For Information
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Mechanism of the Hospital Authority to Ensure Safety in the Use of Medical Equipment and Products

Purpose

This paper sets out the arrangement in place in the Hospital Authority (HA) to ensure safety in the use of medical equipment and products. It also accounts for the recent incident of the use of expired surgical sutures at the Queen Elizabeth Hospital (QEH).

Safety in the Use of Medical Equipment

2. The safety in the use of medical equipment and products has a direct bearing on patient safety and is of paramount importance in a healthcare facility. HA takes the issue of the equipment safety seriously.

3. The safe use of medical equipment and products is a broad domain, covering the use and maintenance of equipment as well as the quality assurance in the supply and use of products such as drugs, sterile supplies and consumables. HA has put in place mechanisms for safeguarding their proper use both at the hospital and at the corporate level.

4. At the hospital level, HA has built up a system of clinical governance whereby equipment with various levels of complexity will only be operated by staff with corresponding experience and qualification. Furthermore, the clinical management teams will regularly conduct quality assurance activities such as mortality and morbidity meetings and clinical audits to ensure any event affecting patient care would be looked at as appropriate. The hospital administration systems support the clinical departments in the regular maintenance of equipment, including centrally coordinated programmes guiding the replacement of old or outdated equipment. The Central Sterile Supplies Departments have established protocols to ensure standards in sterilization of instruments.

5. At the corporate level, HA Head Office has implemented the following measures –

(a) setting up a governance structure for the management of medical equipment;
(b) establishing guiding principles for vetting new medical equipment based on the impact on health outcome; and
(c) developing an infrastructure for tracking medical equipment.

6. More specifically, the Central Technology Office (CTO), set up under the Quality & Safety Division at HA Head Office, is tasked with coordinating and aligning cross-departmental issues concerning medical equipment management using a risk-stratified approach. CTO promulgates the strategy, approach and framework of medical equipment management through the cluster hospitals via the Cluster Technology Committees. Moreover, mindful of the importance of stakeholder buy-in, alignment and consensus building, HA also solicit professional inputs from Clinical Coordinating / Central Committees on equipment safety.

7. In HA, all medical equipment has to undergo acceptance test in respect of safety and functional requirements before they are used on patients. HA arranges maintenance programmes with reference to manufacturer's recommendations.

8. While HA has strived to ensure the safety in the use of medical equipment and products, there are occasional incidents when their use has caused concerns due to different reasons, e.g. malfunction of the equipment, using the equipment not in full compliance of relevant guidelines and standard. HA has established the "Medical Equipment Safety Alert System" to facilitate prompt dissemination of hazard and alert notices involving medical equipment or devices. In order to ensure that prompt and appropriate follow-up will be taken, HA has also set up the Advanced Incident Reporting System (AIRS) for reporting of clinical incidents, including those relating to use of medical equipment. HA will conduct root cause analysis when there is an incident and will propose recommendations for sharing among HA hospitals with a view to preventing recurrences of the incident.

Recent Incident at QEH

9. In respect of a recent incident concerning the use of expired surgical sutures at QEH, HA has taken immediate follow-up actions. A brief account of the incident and the follow-up actions taken are set out in the ensuing paragraphs.

Background

10. On 3 July 2014, a nurse of QEH reported that Ethibond Excel Suture with expiry date in June 2013 had been used in open heart surgery during the period of 1 July to 31 December 2013, possibly affecting a total of 236 patients. Normally for suture, a medical consumable, their product validity check should be conducted by the users before use.

Follow-up Actions

11. HA took immediate follow-up actions including seeking professional inputs from the Chief Infection Control Officer, undertaking epidemiology study on affected patients, conducting a stock-take exercise to confirm no other expired item has been used and liaising with the vendor of Ethibond Excel Suture for information on possible risk of having used the expired sutures on patients.

12. HA has also endeavoured to contact all patients who have been possibly affected. Upon screening through a standard checklist, HA finds that the majority of the patients contacted are in normal condition and 39 patients were identified for further follow-up. For these 39 patients, HA has already arranged surgeons from the Department of Cardiothoracic Surgery to undertake further investigation and provide clinical care as appropriate. All these 39 cases were in stable condition.

13. In line with the existing mechanism concerning patient safety, HA has set up a Root Cause Analysis Panel to determine cause and contributing factors of the incident as well as to make effective recommendations to prevent the re-occurrence of similar incidents. As there is no scientific report regarding the possible adverse effects on patients arising from the use of expired sutures,

HA has also established a separate Clinical Review Panel to look into the clinical matter under such circumstances.

14. All in all, HA takes this incident seriously and has already implemented remedial measures immediately after the incident was discovered. It has also set up panels to investigate the cause of the incident and look into any clinical effects. Every effort has been paid to ensure that similar incident will not occur in future again.

Food and Health Bureau
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