discussed each of the 18 actions recommended by the external expert in the independent review with the PR and Clinical Lead and several actions had been fully implemented. Recommendations made by the expert in relation to clinical protocols (endometrial thickness, baseline scans) had been discussed further within the centre's clinical team and they were keen to implement some of these changes.

**4.20.** The PR confirmed that good progress had been made in purchasing items of equipment recommended by the expert. The PR had committed to introducing new laboratory protocols for vitrification and warming in January and February 2021.

**4.21.** The committee deliberated on the quality of service provided to patients before and during the COVID-19 pandemic and had serious concerns. Staffing limitations during the current pandemic could impact on a patient's chance of a successful pregnancy. The committee requested that the Executive discusses the centre's performance and timescales for improvements with the PR. The Executive was also asked to discuss with the centre a voluntary cessation of treatments for FET in women under 40 years old, until such time that the Executive is satisfied that the external expert's recommendations, which the centre had agreed to implement, have been fully implemented.

**4.22.** Overall, the committee was pleased with the centre's progress and satisfied that the centre was fit to have its licence continued. The committee was satisfied that the PR had an action plan and timeline to address some of the outstanding issues.

**4.23.** The Executive has provided an update on the centre's progress with the PR's response for consideration by Licence Committee.

## 5. Consideration of application

**5.1.** The committee noted the Executive update and the PR's written response.

### Consent to storage

**5.2.** The committee noted that at the time of the inspection on 19 January 2021, eight sets of embryos and two sets of sperm had remained in storage at the centre for more than 10 years without effective consent.

**5.3.** The PR confirmed that legal advice had been sought for all eight couples who wished to keep their embryos in storage, and action had been taken in response to instructions from solicitors acting on behalf of the Trust.

**5.4.** The PR informed the Executive that several attempts had been made to contact the two gentlemen who had sperm in storage without effective consent, however no responses were received. Therefore, in line with legal advice, a decision had been made to allow the samples to perish.

### Consent to disclosure to researchers

**5.5.** The committee noted that in November 2020, the centre had identified discrepancies between completed patient/partner disclosure consents within patient records and the related consent data submitted for inclusion on the register. This resulted in the HFEA putting a temporary block on the release of the centre's data for use in research so that there was no risk that the HFEA would release patient identifying information to researchers without their consent until an audit of all records (circa 16,000) was completed.

**5.6.** The committee noted that some errors were corrected and for the remainder, patients will need to be contacted to confirm their consent. In the meantime, the centre has amended patient registration forms to indicate that they do not consent to disclosure to researchers to prevent disclosure against the patient's wishes. This approach removes any risk that the HFEA releases patient identifying information to researchers without their consent. The Executive will liaise with the PR to monitor progress with this audit.

### Success Rates

**5.7.** The committee noted that the data from the HFEA register to 31 January 2021 showed that the centre's clinical pregnancy rates following FET in women under 40 years old was no longer significantly different to the national average and that this was the first time this has been noted in the centre's data for the previous six months. However, the most recent data from the HFEA's register for the 12 months to 28 February 2021 shows that these rates are likely to be significantly lower than the national average.

**5.8.** Data provided by the PR on the centre's pregnancy rates for FET treatments up to May 2021 mirrors the lower rates seen in the HFEA register data for the month of February 2021, after which there is a continued upward trend in pregnancy rates. This would suggest that the changes made to address this area of practice are having an effect on improving these success rates.

**5.9.** The committee noted that of the 18 recommendations made by the external expert, 11 have been fully implemented and the PR is currently implementing a further six.

**5.10.** The committee noted the Executive's update regarding paragraph 6.6 of the Licence Committee Minutes of the meeting held on 4 March 2021, which reads:

"Recommendations made by the expert in relation to clinical protocols (endometrial thickness, baseline scans) had been discussed further within the centre's clinical team and they were keen to implement changes. However, restrictions in staffing availability had hampered these efforts".

The Executive reported that the centre had submitted that restrictions in staffing availability were not impacting the implementation of these recommendations, and it asked that the relevant sentence be amended in the minutes to reflect this. This was because the centre did not accept the expert's specific recommendation on endometrial thickness. Instead, the centre had decided that to address the issue of endometrial thickness, it would implement a change in its clinical protocol relating to oestradiol administration. The centre reported that it was in the process of implementing this, however staffing availability had delayed this.

### Recommendation

#### Monitoring

**5.11.** The committee noted that the Executive will continue to liaise closely with the PR and monitor the centre's performance.

**5.12.** The committee noted that all areas of practice and progress on outstanding actions will be reviewed in detail at the renewal inspection, due to be conducted approximately six months before the licence expires on 31 July 2022.

## 6. Decision

**6.1.** The committee had regard to its decision tree.

**Consent to Storage**

**6.2.** The committee was satisfied that the Executive will liaise closely with the PR to ensure that he continues to take action to address the embryos that remain in storage without effective consent for eight couples.

**Consent to disclosure to researchers**

**6.3.** The committee noted that the Executive will also liaise with the PR to ensure that the audit of all records of consent to disclosure to researchers progresses as planned.

**Success Rates - FET in women under 40 years old**

**6.4.** The committee noted that the centre has accepted 17 of the 18 actions recommended by the external expert. The PR has fully implemented 11 actions and is currently implementing a further 6.

**6.5.** The committee noted that action taken by the centre has resulted in some improvement in success rates.

**6.6.** The committee also noted that the centre was in the process of implementing another change to its clinical protocol relating to oestradiol administration which it believed was likely to improve endometrial thickness and therefore contribute to further improvements in its success rate for this group of patients. The committee further noted that the centre had not yet implemented this change due to staffing availability.

**6.7.** The committee agreed that all patients should have the opportunity to receive a good service for the best chance of having a successful pregnancy and the service provided should be at its best at all times. Treatment provided by the centre could be a patient's only chance of having a child. The committee deliberated on the timescales for action to make further improvements and agreed that this should be monitored.

**6.8.** The PR should be mindful of the treatments provided during this period of improving the centre's practices, particularly bearing in mind that the centre has identified a change to its clinical protocol which it had not yet been able to implement but which it believed would improve the chances of success for this group of patients. The PR should consider how to ensure transparency for patients in this group so that they are appropriately informed about the centre's current performance and plans for improvement. This would enable them to make an informed decision about whether to commence their treatment in the current circumstances when the centre's FET success rates for this group of patients remain lower than the national average.

**6.9.** The committee considered the centre's overall performance and agreed that the PR should re-consider a voluntary cessation of treatments for FET in women under 40 years old, until such time that the Executive is satisfied that the external expert's recommendations, which the centre has agreed to implement, and improvements to protocols, which the centre itself has identified as needing to take place, have been fully implemented and staff trained accordingly. The committee encouraged the PR to continue to engage with the Executive and where necessary, engage with the external expert to optimise the centre's practices.

Staffing

**6.10.** The committee agreed that the last sentence of paragraph 6.6 of the Licence Committee Minutes of the meeting held on 4 March 2021, concerning restrictions in staff availability should be removed as restrictions in staffing availability did not specifically relate to the recommendation on clinical protocols (endometrial thickness, baseline scans).

**Monitoring**

**6.11.** The committee agreed that in all areas of practice, staff should be in sufficient numbers to provide a good service to patients. The committee agreed that it would have serious concerns if the centre continued to provide a full service with unresolved issues relating to staff. The committee expects all staffing issues to be resolved by the time of this renewal inspection and to see evidence of action taken to further improve the centre's practices, resulting in a better outcome for patients.

**6.12.** The committee was satisfied that all areas of practice, and progress on outstanding actions, will be reviewed in detail at the next licence renewal inspection.

**6.13.** In order for patients to make informed decisions the centre needs to be transparent about its performance and inform patients of any detriment there could be in relation to their chances of a pregnancy associated with its practices. The committee expects to see evidence of action taken to increase transparency with patients.

**6.14.** The committee is mindful that during the period the centre is improving, some patients who have already undergone treatment at the centre, or may have material in storage, could find information on the centre's performance upsetting and may need support.

## 7. Chair's signature

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

**Signature**

**Name**

Jonathan Herring

**Date**

26 July 2021

# Executive update for Licence Committee

8 July 2021

## St. Mary's Hospital (0067)

## Person Responsible: Mr. Gregory Horne

## Executive update

### 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.** A targeted interim inspection of the centre was carried out on 19 January 2021. This was to follow up on progress with recommendations made as a result of the findings of the two previous inspections that took place in January 2020 and March 2019. The report of that targeted inspection was considered by Licence Committee on 4 March 2021 and the minutes of their meeting stated the following:

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

**6.8** The committee requested that the Executive discusses the centre's performance and timescales for improvements with the PR. The Executive should also discuss with the centre a voluntary cessation of treatments for FET in women under 40 years old, until such time that the Executive is satisfied that the external expert's recommendations, which the centre has agreed to implement, have been fully implemented.'

**1.3.** In response to the committee's request the executive discussed this with the Person Responsible (PR) of centre 0067. This executive update is to provide Licence Committee with the PR's response to the committee's request, the centre's progress in addressing the success rates for FET in women under 40 years old, and a brief summary of actions taken in response to other areas of practice identified in recent inspections that remain to be fully implemented. The PR provided his responses and update in a document titled 'HFEA response updated 1.6.21' which is included in the papers provided with this executive update.

### 2. Executive Update on centre's FET success rates

**2.1.** The data from the HFEA register to 31 January 2021 showed that the centre's clinical pregnancy rates following FET in women under 40 years old was no longer significantly different to the national average and that this was the first time this has been noted in the centre's data for the previous six months. However, the executive notes that the most recent data from the HFEA's register for the 12 months to 28 February 2021 shows that these rates are likely to be significantly lower than the national average.

**2.2.** Data provided by the PR on the centre's pregnancy rates for FET treatments up to May 2021 mirrors the lower rates seen in the HFEA register data for the month of February 2021, after which there is a continued upward trend in pregnancy rates. This would suggest that the changes made to address this area of practice are having an effect on improving these success rates.

**2.3.** The PR provided an update on progress with implementing the recommendations made by the external expert following her independent review of this area of practice. The executive notes that of the 18 recommendations made by the external expert, 11 have been fully implemented and the PR is currently implementing a further six.

**2.4.** In relation to the remaining recommendation ('only proceed to warm if endometrial thickness is >8mm'), the PR wishes to make clear that whilst the clinical team at the centre did not consider that there was sufficient evidence base for this, they have taken additional steps 'for addressing optimisation of endometrial receptivity' by changing the route of administration of oestradiol.

**2.5.** The PR has asked the executive to bring this point to the attention of the committee as stated in the final paragraph of the document 'HFEA response updated 1.6.21' which is in relation to the minutes of the Licence Committee's meeting on 4 March 2021.

> 'As mentioned previously there does seem to possibly be an error of interpretation in the HFEA licence committee minutes, of recommendation to proceed with embryo warming if the endometrial thickness is >8mm. In Section 6.6 however, the minutes imply that the endometrial thickness recommendation is one that our team is keen to implement but is restricted from doing so due to staffing availability. Hence Section 6.6 of the minutes seems to contradict section 4.9. I would be grateful if this could be corrected and brought to the attention of the Licence Committee.'

## 3. Executive Update on progress with addressing outstanding recommendations

**3.1.** **Consent to storage**. At the inspection on 19 January 2021 there remained eight sets of embryos and two sets of sperm in storage at the centre for more than 10 years without effective consent to storage. The PR confirmed that legal advice has been sought for all eight couples who wish to keep their embryos in storage, and actions are being taken in response to instructions from solicitors acting on behalf of the Trust. The PR informed the executive that several attempts were made to contact the two gentlemen who had sperm in storage without effective consent and no responses were received therefore, in line with their legal advice a decision has been made to allow these samples to perish.

**3.2.** **Consent to disclosure to researchers**. In November 2020, the centre had identified a high error rate in discrepancies between completed patient/partner disclosure consents within patient records and the related consent data submitted for inclusion on the register. As detailed in the report of the inspection in January 2021, this resulted in the HFEA putting a temporary block on the release of the centre's data for use in research so that there was no risk that the HFEA would release patient identifying information to researchers without their consent until an audit of all records (circa 16,000) was completed. The PR informed the executive that errors were noted in 23% of the first 957 consent forms audited. Of these errors 40% have been corrected but the PR informed the executive that for the remainder the patient needs to be contacted to confirm their consent wishes. Until such time the centre has amended the patient's registration form to indicate they do not consent to disclosure to researchers to prevent disclosure against the patient's wishes. If the centre is able to contact the patient and ascertain their wishes the records will be updated accordingly, but if not, the record will remain that the patient does not consent to disclosure to researchers. Whilst the PR should ensure that all patients wishes are accurately recorded on the HFEA register the executive accepts that this approach removes any risk that the HFEA releases patient identifying information to researchers without their consent. The executive will liaise with the PR to monitor progress with this audit.

## 4. Executive Summary

**4.1.** The executive acknowledges the PR's commitment to addressing the centre's previously poor outcomes for FET in women <40 years and is pleased to note that these success rates appear to be improving. The executive will continue to monitor the centre's success rates in this group of patients to ensure that recent improvements in outcomes are sustained.

**4.2.** The executive will liaise closely with the PR to ensure that he continues to take action to address the embryos that remain in storage without effective consent for eight couples and that the audit of all records of consent to disclosure to researchers progresses as planned.

**4.3.** The centre's licence expires on 31 July 2022 and therefore a renewal inspection is due to be conducted approximately six months before that date. At that time progress with outstanding actions and all areas of practice will be reviewed in detail.