Executive Licensing Panel - minutes

Centre 0080 (Androlgy Unit, Hammersmith Hospital)

Executive Update

Tuesday 17 November 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Dan Howard Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Chief Information Officer Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Jane Darragh	Licensing Manager Research Manager (Induction)

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 the Andrology Unit, Hammersmith Hospital is located in London and has held a storage only licence with the HFEA since 1992. The centre is part of Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility, or short-term storage of sperm for use in the patient's fertility treatment.

1.2. The panel noted that the centre had an interim inspection on 29 October 2020 and the report was considered by the Executive Licensing Panel (ELP) on 14 January 2020.

1.3. The panel noted that, at the time of the interim inspection, there was one critical non-compliance concerning the process used to monitor consent to storage expiry dates. There was also one major area of non-compliance in relation to the centre's quality management system (QMS). The 14 January 2020 ELP expressed serious concern regarding the critical non-compliance, noting this had also been identified at the centre's renewal inspection, conducted on 31 October 2017.

1.4. The 14 January 2020 ELP was satisfied that the centre was fit to have its storage only licence continued, requesting an update report from the inspectorate, regarding the implementation of the recommendations surrounding the consent to the storage of cryopreserved material, by the end of 2020, at the latest. The minutes stated that 'Upon receipt of the update report, the panel would make a further decision on the continuation of the centre's licence.'

1.5. The panel noted that since the interim inspection, the Person Responsible (PR) has fully engaged with the HFEA and has implemented all of the recommendations; there are no outstanding actions.

2. Consideration of Progress Update

2.1. The panel considered the papers, which included an executive update, update on recommendations made at the interim 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 storage only licence continued.

3. Decision

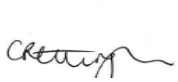
3.1 The panel noted the executive update provided, particularly in relation to the critical non-compliance identified at the centre's interim inspection, concerning the consent to the storage of cryopreserved material; the panel was satisfied that no further action is required.

3.2 The panel endorsed the executive's recommendation that the centre's storage only licence should be continued, looking forward to fewer non-compliances, in relation to the consent to the storage of cryopreserved material, being identified at the renewal inspection.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

23 November 2020

Executive update for Executive Licensing Panel

17 November 2020

Andrology Unit, Hammersmith Hospital (centre 0080)

Person Responsible: Monica Flipia de Brito Figueiredo

Executive update

1. Background

1.1. The Andrology Unit, Hammersmith Hospital is located in London and has held a 'Storage only' licence with the HFEA since 1992. The centre is part of Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility, or short-term storage of sperm for use in the patient's fertility treatment.

1.2. The centre had interim inspection on 29 October 2019 and the report of that inspection was considered by Executive Licensing Panel (ELP) on 14 January 2020.

1.3. At the time of the inspection, there was one critical area of non-compliance concerning the process used to monitor consent to storage expiry dates, and one major area of non-compliance in relation to the centre's quality management system. ELP expressed serious concern regarding the critical non-compliance and also noted this had also been identified at the centre's renewal inspection conducted on 31 October 2017.

1.4. ELP was satisfied the centre was fit to have its storage only licence continued, and requested an update report from the inspectorate, regarding the implementation of the recommendations surrounding the consent to the storage of cryopreserved material by the end of 2020, at the latest. The minutes stated that 'Upon receipt of the update report, the panel would make a further decision on the continuation of the centre's licence.'

1.5. As requested by ELP, Appendix 1 provides an executive update on the actions that PR has taken since the time the report was considered by them on 14 January 2020.

1.6. The centre's inspector considers that the PR has fully engaged with the HFEA and has implemented the recommendations. There are no actions outstanding.

2. Recommendation

2.1. The executive confirms that there is no change to the recommendation made by the inspection team in the interim inspection report considered by ELP on 14 January 2020.

2.2. The executive is satisfied the centre is fit to have its storage only licence continued at this time.

Appendix 1

► Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Consent to the storage of cryopreserved material The centre's processes for storing gametes in line with the consent of the gamete providers are not effective, for reasons detailed in the main body of the report. The centre also received critical non compliances for consent to storage at their previous two inspections. Schedule 3, 8(1) HF&E Act 1990 (as amended).	The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate. The PR should review the electronic storage database for completeness, including the presence of an accurate expiry date for all stored samples, and the process for ensuring the accuracy of the database when there is a change in the status of the patient, their partner, or their consented storage period.	The PR will review the storage databases and ensure its completeness including presence of an accurate expiry date for all stored samples. A review of training will be completed by the PR. The revision will include more training provided to all staff, encompassing, basic user competency in consents. Advanced user competency training in consents, will be given to relevant members of staff. Extension of storage consent training seminar was provided to staff on 29/11/2019.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required. **Update 23 October 2020:** The PR submitted a detailed action plan on 30 January 2020 confirming that the centre's new 'bring forward system' had been implemented, that training and competency assessments of relevant members of staff had been completed, and that a new member of staff had been recruited specifically to

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Code of Practice Guidance 17.21 SLCs T36, T79	The PR should provide the results of this review, including any corrective actions to the centre's inspector by 31 December 2020. The PR should ensure that staff receive appropriate training, in the conditions that must be met to allow the lawful extension of statutory storage of gametes. Details of the proposed training should be provided to the centre's inspector when responding to this report. The PR must ensure that gametes are stored only when valid consent for storage is in place. The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future.	Bring forward system: Master Gamete excel spreadsheet has been created to record all storage consents expiry dates. The spreadsheet will alert members of staff 1 year before the consents expiry date (colour change alert). This spreadsheet will enable the centre to have all information about all patients' storage consent forms in one place. A business case for recruitment of an extra member of staff was sent to the management team to support the full audit. Additionally whilst business case is being considered, overtime was also requested to advance the audit in the meantime. Andrology will audit all patients' files in storage with a completion scheduled for 29/10/2020. The PR will review all long term stored samples, to ensure all appropriate consents are present on files including written medical opinions.	undertake the audit of storage records. Since January 2020, the PR has submitted monthly updates of progress with the audit of the centre's storage records and reassured the centre's inspector at regular intervals, that the audit was being undertaken in an appropriate timeframe and would be fully completed by the due date. The PR submitted report of the audit of all samples in storage at the time of audit on 20 October 2020 and confirmed that the records for all 2706 patient files had been audited. The audit identified a total of 80 patients where there had been periods of time where storage had not been in place. The PR confirmed that the cases identified had arisen due to previous failings at the centre and no issues have been noted in more recent records (since 2018).

	The PR should review all long term stored samples to ensure that all appropriate consents and written medical opinions, completed within the relevant timeframe, are in place. The executive acknowledge that this will take some time. Monthly progress updates should be submitted to the centre's inspector. A summary of the findings of the review, including any corrective actions with timescales for implementation, should be provided to the centre's inspector by 31 December 2020. In any cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken.	A summary of the findings of the review, including corrective actions and timescales for its completion will be provided to the inspector by 29/10/2020. The PR will seek legal advice on how to proceed whenever consents in place do not comply with 2009 storage Regulations. In this case, proposed actions will be forwarded to HFEA before actions being taken. The PR will provide monthly updates to the HFEA inspector on progress including number of files audited.	The PR assured the executive that appropriate actions had been taken to resolve these cases and she is satisfied that there is effective consent for all samples currently in storage at the centre. In view of the audit findings and the PR's assurances, the executive is assured that current practices in the centre are robust and similar issues should not arise in the future. No further action is required.

► **'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 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;
- which can comprise 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**	**Inspection team's response to the PR's statement**
2. Quality Management System (QMS) The centre's quality management system processes are not consistently effective, for reasons detailed in the main body of the report. SLCs T32 and T33.	The PR should ensure that the centre's quality management system processes are effective. The PR should provide a summary report of this review, and an action plan with timescales for implementation, to the centre's inspector by 29 January 2020. The PR should provide the centre's inspector with a copy	The PR has drafted the "bring forward SOP" and this is now up for revision. Once reviewed and submitted onto Q-Pulse Quality management System, a copy of the SOP will be submitted to the inspector on the 29/01/2020. A summary report with review and action plan will be provided to the inspector on the 29/01/2020.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required. **Update 23 October 2020:** The bring forward system was revised and this, together with the new SOP were provided to the centre's inspector on 30 January 2020. In addition, the PR confirmed that Clinic Focus articles are shared with the team and

	of the 'bring forward' system SOP by 29 January 2020.		discussed at quality meetings. The centre now encourages patients to provide ratings to 'Choose a Fertility Clinic', and 11 patients have now submitted feedback. No further action is required.

► '**Other' areas of practice that requires improvement**

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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	Inspection team's response to the PR's statement
None			