

**For Information
on 11 May 2010**

Legislative Council Panel on Health Services

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

PURPOSE

This paper updates Members on the mechanism for handling medical incidents in public and private hospitals.

MECHANISM FOR HANDLING MEDICAL INCIDENTS IN PUBLIC HOSPITALS

Sentinel and Serious Untoward Event Policy

2. The Hospital Authority (HA) has all along attached great importance to the quality of its services and patient safety. It has put in place an established system and guidelines for conducting clinical audits and for the reporting and handling of medical incidents. It has also been promoting a patient centered and learning culture among staff and encouraging staff to report medical incident in a timely and open manner and share their experience in handling medical incidents.

3. On reporting of medical incidents, HA has implemented in October 2007 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. Under the policy, clusters / hospitals are required to report to the HA Head Office any medical incidents classified as sentinel events within 24 hours. They should at the same time handle the incident properly in accordance with the established procedures so as to minimize any possible harm caused to patients and at the same time provide support to the staff involved in the incident. For cases with immediate major impact to the public or involving patients' death, HA will consider disclosing the events to the public.

4. The hospital concerned will also investigate the causes of the event and submit a report to the HA Head Office, which is responsible for monitoring and coordinating the handling of sentinel events as well as implementation of necessary improvements on systems and work procedures at the corporate level. After consideration of the findings in the reports, improvements will be made to the relevant systems and work procedures where necessary with a view to avoiding recurrence of similar incidents in future.

5. As a further improvement to the mechanism for the reporting and handling of medical incidents, HA has implemented since 1 January 2010 a revised sentinel and serious untoward event policy. Under the revised policy, in addition to medical incidents classified as sentinel events, all serious untoward events (which are unexpected events possibly leading to death or serious physical or psychological injury) relating to medication error and patient misidentification would need to be reported by the clusters / hospitals concerned. The list of sentinel and serious untoward events to be reported under the revised policy is set out in **Annex A**.

6. Following the same general principle for handling sentinel events, a serious untoward event will be dealt with properly so as to minimize the harm caused to the patient and provide support to staff involved in the incident. For all sentinel and serious untoward events, the hospital involved would submit an initial report to the HA Head Office in two weeks' time and a final report in eight weeks' time. HA will appoint a panel to investigate the root causes of the events for risk identification and implementation of improvement measures. It will also ensure proper disclosure of these events to the public.

Statistics of sentinel events in HA

7. The HA Head Office compiles every six months a report on sentinel event for submission to the HA Board and release to the public. Through staff training and HA's bi-monthly "Risk Alert" newsletter, HA staff in different clusters could also share and learn from colleagues' experience in handling sentinel events.

8. A total of 44 sentinel events were reported for the period from 1 October 2007 to 30 September 2008 and the number was reduced to 40 for the

period from 1 October 2008 to 30 September 2009. The details are set out in **Annex B**. For medical incidents reported from 1 October 2009 to 30 March 2010, the investigation of some of the cases is still in progress and HA will release the relevant information in due course in accordance with the established mechanism.

Other improvement measures

9. Apart from revising the mechanism for the reporting and handling of medical incidents, HA has implemented other initiatives to further enhance patient safety. For instance, HA has adopted the patient safety round as one of the tools for risk identification at departmental, hospital and cluster levels. Patient safety round is an internationally adopted approach to provide direct communication between management and frontline staff to identify risks and explore improvement measures to reduce adverse medical events and enhance patient safety. In HA, senior management of hospitals, clusters and HA Head Office will lead the rounds and listen to the frontline staff on their concerns and suggestions regarding protocols and procedures in their daily work settings. The HA Head Office has also identified specific areas for conducting safety rounds with cluster management and set up regular platforms for communication, feedback and recommendations across different disciplines and specialties.

10. The use of appropriate technology also plays an important role in enhancing patient safety. HA has adopted the use of 2D barcode extensively to enhance patient identification and avoid human errors such as mix up of blood specimens. HA has also initiated pilot projects on the use of radiofrequency in mortuary services to ensure correct identification of deceased bodies.

MECHANISM FOR HANDLING MEDICAL INCIDENTS IN PRIVATE HOSPITALS

11. 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.

12. 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 Code sets out the standards of good practice for private hospitals to adopt in order to provide quality care to patients. These standards include the need for a private hospital to ensure that services provided are of quality and appropriate to the needs of patients, requirements on the management of staff and management of the premises and services, protection of the rights of patients and their right to know, the setting up of a system to deal with complaints and requirements on the management of medical incidents, etc. The Code also includes requirements on specific types of clinical and support services.

13. Under the Code, private hospitals should comply with the requirements on the management of medical incidents. The requirements include designation of a senior staff to co-ordinate the immediate response to the incident, establishment of procedures to communicate to patients and their families the nature of incidents and follow-up actions, and investigation into the incidents.

14. DH is regularly reviewing the scope of services offered by private hospitals and updates the Code according to latest developments. The Code has been revised in November 2009 and April 2010 incorporating requirements on Accident and Emergency Services, Endoscopy Service and Chinese Medicine Service. Requirements have also added to tighten up control over the care of patients. For example, Section 8.2.6 stipulates that “Patients should be properly assessed by a medical practitioner prior to undergoing any intervention.”

Reporting of incidents

15. With effect from 1 February 2007, DH requires all private hospitals to report sentinel events within 24 hours upon occurrence of the event.

16. The primary objective of requiring the reporting of sentinel events is to identify areas for improvement in the quality and safety of healthcare services. Through the reporting system, DH monitors the operation of private

hospitals and ensures that they take prompt actions in accordance to established mechanisms so as to minimise the harm caused to the patients. The hospitals concerned are also required to investigate into the root causes of the event and take remedial actions with a view to reducing the probability of recurrence of such event in the future.

17. Under the reporting system of DH, private hospitals are required to develop their own policies and mechanisms to identify, report and manage sentinel events. Upon receipt of the notification, a copy of the policies and procedural guidelines has to be submitted to DH when requested. Thereafter, DH will request the hospital to provide evidence for implementation for such policies and procedural guidelines and will conduct spot check during inspections.

Investigation Procedures

18. Upon receipt of the notification, DH will gather preliminary information from the hospital and ensure that it will conduct investigations into the event. DH will also consider disclosing details of an event to the public if it has major impact on the public health care system, or if it constitutes a persistent public health risk or involves a large number of patients. DH may also pay site visit 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 health risk.

19. In addition to timely notification, the private hospital concerned is also required to submit to DH a full investigation report within 4 weeks of the occurrence of the event. The full investigation report should indicate whether a credible root cause of the event has been identified. It should also include a remedial action plan setting out the proposed improvement measures, and tender evidence to substantiate the effectiveness of the implementation of such measures. In addition, the report should state the mechanism to be put in place for monitoring the implementation of the improvement measures.

20. All investigation reports will be studied by DH in depth, and the sentinel events and their causes will be classified upon review. To further enhance the understanding of private hospitals on the underlying problems of sentinel events, DH will analyse and collate information on these events and

compile an annual report which will be issued to all private hospitals. The annual report contains relevant statistics and recommendations from DH on how the quality and safety of healthcare services should be improved in order to prevent similar incidents from happening in the future. DH will follow up on the implementation of the recommendations during subsequent inspections.

Latest Development of the SE Reporting System

21. DH has recently reviewed and revised the SE Reporting System with a view to further facilitating data analysis and enhancing comparability of relevant data with that of the Hospital Authority. Key features include a revised list of reportable SE, the adoption of a three-tier public announcement strategy and routine dissemination of SE information to the public. The revised list of reportable SE (**Annex C**) is in line with HA's classification and has been in use since January 2010.

22. DH also considers it prudent to release information of SEs reported by private hospitals to the general public. In doing so, DH aims to strike a good balance between public's right to know and patient privacy. The arrangement for public announcement to release information related to SEs is set out at **Annex D**.

Statistics on reported incidents in private hospitals

23. There are 13 private hospitals as at 1 April 2010. From 2007 to 2010 (as at 31 March), DH received 39, 33, 52 and 5 SEs from the private hospitals respectively. The details are set out in **Annex E**.

COMPARISON OF THE NUMBER OF MEDICAL INCIDENTS IN HONG KONG AND OVERSEAS JURISDICTIONS

24. The frequency of reported medical incidents in Hong Kong (including public and private sectors) is not high as compared with Australia. A comparison of the number of medical incidents in Hong Kong and Australia is set out in **Annex F**. It should be noted that not many regions/countries adopt the same or similar level of reporting on medical incidents as in Hong Kong and therefore it is difficult to make a direct comparison on the frequency of medical

incidents of Hong Kong with other jurisdictions.

OTHER MECHANISM

Hospital Accreditation

25. Hospital accreditation is widely adopted internationally as a useful measure to improve the quality of healthcare services. To further enhance patient safety and the quality of healthcare institutions in Hong Kong, HA has engaged an Australian consultant to launch a pilot scheme for accreditation of five public hospitals in Hong Kong in April 2009. At the same time, three private hospitals have participated in the pilot scheme.

26. One of the key objectives of the pilot scheme is to develop a set of common hospital accreditation standards for measuring the performance of both public and private hospitals in various aspects in the long run. The set of common standards will include standards with regard to the management of medical incidents and complaints, and the commitment to continuous quality improvement. Through participating in the accreditation process, it is expected that both public and private hospitals' accountability to service quality and safety will be strengthened, and that public confidence in the quality of healthcare will be enhanced.

27. The accreditation process under the pilot scheme is in good progress. One private hospital has been awarded the accreditation status in March 2010 and it is envisaged that the remaining participating hospitals would be accredited in 2010/11.

ADVICE SOUGHT

28. Members are invited to note the content of the paper.

Food and Health Bureau
Hospital Authority
Department of Health
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**Types of events that are required 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

Annex B

**Number of Sentinel Events in HA
(1 October 2007 to 30 September 2009)**

| | Reportable Sentinel Events | From 1 October 2007 to 30 September 2008 | From 1 October 2008 to 30 September 2009 | Total |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------|-----------|
| 1 | Surgery / interventional procedure involving the wrong patient or body part | 5 | 10 | 15 |
| 2 | Retained instruments or other material after surgery / interventional procedure requiring re-operation or further surgical procedure | 10 | 13 | 23 |
| 3 | Haemolytic blood transfusion reaction resulting from ABO incompatibility | 1 | 0 | 1 |
| 4 | Medication error resulting in major permanent loss of function or death of a patient | 0 | 0 | 0 |
| 5 | Intravascular gas embolism resulting in death or neurological damage | 0 | 0 | 0 |
| 6 | Death of an inpatient from suicide (including suicide committed during home leave) | 25 | 15 | 40 |
| 7 | Maternal death or serious morbidity associated with labour or delivery | 1 | 2 | 3 |
| 8 | Infant discharged to wrong family or infant abduction | 1 | 0 | 1 |
| 9 | Unexpected deaths or serious disability reasonably believed to be preventable (not related to the natural course of the individual's illness or underlying condition) | 1 | 0 | 1 |
| | Total | 44 | 40 | 84 |

List of Sentinel Events to be reported by private hospitals

| No | Categories of Sentinel Event |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| <i>Events that leads to death/serious outcomes</i> | |
| 1 | Surgery or interventional procedure involving wrong patient or wrong body part |
| 2 | Unintended retention of instruments or other materials after surgery or interventional procedures |
| 3 | Transfusion reaction arising from incompatibility of blood/blood products |
| 4 | Medication error involving death or serious injury |
| 5 | Intravascular gas embolism resulting in death or serious injury |
| 6 | Death of an in-patient from suicide |
| 7 | Unanticipated maternal death or serious maternal injury associated with labour or delivery and occurring within 42 days after delivery |
| 8 | Infant discharged to wrong family or infant abduction |
| 9 | Unanticipated death or serious injury of a full-term infant within 7 days after birth |
| 10 | Unanticipated death or serious injury that occurs during or within 48 hours after operation or interventional procedures |
| <i>Unanticipated events that possibly lead to death or serious injury/possess significant public health risk</i> | |
| 11 | Medication error that carries a significant public health risk |
| 12 | Patient misidentification which could have led to death or serious injury |
| <i>Others</i> | |
| 13 | Any other events that have resulted in unanticipated death or serious injury, or with significant public health risk |

Arrangement of public announcement of sentinel events in private hospitals

1. *Public announcement by the Department of Health (DH)*

- SE that fulfill the following criteria will be announced by DH upon receipt of notification from private hospitals:-
 - a. Significant public health impact
 - b. Ongoing public health risk
 - c. Preventable by immediate action
- Examples include the followings (the list is not exhaustive):-
 - a. Medication error arising from systemic cause and affecting a number of patients
 - b. Using a batch of contaminated surgical instruments

2. *Public announcement by individual hospital*

- Individual hospital will respond to the media concerning SE that fulfill the following criteria:-
 - a. Unanticipated death cases of any of the reportable SE
 - b. Unanticipated serious morbidity of any of the reportable SE

3. *Dissemination of aggregated data*

- All SE will be uploaded onto DH website on a quarterly basis

Breakdown of sentinel events in private hospitals

| | 2007 | 2008 | 2009 | 2010 (as at 31 March) |
|-----------------------------------------------------------------------------------------------------------------------|-----------|-----------|------------|--------------------------------|
| Unanticipated death or serious injury or complications during or shortly after operation or interventional procedures | 11 | 12 | 15 | 2 |
| Maternal death/serious maternal injury* | 2 (2) | 8 (6) | 12 (11) | 2 (1) |
| Perinatal death/ serious injury** | 14 (9) | 4 (4) | 19 (14) | 1(1) |
| Unintended retention of foreign bodies after surgery or interventional procedures | 1 | 2 | 1 | 0 |
| Wrong site surgery/interventional procedures | 0 | 1 | 1 | 0 |
| Others | 11 | 6 | 4 | 0 |
| Total | 39 | 33 | 52 | 5 |

* Include cases of non-fatal postpartum hemorrhage (as shown in brackets)

** Include cases of Fractured Clavicles/Humerus/Femur/Skull bone in newborns (as shown in brackets)]

**Comparison of the number of medical incidents
in Hong Kong and Australia**

| | 2007-08 | 2008-09 |
|---------------------------------------------------------------------|------------------------|----------------|
| Hong Kong | | |
| HA hospitals | 44 | 40 |
| Private hospitals | 39 (2007) 33 (2008) | 52 (2009) |
| Total population | 6.96 Million | 7 Million |
| Overseas jurisdictions | | |
| Victoria, Australia (including public and private sectors) | 102 | 68 |
| Total population of Victoria, Australia | 5.27 Million | 5.4 Million |
| Western Australia, Australia (including public and private sectors) | 81 | 90 |
| Total population of Western Australia, Australia | 2.15 Million | 2.22 Million |