# 立法會
# *Legislative Council*

LC Paper No. CB(2)1608/16-17(04)

Ref : CB2/PL/HS

**Panel on Health Services**

**Background brief prepared by the Legislative Council Secretariat for the meeting on 19 June 2017**

**Mechanism for handling medical incidents in public and private hospitals**

## Purpose

This paper summarizes the concerns of members of the Panel on Health Services ("the Panel") on the mechanism for handling medical incidents in public and private hospitals.

## Background

Mechanism for handling medical incidents in public hospitals

2. In October 2007, the Hospital Authority ("HA") implemented a Sentinel Event Policy to standardize the practice and procedures for handling sentinel events in all public hospital clusters, thereby strengthening the reporting, management and monitoring of sentinel events in public hospitals. It was further revised to become the Sentinel and Serious Untoward Event Policy ("the Policy") in January 2010, under which a sentinel event is defined as an "unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof" and a serious untoward event is defined as an "unexpected occurrence which could have led to death or permanent harm". The list of the nine types of sentinel events and the two types of serious untoward events for reporting under the Policy are in **Appendix I**.

3. Under the Policy, clusters or hospitals are required to report to HA Head Office through the Advance Incident Report System any medical incidents classified as sentinel events or serious untoward events within 24 hours of their identification. The clusters or hospitals concerned should at the same time handle the incident in accordance with established procedures so as to minimize

any harm caused to the patient concerned and provide support to the staff involved in the incident. For sentinel events, HA Head Office will appoint a Root Cause Analysis Panel ("RCA Panel"), comprising members from the root cause analysis team of the hospital concerned, respective Coordinating Committees, external senior clinicians, HA Head Office coordinator and/or lay persons from Hospital Governing Committee, to investigate the root causes of the events for risk identification and implementation of improvement measures. As regards serious untoward events, the hospital concerned will form an RCA Panel. The RCA Panel shall submit the final investigation report to the HA Head Office within eight weeks' time.

4. Each year, the HA Head Office will submit to the HA Board a report on sentinel and serious untoward events. The report will also be published in public.[1] Internally, HA facilitates the healthcare professionals to share among themselves the experience of handling medical incidents through staff training and the quarterly "Risk Alert" newsletter.

Mechanism for handling medical incidents in private hospitals

5. The Department of Health ("DH") is responsible for the registration of private hospitals in Hong Kong. The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) empowers the Director of Health to register private hospitals subject to conditions relating to the accommodation, staffing or equipment. As the registration authority, DH monitors the performance of private hospitals by conducting routine and surprise inspections, and handling complaints lodged by the general public against private hospitals.

6. To enhance patient safety and quality of health care services provided by private hospitals, DH issued a "Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes" ("the Code") in August 2003. The latest edition of the Code was issued in December 2016.[2] The Code sets out the standards of good practice for, among others, private hospitals to adopt in order to provide quality care to patients. Under the Code, private hospitals should comply with the requirements on the management of medical incidents. The requirements include, among others, designation of a senior staff to co-ordinate the immediate response to the incident, establishment of procedures to communicate to senior staff, patients and their families, regulatory authorities and media the nature of incidents, investigation into and audit after the incidents, and implementation of recommendations to prevent future occurrence of similar incidents. At present, private hospitals are required to report, within 24 hours, to the Director of

---

1 The annual reports on sentinel and serious untoward events can be accessed at the website of HA (http://www.ha.org.hk/report/sentinel_event).

2 The latest edition of the Code can be accessed at the website of DH (http://www.dh.gov.hk/english/main/main_orphf/files/code_english.pdf).

Health ("DoH") the occurrence of those medical incidents falling into specified categories of sentinel events and serious untoward events, with full investigation report be submitted to DoH within four weeks. The list of reportable events is in **Appendix II**.

7. Upon receipt of the notification, DH will gather preliminary information from the hospital and ensure that it will conduct investigation into the event. DH will also consider disclosing details of the event to the public if it has major impact on the public healthcare system, or if it constitutes a persistent public health risk or involves a large number of patients. DH may also pay site visits to the hospital to gather more information relating to the event and conduct its own investigation if it is considered that the event constitutes a high public risk.

## Deliberations of the Panel

8. The Panel discussed issues relating to the mechanism for handling medical incidents in public and private hospitals at a number of meetings between 2007 and 2017. The deliberations and concerns of members are summarized below.

Reporting and disclosure of sentinel events

9. Question was raised as to whether there was any international standard classification of sentinel events. According to HA, there was no international standard classification of sentinel events. The categories and definitions of sentinel events under the Policy were modelled largely on the sentinel event reporting mechanism of Western Australia.

10. Noting that private hospitals were allowed to develop their own mechanisms to manage medical incidents, members were concerned about the discrepancies among private hospitals in handling the incidents. The Administration advised that it was supportive of rolling out hospital accreditation to both public and private hospitals. A set of uniform Hong Kong accreditation standards had been developed by the Australian Council on Healthcare Standards for measuring the performance of both public and private hospitals in various aspects covering, among others, the management of medical incidents. A total of 30 public hospitals and most private hospitals had participated in hospital accreditation.

11. Members considered that the hospitals concerned should, upon reporting a sentinel or untoward event within 24 hours, at the same time inform patients' family members of the details of the incidents and provide them with suitable assistance. They noted that HA would obtain the consent of patients and/or

their family members before disclosing the incident to the public. After investigation, meetings would be arranged with patients and/or their family members to explain the outcomes of the investigation before releasing them to the public. Measures would be taken to ensure that the identity of the patients would be protected. Question was raised as to whether information disclosed by the frontline staff to the investigation panel was subject to legal privilege under the Policy. There was also a concern that in deciding whether to make public a sentinel event, HA would do so if the event had an immediate major impact on the public or involved a patient's death, whereas DH would do so if the event was of significant public health impact or on-going public health risk.

12. HA advised that appropriate level of confidentiality would be applied to the root cause analysis report to protect the identity of patients and staff concerned. In line with the existing practice for the investigation of all adverse medical incidents, HA would first seek legal opinion before providing any confidential information so requested. As regards the case of private hospitals, members were subsequently advised that the Administration would introduce a new piece of legislation, namely the Private Healthcare Facilities Bill ("the Bill"), for the purposes of revamping the regulatory regime for, among others, private hospitals ("the new regulatory regime"). It was proposed that, among other things, private hospitals should have a comprehensive sentinel events management system. During the public consultation exercise conducted on the regulatory regime, concern was raised on the protection of personal data of the individuals affected in medical incidents.

Occurrence rate of medical incidents

13. Question was raised about the occurrence rate of medical incidents in public and private hospitals. The Administration advised that it was difficult to compare the performance of public and private hospitals given the variations in their policies and mechanisms to identify, report and manage medical incidents. Nevertheless, the Administration considered that the introduction of hospital accreditation in Hong Kong would enhance the transparency and accountability of both public and private hospitals, including their standards with regard to the management of medical incidents.

14. On the level performance of public hospitals in Hong Kong as compared with other developed countries in terms of the ratio of sentinel events to service volume, members did not subscribe to the Administration's view that it was difficult to make a direct comparison between local medical incidents statistics with those in other countries because of the differences in the mechanisms and culture of reporting medical incidents. In their views, HA should conduct a comparison on an item-by-item basis with a view to measuring the performance of public hospitals on each category of the sentinel and serious untoward events.

HA, however, considered it more appropriate to study the general trend, rather than the absolute figure, of each category of incidents so as to identify improvement measures to avoid the recurrence of the incidents.

Contributing factors of medical incidents

15. Members were gravely concerned that the number of sentinel and serious untoward events in public hospitals had not been significantly reduced after the implementation and revision of the Sentinel Event Policy in 2007 and 2010 respectively. Concern was raised over the reported cases of medication error resulting in major permanent loss of function or death; retained instruments or other materials after surgery or interventional procedures, as well as maternal death. Question was raised as to whether the increased complexity of the surgical procedures and variety of equipment used during the procedures had contributed to an increase in the number of the sentinel event involving retained instruments after surgery. Members also cast doubt on the effectiveness of the existing mechanism for sentinel and serious untoward event management in HA.

16. HA advised that given the complex healthcare settings, it would be difficult for hospitals to attain zero medical incidents. HA had put in place a clinical governance structure to safeguard the standard of care and improve service quality. Initiatives, such as extension of the reporting criteria to cover all serious untoward events relating to medication error and patient misidentification, were also implemented to further improve the mechanism for handling medical incidents in public hospitals. In addition, measures were introduced to enhance medication safety and surgical safety, such as the electronic Inpatient Medication Order Entry System[3] to automate and check the prescription and dispensing of drugs, and the "Surgical Safety Checklist"[4] in all operating theatres.

17. Members considered that HA should conduct detailed analysis on each medical incident to formulate improvement measures to avoid recurrence of a similar incident. The Administration advised that HA would set up RCA Panel to identify root causes and contributing factors of the reported incidents. At the central level, the clinical coordinating committee of the specialty concerned would look into each incident to review whether relevant systems and work

---

[3] The System was implemented in 12 acute hospitals. According to the Administration, it would be rolled out to the remaining three acute hospitals by the end of 2017-2018 with the exception of Kwong Wah Hospital which would launch the system upon completion of its redevelopment project.

[4] The Checklist involved the "Time-out" process whereby the entire clinical team in the operation theatre takes an explicit moment of pause to check and verify the identity of patient, go through the procedure to be performed and consider any anticipated critical events before undertaking an operation.

procedures need to be improved. Lessons learnt and improvement measures identified would be shared among the healthcare professionals.

18. Members were concerned as to whether healthcare manpower constraint, high turnover rate of experienced doctors, and human error were the common root cause of medical incidents in public hospitals. Some members urged HA to recruit more part-time doctors and non-local doctors by way of limited registration to further increase manpower strength in public hospitals, and take steps to alleviate the work pressure on frontline doctors in public hospitals.

19. According to the Administration, the root cause of each incident varied, which covered areas such as experience of doctors, communication amongst disciplines for emergency management of critically ill patients and manpower shortage issues. Remedial measures would be implemented to address the leading causes of the medical incidents. To address manpower needs, HA had implemented a series of measures to attract and retain doctors and nurses. These included, among others, a Special Retired and Rehire Scheme to re-employ suitable serving clinical doctors and nurses upon their retirement and a Special Honorarium Scheme to encourage healthcare staff to work extra hours on a voluntary basis. On the other hand, the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development would release its report in June 2017 to provide recommendations on, among others, ways to meet the projected demand for healthcare manpower.

Disciplinary actions and penalties

20. Members noted that HA would, where appropriate, take appropriate disciplinary actions having regard to the circumstances of individual medical incidents. Types of disciplinary actions included verbal warning, written warning, stoppage of increment, deferment of increment and dismissal, etc. There was a concern as to whether HA would refer cases concerning professional conduct of its doctors involved in sentinel events to the Medical Council of Hong Kong ("the Medical Council") for disciplinary inquiry.

21. HA advised that for each sentinel event reported to HA Head Office, the issue of whether there was a case of possible professional misconduct of the doctor(s) concerned and the need to provide the relevant information to the Medical Council for follow up would be considered under HA's human resources proceedings. HA, however, stressed that many medical incidents were caused by system rather than human factors, and only those acts which had fallen short of the standards expected among members of the profession would be regarded as misconduct in a professional respect.

22. Members noted that private hospitals would not be penalized for failing to comply with the Code. They held the view that sanctions should be imposed on private hospitals for non-compliance with the requirements on management of medical incidents, and for repetitive occurrence of medical incidents of similar nature. The Administration advised that the new regulatory regime would cover, among others, regulatory measures to tackle with breaches of the law and licensing requirements including codes of practice. These regulatory tools, such as powers for suspension of service or even cancellation of licence, would enable DH to better regulate private hospitals. The Administration would also stipulate in the Bill offences to deter serious and intentional non-compliance under the new regime. Licensees and chief medical executives, who played significant roles in managing private healthcare facilities, could be subject to sanctions for certain contraventions.

**Recent developments**

23. On 9 May 2017, the United Christian Hospital ("UCH") announced a serious untoward event involving an medication error.[5] While UCH had identified the error on 6 April 2017, it only met with and explained the clinical course of the patient to the patient's family upon their enquiry on 19 and 21 April 2017. In addition, UCH failed to report to HA Head Office the serious untoward event within 24 hours of its identification as required under the Policy. The serious untoward event has aroused wide public concern over the handling of medical incidents by public hospitals and the effectiveness of the Policy.

24. On 10 May 2017, HA announced the setting up of an independent panel to conduct a comprehensive review of the Policy. According to the press release issued by HA on 11 May 2017, the independent panel would undertake the tasks of (a) reviewing the definition and scope of sentinel and serious untoward event in relation to clinical incidents with international benchmarking; (b) reviewing the sentinel and serious untoward event reporting mechanism; (c) reviewing the mechanism of open disclosure and public disclosure; and (d) making recommendations for follow up actions as appropriate. It was expected that the independent panel would submit its report to the HA Board in eight weeks' time.

---

[5] On 6 April 2017, the clinical department of UCH reviewed the medical record of a 43-year-old female patient who was transferred to Queen Mary Hospital for liver transplant assessment and subsequently underwent two separate liver transplant surgeries. It was found that being unaware of the patient's hepatitis B carrier status, the medical staff of renal specialist outpatient clinic did not prescribed antiviral prophylaxis when the patient started on steroid in January 2017. According to clinical experience, doctors generally consider prescribing antiviral prophylaxis together with high-dose steroid therapy for Hepatitis B carrier in order to reduce the risk of acute hepatitis flare-up.

25. At the Council meeting of 31 May 2017, an oral question was raised on medical incidents in public hospitals. The question and the Administration's reply are in **Appendix III**.

26. The Administration will brief the Panel on the mechanism for handling medical incidents in public and private hospitals on 19 June 2017.

**Relevant papers**

27. A list of the relevant papers on the Legislative Council website is in **Appendix IV**.

Council Business Division 2
Legislative Council Secretariat
16 June 2017

**Appendix I**

## Medical events to be reported under HA's Sentinel and Serious Untoward Event Policy

### Sentinel events

1. Surgery / interventional procedure involving the wrong patient or body part
2. Retained instruments or other material after surgery / interventional procedure
3. ABO incompatibility blood transfusion
4. Medication error resulting in major permanent loss of function or death
5. Intravascular gas embolism resulting in death or neurological damage
6. Death of an in-patient from suicide (including home leave)
7. Maternal death or serious morbidity associated with labour or delivery
8. Infant discharged to wrong family or infant abduction
9. Other adverse events resulting in permanent loss of function or death (excluding complications)

### Serious untoward events

1. Medication error which could have led to death or permanent harm
2. Patient misidentification which could have led to death or permanent harm

*Source: Hospital Authority's Annual Report on Sentinel and Serious Untoward Events (October 2015 to September 2016)*

**Appendix II**

## List of events to be reported by private hospitals

### Sentinel events

1. Surgery / interventional procedure involving the wrong patient or body part
2. Retained instruments or other material after surgery / interventional procedure
3. ABO incompatibility blood transfusion
4. Medication error resulting in major permanent loss of function or death
5. Intravascular gas embolism resulting in death or neurological damage
6. Death of an in-patient from suicide (including home leave)
7. Maternal death or serious morbidity associated with labour or delivery
8. Infant discharged to wrong family or infant abduction
9. Other adverse events resulting in permanent loss of function or death (excluding complications)

### Serious untoward events

1. Medication error which could have led to death or permanent harm or carries a significant public health risk
2. Patient misidentification which could have led to death or permanent harm

*Source: Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes issued by the Department of Health (December 2016 edition)*

# Press Releases

LCQ6: Medical incidents in public hospitals
**********

Following is a question by the Dr Hon Helena Wong and a reply by the Secretary for Food and Health, Dr Ko Wing-man, in the Legislative Council today (May 31):

Question:

The Hospital Authority (HA) has adopted a sentinel event reporting mechanism since 2007 and added two types of serious untoward events to the mechanism since 2010. Under the mechanism, public hospitals must report such events to the HA Head Office within 24 hours. On the other hand, when two doctors in the Renal Specialist Outpatient Clinic of the United Christian Hospital (UCH) provided high-dose steroid treatments to a hepatitis B (HBV) carrier in January and February this year respectively, they did not concurrently prescribe antiviral prophylaxis to reduce the risk of acute hepatitis flare-up triggered by steroid treatments. Subsequently, the patient suffered from acute hepatitis and underwent two liver transplant surgeries. UCH had all along not reported the event since uncovering this serious untoward event on the 6th of last month, and it did so only after the patient's family made enquiries on the 19th of last month. UCH then made public the event on the 9th of this month. In addition, it has been reported that such nephrologists are not authorised to prescribe hepatology drugs, and they have to refer such cases to the relevant specialists or more senior doctors for decision. In this connection, will the Government inform this Council if it knows:

(1) the number of cases, in each year since HA's adoption of the sentinel event reporting mechanism, in which public hospitals failed to comply with the requirements of reporting such events within 24 hours and details of such cases (including the names of the hospitals involved and whether the staff members involved in delayed reporting on such events were punished); whether HA will conduct an investigation to see if there were events in the past 10 years which have so far not been reported but should have been reported as required, and announce the investigation outcome; if HA will, of the details; if not, the reasons for that;

(2) whether HA will conduct a comprehensive investigation to ascertain whether there were cases, other than the aforesaid UCH incident, in the past 10 years in various public hospitals in which patients were not prescribed anti-HBV prophylaxis despite medical needs and subsequently suffered from acute hepatitis; if HA will, of the details; if not, the reasons for that; and

(3) whether HA will review and relax the restrictions currently imposed on specialists' prescribing drugs of other specialties so as to avoid delays in treatment for patients; if so, of the details; if not, the reasons for that?

Reply:

President,

The Food and Health Bureau (FHB) and the Hospital Authority (HA) are highly concerned about the event mentioned in the question. An independent root cause analysis panel has been set up by the United Christian Hospital (UCH) to investigate the hospital's clinical management of the patient and its communication with the patient and her family, as well as to make recommendations on improvement measures to prevent any recurrence. Apart from the investigation into this event, the HA has also established an independent review panel to conduct a comprehensive review of the current Sentinel and Serious Untoward Event Policy (the Policy), which covers examination of the definition and scope of sentinel and serious untoward events related to clinical incidents, reporting mechanism, as well as notification and announcement mechanisms. The review panel will make recommendations to the HA on follow-up actions according to the findings.

Both panels have commenced their work. The root cause analysis panel is expected to complete its work in mid-June, while the one reviewing the Policy will submit its report to HA Board in early July. The FHB and the HA are closely monitoring the progress of the panels and, with reference to the findings, will formulate improvement measures to ensure implementation and compliance of the Policy, with particular emphasis on the timeliness of notification and announcement.

My reply to the various parts of the question is as follows:

(1) Since the implementation of the Policy by the HA in 2007, about 80% of cases were reported within 24 hours. The remaining cases could not be reported within 24 hours mainly because they were more complicated that the hospitals and clusters concerned might need more time to gather information from the staff members, patients and their family members and to maintain close liaison with relevant departments before determining the nature and category of the events and reporting the cases.

As for cases which are not reported within the time specified, HA Head Office will seek explanation from the clusters and hospitals concerned and conduct reviews to ensure that all hospitals and clusters report the cases to HA Head Office via the Advanced Incident Reporting System (AIRS) within 24 hours and handle the cases in accordance with the established procedures.

In case of any medical incidents, the hospitals concerned should report the incidents, including those outside the scope of specified sentinel and serious untoward events to be reported, to HA Head Office via the AIRS. The hospitals and clusters concerned and HA Head Office will take appropriate actions, such as conducting investigation and reviews, having regard to the nature of the incidents. Where necessary, the HA will appoint an expert panel to conduct detailed analysis with a view to identifying the possible causes of the incidents, and exploring and formulating improvement measures.

By implementing the Policy, the HA intends to encourage its staff to report sentinel and serious untoward events in a timely and open manner to facilitate early investigation so that lessons can be learnt from the events to prevent the recurrence of similar incidents in the future. Hence, instead of releasing the number of sentinel and serious untoward events of individual hospitals, the HA announces the overall figures of all hospitals through its "Risk Alert" and the Annual Report on Sentinel and Serious Untoward Events.

As I have mentioned above, the HA has nevertheless established an independent review panel to conduct a comprehensive review of the Policy, which covers examination on the definition and scope of the events related to clinical incidents, reporting mechanism as well as notification and announcement mechanisms. The review panel will make

recommendations to the HA on follow-up actions according to the findings.

(2) In the past 10 years, HA Head Office received a total of three reported cases related to medical incidents in which patients were not prescribed anti-HBV prophylaxis and subsequently suffered from acute hepatitis. The first two cases were investigated and analysed by the respective root cause analysis panels, and later published in the HA's "Risk Alert". The third case is under investigation.

(3) With the advancement of medical technologies, new drugs come into the market from time to time. These drugs are proven to vary in safety, efficacy and cost-effectiveness, as well as their side effects and health outcome. The HA Drug Formulary (HADF) was put in place with a view to ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy through standardisation of policies on drugs and drug utilisation in public hospitals and clinics. In the HADF, general drugs are those with well-established indications and effectiveness available for general use as indicated by relevant clinical conditions, while special drugs are those used under specific clinical conditions with specific specialist authorisation to ensure the safety and efficacy of the drugs used by different specialties.

The HA currently sets out guidelines on the clinical specialties recommended for drug prescription for each type of special drugs as well as the clinical indications of the drugs. The Cluster or the Hospital Drug and Therapeutics Committees may include additional clinical specialties internally for drug prescription for operational needs. Specialists other than those recommended clinical specialties may also prescribe special drugs according to the clinical needs of individual patients upon consultation with the latter. The HA reviews, on a regular basis, the HADF, the clinical indications of various drugs and the clinical specialties recommended for drug prescription, to ensure that its clinical services and drug utilisation can keep up with the latest development of medical technology and scientific evidence. The HA also reviews the prevailing procedures in accordance with the established mechanism to facilitate prescription of special drugs by the specialists concerned.

Ends/Wednesday, May 31, 2017
Issued at HKT 16:12

**Appendix IV**

**Relevant papers on the mechanism for handling medical incidents in public and private hospitals**

| Committee | Date of meeting | Paper |
|---|---|---|
| Panel on Health Services | 10.12.2007 (Item V) | Agenda<br>Minutes |
| | 9.11.2009 (Item IV) | Agenda<br>Minutes<br>CB(2)647/09-10(01) |
| | 14.6.2010 (Item IV) | Agenda<br>Minutes |
| | 14.11.2011 (Item V) | Agenda<br>Minutes |
| | 9.1.2012 (Item IV) | Agenda<br>Minutes<br>CB(2)1764/11-12(01) |
| | 21.7.2014 (Item II) | Agenda<br>Minutes |
| | 13.1.2015 (Item I) | Agenda<br>Minutes |
| | 16.2.2015 (Item IV) | Agenda<br>Minutes<br>CB(2)147/15-16(01) |
| | 17.2.2015 (Item I) | Agenda<br>Minutes |
| | 18.4.2016 (Item V) | Agenda<br>Minutes |
| | 26.1.2017 (Item I) | Agenda<br>Minutes |

| Committee | Date of meeting | Paper |
|---|---|---|
| Panel on Health Services | 28.2.2017 (Item VI) | Agenda |

Council Business Division 2
Legislative Council Secretariat
16 June 2017