Executive Licensing Panel - minutes

Centre 0068 (Leicester Fertility Centre)

Renewal Inspection Report Update

Tuesday, 12 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Niamh Marren Danielle Vincent	Director of Finance and Resources Regulatory Policy Manager Communications Manager
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 Leicester Fertility Centre is located within Leicester Royal Infirmary and has held a licence with the HFEA since 1992. The centre currently provides a full range of fertility services and has submitted an application to have their licence varied to allow treatment involving embryo testing; this application will be presented separately to this update report.

1.2. The panel noted that a renewal inspection was carried out at the centre, on 26 and 27 July 2018 and was considered by the Executive Licensing Panel (ELP) at its meeting on 26 September 2018.

1.3. At the meeting on 26 September 2018, the ELP 'voiced particular concern about the non-compliance relating to the safety and suitability of premises and facilities, noting this affected the treatment and phlebotomy rooms. The panel requested that, one or more unannounced inspections are conducted, between now and the interim inspection, to ensure the centre is addressing this non-compliance'. The panel requested to receive an update report on the centre's progress in relation to this non-compliance.

1.4. The panel noted that since the inspection, the Person Responsible (PR), has provided extensive information, addressing all the recommendations in the inspection report.

1.5. The panel noted that the centre's inspector and a clinical inspector, who had been on the renewal inspection in June 2018, performed an unannounced inspection at the centre on 6 August 2019; the focus of the inspection was to review the safety and suitability of the premises and facilities.

1.6. The panel noted the updated non-compliance table from the report of the renewal inspection performed in 2018. This table includes the PR's response at the time of the presentation of the report and has been amended to include further action taken, information received and observations from the inspection visit of 6 August 2019.

1.7. The panel noted that the PR has addressed all of the recommendations made in the renewal report. The limitations in space at the centre were acknowledged. However, it was considered that the PR has taken appropriate action to ensure that patients are cared for in an environment that is clean and well presented. The PR has also commissioned risk assessments of the cryostore and has taken action to mitigate risks; the PR will keep this under review and inform the centre's inspector of any changes to the current facilities.

1.8. The panel noted that the inspectorate's recommendation that a standard interim inspection takes place at the centre in 2020, which includes the inspection of the centre's premises and facilities.

2. Consideration of Progress Update

2.1. The panel considered the papers, which included an executive update, inspection report, update on recommendations made in the report and licensing minutes since the last renewal.

2.2. The panel noted the update on the implementation of the recommendations made in the renewal inspection report.

3. Decision

3.1. The panel noted that the non-compliances had been fully addressed and endorsed the inspectorate's recommendation that a standard interim inspection takes place at the centre in 2020, which includes the inspection of the centre's premises and facilities.

4. Chair's signature

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

Signature

Name

Richard Sydee

Date

18 November 2019

Update report for Executive Licensing Panel 12 November 2019

Centre number	0068
Centre name	Leicester Fertility Centre
Person Responsible	Jane Blower

Executive update regarding non compliances related to safety and suitability of premises

Background:

1. Leicester Fertility Centre is located within Leicester Royal Infirmary and has held a licence with the HFEA since 1992.

2. The centre provides a full range of fertility services and has submitted an application to have their licence varied to allow treatment involving embryo testing. The application will be presented to the committee separately to this update report.

3. Following a renewal inspection in June 2018 recommendations were made in relation to two major and one 'other' non compliance.

4. The renewal report was considered by an Executive Licensing Panel (ELP) on 26 September 2018.

5. The panel voiced particular concern about the non-compliance relating to the safety and suitability of premises and facilities, noting this affected the treatment and phlebotomy rooms. The panel requested that, one or more unannounced inspections are conducted, between now and the interim inspection, to ensure the centre is addressing this non-compliance. The panel requested to receive an update report on the centre's progress in relation to this non-compliance.

6. The Person Responsible (PR) has, since the inspection, provided extensive information to address all of the recommendations in the inspection report.

7. The centre's inspector and a clinical inspector who had been on the renewal inspection in June 2018 performed an unannounced inspection at the centre on 6 August 2019. The focus of the inspection was to review the safety and suitability of the premises and facilities.

8. Annex 1 to this update includes the non-compliance table from the report of the renewal inspection performed in 2018. This table includes the PR's response at the time of the presentation of the report and has been amended to include further action taken, information received and observations from the inspection visit of 6 August 2019.

Summary:

1. In summary, the PR has addressed all of the recommendations.

2. The executive acknowledges the limitations in space at the centre however it is considered that the PR has taken appropriate action to ensure that patients are cared for in an environment that is clean and well presented.

3. The PR has commissioned risk assessments of the cryostore and has taken action to mitigate risks. She will keep this under review and inform the centre's inspector of any changes to the current facilities.

Recommendation:

The inspection team recommends that the centre has a standard interim inspection in 2020 which includes inspection of the centre's premises and facilities.

Janet Kirkland MacHattie
HFEA inspector

Annex

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Safety and suitability of premises and facilities: On inspection the following issues were noted: • The centre facilities are cramped, and inadequate storage provision has resulted in large cardboard boxes of consumables being stored under work tables and in the corridors. • The inspection team was also concerned that staff did not appear to have a designated area to have a scheduled break from their work activities away from their desks or work stations. This is a health and safety risk and not conducive to good ways of working and likely to impact on staff morale. • A room housing the liquid nitrogen dewars was full to capacity and the dewars were obstructing access to clinical equipment. As a	**The PR should ensure that the centre's premises are safe and suitable for purpose and the level of activities undertaken.** **The PR should commission an independent review of the premises for their suitability to provide ongoing treatment services including, (but not exclusively), the issues identified in this report.** **The PR should review current activity levels in line with the capacity to provide treatment services in a safe environment and with the staff available. This should include, (but not exclusively), capacity and suitability of the premises for current treatment activity levels, capacity and suitability for treatment activity should the PR proceed with an application to include embryo testing to the licence at a later date, and arrangements for the removal of surplus and de-commissioned items.**	This review will be undertaken with the support of the Trust. The Trust is planning to relocate the department as part of the plans to build a new purpose designed Womens Hospital The card board boxes stored under the worktables have been removed. There are no boxes stored in the corridors. The Trust provides a 24/7 staff restaurant which staff are able to use The clinical equipment referred to is obselete and has been de-	The executive acknowledges the PR response and commitment to implementing this recommendation. No further action beyond submission of commissioned reports of suitability of premises for current and proposed activity due by 26 January 2019. Summary report received on 23 January 2019. **Inspection team review of premises on 6 August 2019:** Whilst space is at a premium the centre appeared to be clean and well presented. There were no cylinders, boxes or obstacles in the corridor and no boxes stored under the tables in any of the rooms. Staff can access the hospital canteen if they want a break away from their desks or activities and there is a small

consequence, empty cylinders were kept in the main corridor. • In the theatre there were areas of bare plaster and paint peeling off the wall in some places. • Two treatment rooms and the phlebotomy room were visibly dusty. SLC T17. Health and Safety at Work Act 1974.	**A copy of the summary reports of these reviews should be provided to the centre's inspector by 26 January 2019.**	commissioned and was awaiting disposal, it has now been decommissioned and disposed of in accordance with Trust policy. Empty cylinders were awaiting collection by the porters for re-filling. These were fully labelled Reports will be provided within the timescale requested by the HFEA. The bare plaster has been repaired We are working with domestic services to ensure cleaning and audits are more robust	staff kitchen where they can, if they wish, prepare their own refreshments. The PR had commissioned a risk assessment of the cryostore and actions towards mitigating risks had been taken. The inspection team did note that the floor of the cryostore was cracked in places and the risk assessment was repeated in September 2019 to take this risk in to account. The risk assessments provided by the centre are clear and comprehensive. On this observational visit it was noted that there are still items not related to the storage of gametes and embryos in the dewar room, however the clinical inspector who was present for the previous inspection noted improvement. There were less dewars and access to these items had improved. The centre team has risk assessed access to the dewar room and the contents and have

			action plans in place to mitigate any perceived risks. The theatre was clean and well presented. There was no paint peeling off the walls or bare plaster. The consulting rooms, phlebotomy and treatment rooms were clean, well presented and free of dust. **It was considered that the PR has, within the limitations of the premises, complied with the recommendation.**
2. Medicines management: The carry-over of stock is not recorded in the controlled drugs register and the centre only record a single patient identifier (patient name) in the controlled drugs register. SLC T2. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.	The PR should ensure medicines management practice is compliant with regulatory and best practice guidance. The PR should review medicines management practice and address the issues identified in this report. A summary report of this review including corrective actions taken, should be provided to the centre's inspector by 26 September 2018.	The issues identified and the audits will be carried out with the support of the Trust chief pharmacist	The executive notes the PR's response and looks forward to receipt of the summary report of the review of medicines management practice due by 26 September 2018. Further action required. Medicine management review received 2 September 2019. Audits and review received. **No further action was required.**

	Three months after the review, the PR should audit medicines management practices to ensure that corrective actions implemented, have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 26 January 2019.		**The PR has fully complied with this recommendation.**

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates 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	Executive Review
3. QMS: Corrective actions in the consent audit were not progressive in that they would not achieve improvement in practice. For example, corrective actions were listed as 'continue to monitor at management meetings' and 'significantly higher number of consent issues'. SLC T36. CoP 23.27 and 23.28.	The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice. The PR should conduct a review of all audits undertaken in the last two years to ensure that corrective actions are appropriate and have been effective in achieving compliance and improvements. A summary report of this review, including any further actions implemented, should be provided to the centre's inspector by 26 January 2019.	A review of audits will be undertaken and reccomendations for actions implemented.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required. Audit plan and review received on 23 January 2019. A new quality manager has been appointed since the previous inspection. **The PR has complied with this recommendation.**

Responses from the Person Responsible to this inspection report