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Panel on Health Services

Information note prepared by the Legislative Council Secretariat for the meeting on 20 October 2014

Mechanism put in place by the Hospital Authority to ensure safety in the use of medical equipment and products

The subject of mechanism put in place by the Hospital Authority ("HA") to ensure safety in the use of medical equipment and products has not been discussed by the Panel on Health Services ("the Panel"). In July 2014, it was reported that expired Ethibond Excel Suture was used in open heart surgery during the period from July to December 2013 at the Queen Elizabeth Hospital ("QEH") ("the incident"). In response to members' concern about the incident, the Administration has provided an information paper on the subject (LC Paper No. CB(2)2059/13-14(01)) for circulation to the Panel on 18 July 2014.

2. According to HA, all medical equipment has to undergo acceptance test in respect of safety and functional requirement before they are used on patients. To safeguard the proper use of medical equipment and products, mechanism has been put in place by HA at the hospital and corporate levels which covers, among others, requiring equipment with various levels of complexity be operated by staff with corresponding experience and qualification; establishing protocols to ensure standards in sterilization of instruments; setting up a governance structure for the management of medical equipment; establishing guiding principles for vetting new medical equipment; and developing an infrastructure for tracking medical equipment. This apart, HA has established the "Medical Equipment Safety Alert System" to facilitate prompt dissemination of hazard and alert notices involving medical equipment or devices. HA has also set up the Advanced Incident Reporting System for reporting of clinical incidents, including those relating to use of medical equipment.

3. On the incident took place in QEH, the immediate follow-up actions taken by HA included 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. HA also contacted all patients who had been possibly affected.

4. HA has set up a Root Cause Analysis Panel and a Clinical Review Panel to identify root cause of the incident and make recommendations to prevent the re-occurrence of similar incidents, and to study the possible clinical adverse effect on patients arising from the use of expired sutures respectively. The studies of the two Panels have been completed. According to HA, it was found that the incident was caused by over-procurement of a batch of specialty-based sutures, the existence of different lines of reporting in the operating theatre and the lack of monitoring by personnel involved in the procurement of the medical consumables concerned. After a thorough review on the affected patient cases by the two Panels, it was confirmed that the number of affected patients should be 104. Among these patients, 13 patients had passed away due to their own medical illnesses. Their causes of death were not related to the use of expired sutures. During investigation, the Clinical Review Panel had conducted testing on similar sutures from the supplier which had been expired for six months. The test results on the expired sutures kept in vacuum-sealed packaging on bacteria culture and quality were unremarkable.

5. Based on the above findings, the Root Cause Analysis Panel made the following recommendations -

(a) QEH should enhance the supervision and monitoring of the procurement and inventory control process with strengthening of the expiry alert mechanism;

(b) the management of QEH should review the governance of specialty-based perioperative teams in order to enhance the administrative and managerial functions, and to align the authority and responsibilities of the supervisory personnel; and

(c) a speak-up culture should be cultivated among healthcare workers, and staff consultation opportunities should be available and made known to the front line.

6. The press release concerning the incident issued by QEH on 5 July 2014 and the press release entitled "Queen Elizabeth Hospital investigation reports regarding incident on use of expired surgical sutures on patients" issued by HA on 12 September 2014 are in **Appendices I and II** respectively. According to HA, QEH has accepted and implemented the above recommendations.

Council Business Division 2
Legislative Council Secretariat
16 October 2014

Press Releases *5 July 2014*

QEH uses expired surgical sutures
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The following is issued on behalf of the Hospital Authority:

The spokesperson for Queen Elizabeth Hospital made the following announcement today (July 5) regarding use of expired surgical sutures on patients:

On July 3 (Thursday), a report was made to the Cardiothoracic Surgery Department that between July to December 2013, surgical sutures (proper name: Polyester sutures) with expiry date in June 2013 had been used on patients who had undergone heart surgery. The usual shelf life of these surgical sutures is 4 years. The package was vacuum sealed and sterilised.

The hospital is highly concerned about the incident and has consulted the opinions of infection control experts regarding the risk of using expired sutures. The experts considered that it was improper to use sutures beyond its expiry date; however, they advised that the breach of sterility for briefly expired items depends also on other factors such as storage conditions and whether the packing was intact or not. However, they advised that a pack of such expired sutures not opened before use and properly stored was not likely to be contaminated and the health risk to patients was low. According to practice in operating theatres, the package of sutures usually remains unopened before use.

The number of affected patients is 239, of whom 206 are in stable condition after surgery and the remaining 33 patients had passed away due to their own illnesses. After preliminary assessment by the experts, it was opined that there was no abnormality in post-operation infection when expired sutures were used and hence the cause of death of these 33 patients was not related to the use of these sutures. The hospital is currently contacting all affected patients to arrange for health assessment. Appropriate tests will be arranged if required to ensure patient safety. A 24-hour enquiry hotline 2958 5417 has also been set up for facilitate further enquiries from affected patients and relatives.

Our hospital would like to apologise to all affected patients and the public and will make a thorough investigation with an aim to preventing the happening of similar incidents again. The incident has been reported to the hospital management and Hospital Authority Head Office (HAHO) via "Advance Incident Reporting System". Appropriate actions will be taken according to the human resources policies of the Hospital Authority if needed. The investigation will be completed in six to eight weeks and the report will be submitted to the HAHO.

In the operating theatres, a comprehensive system is in place to ensure safety in the use of medical equipment and products. After the incident, a stock-take exercise in the operating theatres has been conducted to further ensure the quality and safety of medical equipment and products. The hospital has also reminded its staff to stay alert on safety issue of medical supplies.

Ends/Saturday, July 5, 2014
Issued at HKT 19:26

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Press Releases *12 September 2014*

Queen Elizabeth Hospital investigation reports regarding incident on use of expired surgical sutures on patients

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The following is issued on behalf of the Hospital Authority:

The spokesperson for Queen Elizabeth Hospital (QEH) today (September 12) announced the findings of the investigation reports regarding an earlier announced incident on the use of expired surgical sutures on patients.

On July 3, 2014, a report was made to the Cardiothoracic Surgery Department that between July and December 2013, expired surgical sutures (proper name: polyester sutures) with an expiry date in June 2013 had been used on patients who had undergone heart surgery. The usual shelf life of these surgical sutures is five years. The package was vacuum sealed and sterilised.

The hospital was deeply concerned about this incident and set up a Root Cause Analysis Panel and a Clinical Review Panel for investigation (membership lists of the two panels are appended). After thorough investigation, the Root Cause Analysis Panel found that the incident was due to over-procurement of a batch of specialty-based sutures. These expired sutures were subsequently used by nursing staff against the usual nursing standards in perioperative care. The existence of different lines of reporting in the operating theatre and the lack of monitoring by personnel involved in the procurement of the medical consumables concerned also contributed to the occurrence of the incident.

After a thorough review on the affected patient cases by both panels, it was confirmed that the number of affected patients should be 104 instead of 239 as announced earlier on July 5. The patient figures announced earlier were based on preliminary assessment, and were rectified after the hospital arranged more thorough checking on each patient's medical records. Among these 104 patients, 13 had passed away due to their own medical illnesses.

In the process of investigation, the Clinical Review Panel obtained similar sutures which had been expired for six months from the supplier for testing. The test results on the expired sutures kept in vacuum-sealed packaging on bacteria culture and quality were unremarkable. The Clinical Review Panel also thoroughly reviewed the clinical records of the 13 death cases and concluded that their causes of death were not related to the use of expired sutures.

Based on the above findings, the Root Cause Analysis Panel made the following recommendations:

1. The hospital should enhance the supervision and monitoring of the procurement and inventory control process with strengthening of the expiry alert mechanism, particularly for medical consumables that are not included in the Inventory Control System, e.g. slow-moving and specialty-use surgical sutures.

2. The hospital management should review the governance of specialty-based perioperative teams in order to enhance the

administrative and managerial functions, and to align the authority and responsibilities of the supervisory personnel.

3. A speak-up culture should be cultivated among health-care workers, and staff consultation opportunities should be available and made known to the front line.

The QEH Hospital Chief Executive, Dr Albert Lo, said the two reports have been submitted to the Hospital Authority Head Office, while the hospital has accepted and implemented the panel recommendations. On behalf of QEH, Dr Lo apologised to all affected patients and relatives once again. The hospital is contacting the affected patients to explain the details and appropriate tests will be arranged.

Dr Lo remarked that the hospital will follow up in accordance with established human resources procedures. He also expressed gratitude to the Chairmen and Members of the two panels for their endeavours and efforts.

Ends/Friday, September 12, 2014
Issued at HKT 18:34

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(Appendix)

Root Cause Analysis Panel

Chairman
Dr WONG Kit-fai
Deputy Hospital Chief Executive (Corporate Affairs), Queen Elizabeth Hospital

Members
Dr Rebecca LAM
Chief Manager (Patient Safety & Risk Management), Hospital Authority

Ms Sylvia WONG
Department Operations Manager (Operation Theatre Services), Queen Mary Hospital

Ms May YIP
Chief Supplies Officer (Procurement Information System and Technology), Hospital Authority

Ms Rebecca FONG
Department Operations Manager, Hong Kong Eye Hospital

Ms Angela WONG
Senior Manager (Patient Safety), Queen Elizabeth Hospital

Clinical Review Panel

Chairman
Professor Paul LAI Bo-san
Acting Chairman & Professor (Surgery), The Chinese University of Hong Kong

Members
Dr Vincent CHENG
Infection Control Officer, Hong Kong West Cluster /
Consultant (Microbiology), Queen Mary Hospital

Dr TSANG Kin-keung
Consultant (Medicine), Tseung Kwan O Hospital

Dr CHEUNG Hung-leong
Consultant (Cardiothoracic Surgery), Queen Elizabeth Hospital

Dr NG Wing-shun
Associate Consultant (Cardiothoracic Surgery), Queen Elizabeth Hospital

Ms Angela WONG
Senior Manager (Patient Safety), Queen Elizabeth Hospital