中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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7 October 2015

Ms Maisie LAM
Clerk to Panel
Panel on Health Services
Legislative Council Complex
1, Legislative Council Road
Central

Dear Ms LAM,

Panel on Health Services

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

At the meeting of the Panel on 20 October 2014 on the captioned, the Panel requested that supplementary information be provided. Having consulted the Hospital Authority (HA), I provide the relevant information in the ensuing paragraphs.

(a) Measures to ensure safety in the use of medical equipment and products and the monitoring mechanism in place to ensure that the established guidelines were followed

2. HA has set up the Central Technology Office (CTO) under the Quality & Safety Division to coordinate and align 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 solicits professional inputs from Clinical Coordinating / Central Committees on equipment safety.

3. HA requires all medical equipment 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.

4. 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.

5. HA will keep a close eye on the implementation of the above measures and consider further improvement measures as necessary to ensure patient safety.

(b) A summary of the findings and recommendations of the Root Cause Analysis Panel on the incident concerning the use of expired surgical sutures at the Queen Elizabeth Hospital

6. Queen Elizabeth Hospital established a Root Cause Analysis Panel and a Clinical Review Panel to investigate the incident and to make recommendation concerning the use of expired surgical sutures. The findings of the investigation are as follows –

(a) the incident was due to over-procurement of a batch of specialty-based sutures;

(b) these expired sutures were subsequently used by nursing staff against the nursing standards in perioperative care;

(c) there had been different lines of reporting in the operating

theatre;

(d) there had been lack of monitoring in the procurement of the implicated medical consumables;

(e) among the affected 104 patients, 13 had passed away and their death was due to their own medical illnesses;

(f) manufacturer of the suture had been consulted and they commented that "the sterility of a recent expired product is not expected to be compromised, especially when the packaging of the product remains intact";

(g) microbiology tests conducted by the Public Health Laboratory Centre of the Department of Health revealed no bacterial growth; and

(h) tensile strength of the expired sutures have no significant difference from the non-expired sutures, as tested and confirmed by the Department of Mechanical and Automation Engineering at the Chinese University of Hong Kong .

7. The recommendations made by the panels are as follows –

(a) the hospital should enhance the supervision and monitoring of the procurement and inventory control process by strengthening 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;

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

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

(d) follow-up assessment of those surviving patients.

8. HA has followed up with all the recommendations accordingly.

Yours sincerely,

(Patrick LEE)
for Secretary for Food and Health

cc: Chief Executive, HA (Attn: Ms Emily Chan)