Executive Licensing Panel - minutes

Centre 0167 (University College London Hospitals)

Executive Update

Tuesday, 1 December 2020

HFEA Teleconference Meeting

Panel members	Claire Ettinghausen (Chair) Joanne Anton Laura Riley	Director of Strategy and Corporate Affairs Head of Policy Head of Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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 University College London Hospitals is part of the University College London Hospitals NHS Foundation Trust. The centre has held a licence with the HFEA since 1997 and provides intrauterine insemination (IUI) with partner and donor sperm. The centre also offers a sperm storage service for patients who are having treatment that may impair their fertility.

1.2. The panel noted that the centre provides a satellite in vitro fertilisation (IVF) service to NHS patients in conjunction with The Centre for Reproductive and Genetic Health (centre 0044).

1.3. The panel noted that the centre's current licence was issued in November 2017, for a period of 4 years, and is due to expire on 31 October 2021. The Person Responsible (PR) was varied in January 2019.

1.4. The panel noted that the centre has a previous history of storage consent issues, first identified in 2013 when over 3000 sperm samples were found to be in storage without effective consent. Following advice from both a legal specialist and an external advisor, an action plan was submitted to the HFEA with the expectation that it would be fully implemented by August 2013. When responding to the report immediately after the inspection, the previous PR agreed to implement the recommendations, but later reported that staff changes had made progress slower than anticipated

1.5. The panel noted that, at the centre's interim inspection in June 2015, whilst significant progress had been made, there were still 1305 samples in storage without valid consent and a critical non-compliance was cited. The previous PR assured the inspection team that a full-time member of staff had been employed to address the matter and provided a plan for resolution by March 2016. Monthly progress updates were sent to the centre's inspector and implemented within the revised timescale.

1.6. In May 2017, at the centre's renewal inspection, three sperm samples were in storage without effective consent: given the centre's progress in resolving the storage issues, the non-compliance was down-graded to a major non-compliance and actions were taken by the centre to fully comply with the recommendations, following the inspection, prior to Executive Licensing Panel (ELP) meeting on 30 June 2017.

1.7. At an unannounced interim inspection, conducted at the centre on 5 May 2019, a critical non-compliance was identified relating to approximately 100 samples in storage without effective consent. One major and two 'other' areas of non-compliance were also identified.

1.8. The panel noted that, given the centre's history of storage consent issues and in accordance with the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 28 May 2019 to consider the extent of the critical non-compliance and to determine whether any informal or formal regulatory action was required. Whilst it was considered that there were no immediate risks to patients, staff, gametes or embryos, the critical non-compliance regarding consent to storage of cryopreserved materials was deemed significant. Those attending the management review meeting were not assured that the centre had robust systems in place to effectively manage the issues related to the consent to storage of cryopreserved materials. It was agreed that the PR should meet with the HFEA to discuss the seriousness of the inspection findings, prior to providing a response to this report, to seek assurances from the PR that the non-compliances identified in the report will be addressed as a priority.

1.9. In June 2019, the executive met with the PR to discuss the findings of the report and seek assurances that the non-compliances identified would be addressed as a priority. Following this meeting, the PR was invited to provide a response to the inspection report and give a comprehensive report of all samples being stored beyond their consented storage period and the

actions taken to address each case; the PR's response was considered to be unsatisfactory as she had not provided the requested report of the number of patients for whom gametes remain in storage beyond their consented storage period, she had not provided an action plan with the specific detail that was requested and the proposed actions to be taken to ensure compliance with the HF&E Act and the relevant HFEA Statutory Storage Regulations and she had not clarified the centre's position in seeking legal advice for the gametes identified as in storage beyond their consented storage period.

1.10. After a further meeting with the PR and the centre's laboratory manager, to discuss the responses to the report, the PR was again invited to send a further response to the report. This was received on 1 August 2019 to the satisfaction of the executive and the PR's amended responses were documented in the compliance table at the end of the interim inspection report, presented to the Licence Committee (LC) on 7 November 2019.

1.11. The panel noted that the 7 November 2019 LC, when considering the interim report, were satisfied that the centre was fit to have its licence continued and endorsed the executive's recommendation to carry out a short notice focused inspection within the next twelve months.

1.12. The panel noted that, in 2020 the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, decision was taken in March 2020, by the HFEA to suspend all inspections of licenced premises until November 2020 and the LC endorsement to undertake a short noticed inspection within the required timescale has not been possible.

1.13. The panel noted the update provided, giving a full review of the recommendations identified in the last interim inspection report and the progress made by the PR in ensuring compliance. The review had consisted of a desk based review of the actions undertaken by the PR in response to the recommendations made in the interim inspection report, the engagement of the PR with the executive and a discussion with the PR and laboratory manager. The panel noted that:

- Since the interim inspection, the PR has fully engaged with the executive and has provided documented evidence of compliance with all the recommendations made in the interim inspection report. There are no actions outstanding;
- The PR has provided the centre's inspector with regular audit summaries pertaining to storage consent, between November 2019 and August 2020. These have each been reviewed by two members of the executive, neither had any concerns with the current storage situation at the centre and are pleased with the efforts that the PR has made in achieving compliance;
- The latest audit, undertaken in August 2020, provides assurance that all samples in storage have effective consent in place;
- The PR has provided a detailed action plan for consents approaching expiry up until January 2021 and further details of the number of samples approaching expiry until April 2021 and the actions being taken to contact patients;
- The executive has recently held a conference call with the PR and the laboratory manager where the actions taken by the PR, since the last interim inspection were discussed. The executive was satisfied with the PR's responses during the discussions.

1.14. The panel noted that the centre has followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.15. The panel noted that the executive will be undertaking a licence renewal inspection in Spring 2021, where regulatory compliance will be further assessed.

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 four years. years.

2.2. The panel noted the confirmation from the executive that the centre is fit to have its treatment (insemination using partner/donor sperm) storage licence continued.

3. Decision

3.1 The panel noted the executive update provided, in relation to the centre's non-compliance concerning storage consent, initially identified in 2013. The panel acknowledged the PR's positive engagement with the executive, since the interim inspection, conducted on 5 May 2019, providing regular audit summaries and a detailed action plan for consents approaching expiry up until January 2021 and April 2021.

3.2 The panel endorsed the executive's recommendation that the centre's treatment (insemination using partner/donor sperm) storage licence should be continued, noting that a renewal inspection would be undertaken at the centre in Spring 2021.

4. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

7 December 2020

Executive update for Executive Licensing Panel

1 December 2020

University College London Hospitals (centre 0167)

Person Responsible: Dr Ephia Yasmin

Executive update following previous interim inspection report

1. Background

1.1. University College London Hospitals is part of the University College London Hospitals NHS Foundation Trust. The centre has held a licence with the HFEA since 1997 and provides intrauterine insemination (IUI) with partner and donor sperm. The centre also offers a sperm storage service for patients who are having treatment that may impair their fertility.

1.2. The centre provides a satellite in vitro fertilisation (IVF) service to NHS patients in conjunction with The Centre for Reproductive and Genetic Health (HFEA Licensed centre 0044).

1.3. The centre's current licence was issued in November 2017 and was varied to change the Person Responsible (PR) in January 2019. The current licence was issued for a period of 4 years and is due to expire on 31 October 2021.

1.4. The centre has a previous history of storage consent issues first identified in 2013, when over 3000 sperm samples were found to be in storage without effective consent. Following advice from both a legal specialist and an external advisor, an action plan was submitted to the HFEA with the expectation that it would be fully implemented by August 2013. When responding to the report immediately after the inspection, the previous PR agreed to implement the recommendations, but later reported that staff changes had made progress slower than anticipated.

1.5. At the subsequent interim inspection in June 2015, it was noted that whilst significant progress had been made, there were still 1305 samples in storage without valid consent and a critical non-compliance was cited. The previous PR assured the inspection team that a full-time member of staff had been employed to address the matter and provided a plan for resolution by March 2016 and monthly updates on progress were sent to the centre's inspector and implemented within the revised timescale.

1.6. At the renewal inspection in May 2017, three sperm samples were in storage without effective consent but given the centre's progress in resolving the storage issues the non-compliance was down-graded to a major non-compliance and actions were taken by the centre to fully comply with the recommendations following the inspection and prior to Executive Licensing Panel (ELP) meeting.

1.7. An unannounced interim inspection was conducted at the centre on 5 May 2019 where a critical non-compliance was identified relating to approximately 100 samples in storage without effective consent. The following areas of non-compliances were also identified:

Major areas of non-compliance:

- The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Ebola virus exposure or infection and should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola risks are clearly documented within the patient's records.

'Other' areas of non-compliance or poor practice:

- The PR should arrange for safety signage to be installed on the door of the cryostore room.
- The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice.

1.8. Given the centre's history of storage consent issues and in accordance with the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 28 May 2019 to consider the extent of the critical non-compliance and to determine whether any informal or formal regulatory action was required. Whilst it was considered that there were no immediate risks to patients, staff, gametes or embryos, the critical non-compliance regarding consent to storage of cryopreserved materials was deemed significant. Those attending the management review meeting were not assured that the centre had robust systems in place to effectively manage the issues related to the consent to storage of cryopreserved materials. It was agreed that the PR should meet with the HFEA to discuss the seriousness of the inspection findings prior to providing a response to this report and seek assurances from the PR that the non-compliances identified in the report will be addressed as a priority.

1.9. In June 2019 the executive met with the PR to discuss the findings of the report and to seek assurances that the non-compliances identified in the report would be addressed as a priority. Following the meeting the PR was invited to provide a response to the inspection report and provide a comprehensive report of all samples being stored beyond their consented storage period and the actions taken to address each case. When the PR's response was received it was considered to be unsatisfactory for the following reasons: She had not provided the requested report of the number of patients for whom gametes remain in storage beyond their consented storage period, she had not provided an action plan with the specific detail that was requested and the proposed actions to be taken to ensure compliance with the HF&E Act and the relevant HFEA Statutory Storage Regulations. In addition, she had not clarified the centre's position in seeking legal advice for the gametes identified as in

storage beyond their consented storage period.

1.10. Following a further meeting with both the PR and the centre's laboratory manager to discuss the PR's responses to the report, the PR was again invited to send a further response to the report. This was received on 1 August 2019 to the satisfaction of the executive and the PR's amended responses were documented in the compliance table at the end of the interim inspection report which was presented to Licence Committee (LC) on 7 November 2019.

1.11. LC considered the findings in the interim inspection report and was satisfied that the centre was fit to have its licence continued and endorsed the executive's recommendation to carry out a short notice focused inspection within the next twelve months.

1.12. In 2020 the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19).

1.13. In response to UK measures to contain and mitigate the spread of the virus, a decision was taken in March 2020, by the HFEA to suspend all inspections of licenced premises until November 2020 and the LC endorsement to undertake a short noticed inspection within the required timescale has not been possible.

1.14. This executive update is provided to ELP following a full review of the recommendations identified in the last interim inspection report, so as to update the committee on the progress the PR has made in ensuring compliance. The review has consisted of a desk based review of the actions the PR has undertaken in response to the recommendations made in the interim inspection report, the engagement of the PR with the executive and a discussion with the PR and laboratory manager.

- Since the interim inspection: The PR has fully engaged with the executive and has provided documented evidence of compliance with all the recommendations made in the interim inspection report. There are no actions outstanding.
- The PR has provided the centre's inspector with regular audit summaries pertaining to storage consent, between November 2019 and August 2020. These have each been reviewed by two members of the executive, neither had any concerns with the current storage situation at the centre and are pleased with the efforts that the PR has made in achieving compliance.
- The latest audit undertaken in August 2020 provides assurance that all samples in storage have effective consent in place.
- The PR has also provided a detailed action plan for consents approaching expiry up until January 2021 and further details of the number of samples approaching expiry until April 2021 and the actions being taken to contact patients.
- The executive has recently held a conference call with the PR and the laboratory manager where the actions taken by the PR, since the last interim inspection were discussed. The executive was satisfied with the PR's responses during the discussions.

1.15. The centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.16. The executive will be undertaking a licence renewal inspection in the spring of 2021, where regulatory compliance will be further assessed.

2. Recommendation

2.1. The executive is satisfied the centre is fit to have its Treatment (Insemination using partner / donor sperm) and Storage licence continued at this time.