Executive Licensing Panel - minutes

Centre 0250 (Glasgow Centre for Reproductive Medicine)

Executive Update

Friday, 28 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Hannah Verdin (Chair) Anna Coundley Anjeli Kara	Head of Regulatory Policy Information Access and Policy Manager Regulatory Policy Manager
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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The Glasgow Centre for Reproductive Medicine is located in Cardonald Business Park on the outskirts of Glasgow and has held a treatment (including embryo testing) and storage licence with the HFEA since November 2006.

1.2. The Executive Licensing Panel considered the centre's interim inspection report at its meeting on 15 July 2016. The committee had concerns relating to a medicines management non-compliance and were not suitably reassured by the PR's response. As recommendations were due to be completed by 17 August 2016, the ELP adjourned their decision regarding a continuation of the centre's treatment (including embryo testing) and storage licence until the inspectorate could provide an update on the completion of the recommendations.

1.3. The panel noted there has been substantial delay in the Executive providing the required update as the signed minutes of the interim inspection report were not sent to the centre's inspector who, at the time was recently in post and unaware of the requirement to receive committee minutes. A routine audit of Choose a Fertility Clinic (CaFC) report papers in June 2017, identified that an update had not been provided as required.

2. Consideration of application

2.1. The panel considered the papers, which included an executive update, inspection report and licensing minutes for the last three years.

2.2. The panel noted the Executive's findings, especially that recommendations relating to medicines management had been addressed.

2.3. The panel noted that, since the interim inspection, a new Person Responsible (PR) had been appointed.

2.4. The panel noted the inspectorate's recommendation to continue the centre's treatment (including embryo testing) and storage licence without any additional conditions.

3. Decision

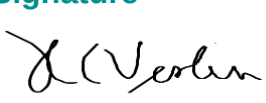
3.1. The panel welcomed the executive update and was satisfied that all actions had been completed within the prescribed timescales.

3.2. The panel was satisfied that the centre was fit to have its licence continued

4. Chair's signature

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

Signature



Name

Hannah Verdin

Date

4 August 2017

HFEA Compliance Department Executive Summary

Executive Summary for Executive Licensing Panel 28 July 2017

Centre number	0250
Centre name	Glasgow Centre for Reproductive Medicine (GCRM)
Person Responsible	Richard Fleming

Interim inspection report

Background

1. At the meeting on 15 July 2016, the Executive Licence Panel (ELP) considered an interim inspection report for Glasgow Centre for Reproductive Medicine (GCRM). The committee had concerns relating to medicines management non-compliance and were not suitably reassured by the PR's response. As recommendations were due to be completed by 17 August 2016, the ELP adjourned their decision regarding a continuation of the centre's Treatment (including embryo testing) and Storage licence until the inspectorate could provide an update on the completion of the recommendations.
   There has been substantial delay in the Executive providing this update to the ELP. The signed minutes of the interim inspection report were not sent to the centre's inspector who, at the time was recently in post and unaware of the requirement to receive committee minutes. A routine audit of Choose a Fertility Clinic (CaFC) report papers in June 2017, identified that an update had not been provided as required.

2. This update is summarised in appendix 1.

3. Since the inspection, a new PR has been appointed.

Recommendation

The Executive recommends continuation of the centre's Treatment (including embryo testing) and Storage licence without any additional conditions.

Inspector Name
Polly Todd

Job title
Clinical Inspector

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 area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Medicines management: The following issues were noted on inspection: • the centre is currently using a controlled drugs cupboard that is attached to an internal wall so can easily be removed. Examination of the controlled drugs register notes that: • alterations of errors are not made in accordance with regulatory and best practice requirements; • some entries are illegible; • it is unclear in some instances the amount of drug that has been given to the patient and how much has been discarded;	The PR should ensure that controlled drugs are stored in accordance with statutory regulations. Considering the reoccurring nature of this non-compliance, the PR should provide, when responding to this report, assurance that the controlled drugs cabinet attached to an internal wall will not again be used for the storage of controlled drugs. If the PR cannot provide adequate assurance, he should consider whether it is appropriate to remove the cabinet. The PR should ensure that medicines management practices are compliant with	All controlled drugs have been relocated to CD cupboard on external wall. Key removed from previous CD cupboard in theatre. Noted	The inspection team acknowledge the actions taken by the PR by relocating the controlled drugs. The PR should provide a summary of the required review of medicines management practices by 17 August 2016 and a summary of the subsequent audit by 17 November 2016. Further action required. **Executive update 20 June 2017:** The Executive acknowledges receipt of the required evidence of compliance within the agreed timescales. • The PR has provided a

• in one entry the amount of drug given to the patient has not been recorded but the entry has still been signed and witnessed by two practitioners; • the 'carry over' of drugs has not been witnessed in all cases; • some pages are not labelled according to regulatory requirements, the dosage, strength and volume of drugs is missing from a number of pages; • staff have not received training in controlled drugs or general medicines management; • drugs are not dispensed according to regulatory and pharmaceutical standards. The name and signature of dispenser and checker and source of the dispensed medicine is missing from the dispensing label. This non-compliance has been	regulatory standards and practice guidance. The PR should review medicines management practices, including staff training requirements, to identify the factors that have led to these non-compliances and to ensure appropriate actions are taken to address each and every factor, so that medicines management practices thereafter comply with all regulatory requirements. A summary report of this review, with corrective actions, should be provided to the centre's inspector by 17 August 2016. Within three months of the implementation of the corrective actions, the PR should conduct a full audit of medicines management practices, to ensure the corrective actions implemented have been effective in	Noted Noted	medicines management training programme; • medicines management has been added to the centre's 'Orientation pack' as a core competency for staff. • Evidence provided, demonstrates that dispensing labels are now compliant with practice standards; • an SOP for the ordering, control and management of controlled drugs has been provided; • a medicines management audit was received the satisfaction of the Executive. No further action required.

upgraded to critical because of to the non-implementation of a previous recommendation made after the inspection in 2014 and the cumulative nature of the multiple concerns regarding medicines management at this inspection. Department of Health (DH) (2007) 'Safer Management of Controlled Drugs; a guide to good practice in secondary care (England) section 4.7.14 and section 4.11.1.1; DH (2013) Controlled Drugs (Supervision of management and use) Regulations 2013; Misuse of Drugs (Safe Custody) Regulations 1973; Misuse of Drugs Regulations (2001) Regulation 19, 20 (c) and 27; NMC 'Standards for medicines management' (2010) Standard 4	achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 November 2016.	Noted	

section 4, standard 26, sections 31-36 and standard 32; SLC T2 and T15.			

‘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.

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: The centre’s audit programme is not suitably robust because: a) The centre has not completed the following audits; • controlled drugs and medicines management • satellite services. b) Staff were unable to provide evidence of a	The PR should review the audit programme to ensure it is compliant in the range of activities audited as well as in the robustness of the audits performed; i.e. audits should review (at least every two years) all activities authorised by the centre’s licence and other activities carried out in the course of providing treatment services, against the CoP requirements, the centre’s SOPs and the quality indicators.	Noted	Since the inspection the PR has provided evidence that a witnessing audit has been undertaken. The PR should provide evidence of implementation of the outstanding areas for action by 17 August 2016. Further action required. **Executive update 20 June 2017:** The Executive acknowledges receipt of the required

witnessing audit having been completed. c) The safeguarding policies for adults and children do not indicate what to do if staff become aware of a risk to an adult or child and do not relate to current practice in terms of the frequency and level of staff training undertaken. d) The centre's witnessing SOP does not describe what to do in the event of a mismatch. e) Review of the audit of storage consent shows that one sample should have been discarded on 25 July 2015 but was not discarded until 18 April 2016 i.e. effective corrective actions in response to non-compliance were not implemented in a timely manner. The audit also does	The PR should provide a summary report of this review including the necessary corrective actions with timescales for implementation, and also the audit programme, to the centre's inspector by 17 August 2016. A sample of audits will be requested thereafter to confirm their robustness. Considering the importance of the audit of satellite services the PR should conduct this audit and provide the centre's inspector with a summary report of the findings by 17 August 2016. The PR should address the other concerns within the QMS outlined in this report and provide a summary report to the centre's	Noted Noted	evidence of compliance within the agreed timescales. No further action required.

not detail the circumstances of this breach of storage consent or any corrective actions to prevent recurrence. SLC T9 (b); T33(b); T36; HFEA Clinic Focus (March 2016).	inspector detailing the actions taken by 17 August 2016.		
3. **Equipment and materials**: • The Oosafe 6-well plates in use at the centre are not CE marked. The use of non CE marked equipment was a non-compliance at the inspection in 2014 and was fully implemented. This non-compliance relates to different equipment in use at the centre. SLC T30	The PR should ensure that CE marked devices are used where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided. In consideration of this, the PR should provide the centre's inspector with information which should document either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance with this recommendation.	Alternative CE plates are being investigated but we are aware that options are limited.	The inspection team acknowledge the PR's response and commitment to implement this recommendation. The PR should provide an update regarding the sourcing of a suitable CE marked alternative or a plan of action to address this area of non-compliance by 17 August 2016. Further action required. **Executive update 20 June 2017:** The PR provided evidence

	This information should be submitted to the centre's inspector by 17 August 2016.		that there were no suitable CE marked alternative products available. Confirmation received from the current supplier that class IIa certification is expected September 2017. The Executive has agreed to extend the deadline for this recommendation to September 2017. The PR has given a commitment to using the appropriately CE marked products when they become available. Further action required.
4. **Welfare of the child:** • In one patient record, a referral letter states that the patient has a 'psychiatric history' but the patient has ticked 'no' on the WOC form to 'history of psychiatric	The PR should ensure that patients are not provided with treatment services unless a full account has been taken of the welfare of any child who may be born as a result of that treatment, and of any other child who	Noted	The inspection team acknowledge the PR's acceptance of the required actions and timescales for providing a summary of the review and subsequent audit. Further action required.

illness'. This form was signed off by a practitioner with no evidence that the patient's mental health history or denial of it had been explored or considered before agreeing to treatment. HF&E Act 1990 (as amended) Section 13 (5); SLC T56.	may be affected by that birth. The PR should review the procedure for WOC assessment, including staff training requirements, and provide a summary report of this review, including any corrective actions, to the centre's inspector by 17 August 2016. Within three months of this review the PR should perform an audit of WOC assessment, to ensure the assessments performed are robust. A summary report of the audit's findings should be provided to the centre's inspector by 17 November 2016.	Noted Noted	**Executive update 20 June 2017**: The Executive acknowledges receipt of the required evidence of compliance within the agreed timescales. No further action 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. **Infection control:** • The chair in the men’s production room has a wipe clean surface but has piping around the edges which would be difficult to clean to infection control standards; • patients’ blood samples are stored with medicines. The Health and Social Care Act 2008; Code of Practice on the prevention and control of infections and related guidance SLC T17	The PR should ensure that infection control practices and procedures are compliant with practice guidance. The PR should ensure that all equipment can be cleaned and disinfected in accordance with statutory and practice guidance. The PR should ensure that blood and other biological samples are not stored with medicines. The PR should inform the centre’s inspector of the measures taken to implement this recommendation, with timescales, by 17 August	Noted Bloods are now stored separately	The inspection team acknowledge the PR’s actions to date and commitment to implement this recommendation. Evidence of implementation of the remaining requirement should be provided by 17 August 2016. Further action required. **Executive update 20 June 2017:** The Executive acknowledges receipt of the required evidence of compliance within the agreed timescales. No further action required.

	2016.		
6. Consent to disclosure to researchers: • Of the seven records reviewed on inspection, one discrepancy was found between completed patient/partner disclosure consents in the patient files and the related consent data submitted for inclusion on the register. This discrepancy does not lead to a risk that the HFEA may release patient identifying information to researchers without consent, but may mean that the consent wishes of the patient are not followed. SLC T9e, CH (10)05 and General Direction 0005.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately reported to the HFEA register. The PR should correct the submission that has been identified as incorrect. The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given by the patient and recorded on disclosure consent forms. A summary report of the review and of the actions taken, should be provided to the centre's inspector by 17 August 2016.	Noted	Since the inspection the PR has confirmed that the HFEA have been provided with the corrected consent data. The PR should provide a summary of the review by 17 August and of the subsequent audit by 17 November 2016. Further action required. **Executive update 20 June 2017:** The Executive acknowledges receipt of the required evidence of compliance within the agreed timescales. No further action required.

	Within three months of the implementation of the corrective actions the PR should re-audit practice to ensure these actions have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 November 2016.	Noted Noted	