HALF YEARLY REPORT ON SENTINEL & SERIOUS UNTOWARD EVENTS

1 October 2010 – 31 March 2011

HOSPITAL AUTHORITY HONG KONG

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醫院管理局
HOSPITAL AUTHORITY

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ACKNOWLEDGEMENT

We would like to express our greatest appreciation of the continuous support from all frontline colleagues, clinicians, executives of hospitals, and colleagues of cluster quality and risk management departments in improving patient safety in the Hospital Authority. We would also like to thank them for their invaluable advice and contributions to the production of this report for learning and sharing.

Patient Safety and Risk Management Department
Quality & Safety Division

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EXECUTIVE SUMMARY

The Hospital Authority (HA) has implemented the Sentinel Event Policy since 1 October 2007, which was further revised to become "The Sentinel and Serious Untoward Event Policy" (The Policy) on 1 January 2010. The Policy now requires the reporting, response to and management of Sentinel Events (SEs) as well as Serious Untoward Events (SUEs) relating to patient misidentification and medication incidents. It aims at raising awareness of clinical risks among colleagues and identifying gaps or deficiencies in our healthcare system with a view to working out safer designs and processes.

2. Under the Policy, an SE is defined as an "unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof"; and an SUE as an "unexpected occurrence which could have led to death or permanent harm". This half-yearly report covers the reported sentinel and serious untoward events occurring in the period from 1 October 2010 to 31 March 2011. A total of 23 SEs and 47 SUEs were reported during this period.

3. "Death of an inpatient from suicide (including home leave)" ranked top among all categories of SEs (11 out of 23 cases or 47.8%). The second most common category of SEs was "retained instruments or other material after surgery / interventional procedure" (9 cases; 39.1%). This was followed by "surgery / interventional procedure involving the wrong patient or body part" (2 cases; 8.7%).

4. Out of the 23 reported SEs, 12 were classified as having "extreme consequences" where the patients died (including 11 cases of patient suicide and one maternal death associated with delivery); one was classified as having "major" consequences; and another 10 as "minor" or "insignificant".

5. Out of the 47 reported SUEs, 42 (89.4%) were related to medication error and 5 (10.6%) to patient misidentification. Ten cases (21.3%) had "major" or "moderate" consequences and 37 cases (78.7%) "minor" or "insignificant".

6. A Root Cause Analysis (RCA) Panel was set up for each SE/ SUE to identify root causes and make recommendations for continuous improvement and risk management. The lessons learned from RCA and the recommendations on preventing recurrence of these events were shared with all staff in the half-yearly Patient Safety Forum, quarterly (previously bi-monthly) "HA Risk Alert" (HARA) Newsletter and Half-yearly / Annual Report on Sentinel and Serious Untoward Events. To facilitate access to the education materials, the HARA Newsletters are available on designated HA intranet and internet web pages.

7. This report represents the conjoint efforts of frontline colleagues, hospital management, as well as executives in quality and risk management departments of hospitals and clusters, and the HA Head Office (HAHO).

CHAPTER 1 – INTRODUCTION

8. The fundamental principle of all healthcare processes is to do no harm. The HA has been striving to ensure patient safety, and enhance standard of care through different risk reduction and quality improvement programs. It not only delivers services that satisfy the medical needs of patients in Hong Kong but also builds a healthcare system trusted by the community.

9. "To err is human", hence risks cannot be completely eradicated from the healthcare system; but should be avoided, minimized and managed. HA has since January 2010 adopted the Sentinel and Serious Untoward Event Policy (The Policy), which superseded the previous Sentinel Event Policy implemented in October 2007. To widen the scope of risk identification, a category of Serious Untoward Events (SUEs) has been included in the Policy. This category refers to adverse events which could have led to permanent harm or death in a patient but have fortunately not resulted in dire injury either because the worst consequence of the error has not occurred or because the error has been spotted and remedied in time. As such, an incident which arises from medication error or patient misidentification fulfilling such criteria must be reported as SUE.

10. The Policy guides HA in incident reporting, open disclosure and management of near misses and adverse events. In the process of incident management, examinations of current system are carried out, followed by thorough investigations and

identification of root causes. Improvement actions are then formulated and lessons learned are shared through various means, including this half-yearly publication, HARA, and other education forums, so as to raise staff awareness and minimize recurrence of similar events.

11. This Half-yearly Report is a summary of all sentinel and serious untoward events reported by HA hospitals from 1 October 2010 to 31 March 2011. The Report included a review of all reported cases as well as recommended risk reduction measures and learning points identified through root cause analyses.

CHAPTER 2 – SENTINEL AND SERIOUS UNTOWARD EVENT POLICY

12. The Policy came into effect on 1 January 2010 to supersede the Sentinel Event Policy implemented in October 2007.

Sentinel Events (9 Categories)	
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 inpatient 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 (2 Categories)	
1	Medication error which could have led to death or permanent harm
2	Patient misidentification which could have led to death or permanent harm

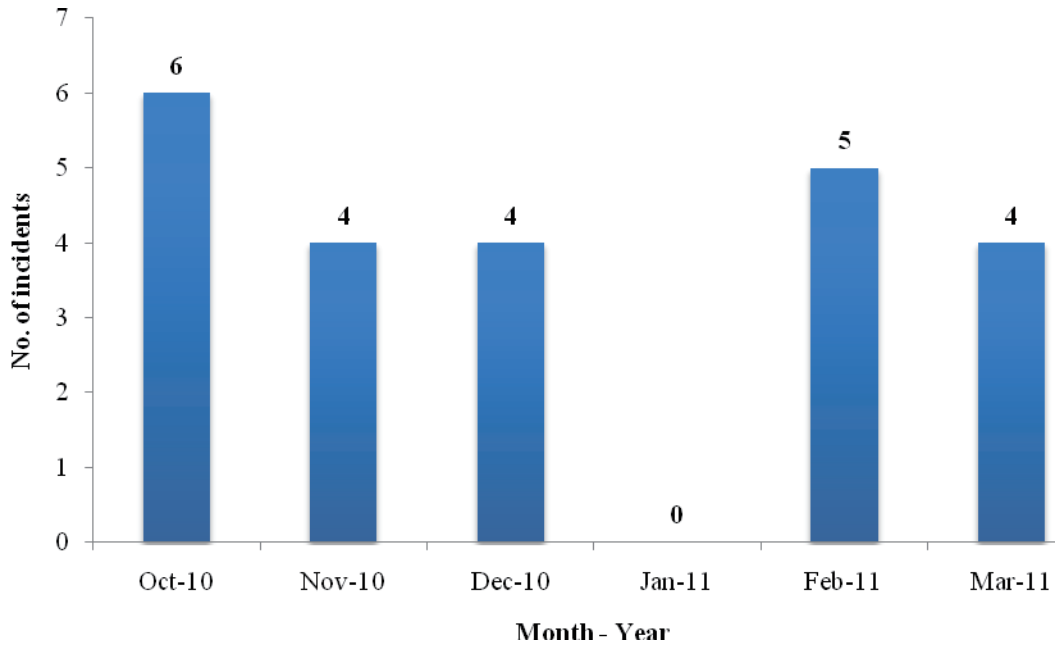
13. The Policy provides a framework for the reporting, response to and management of SEs and SUEs. The hospital management is required to report SEs and SUEs, and HAHO will appoint a RCA panel to investigate the event and recommend improvement measures. The hospitals are required to implement the improvement measures and report progress to HAHO.

CHAPTER 3 – SENTINEL EVENTS REPORTED FROM 1 OCTOBER 2010 TO 31 MARCH 2011

Frequency of Reportable SEs

14. A total of 23 SEs were reported from 1 October 2010 to 31 March 2011. The number of reportable SEs by month is shown in Figure 1.

Figure 1: Reportable Sentinel Events by Month



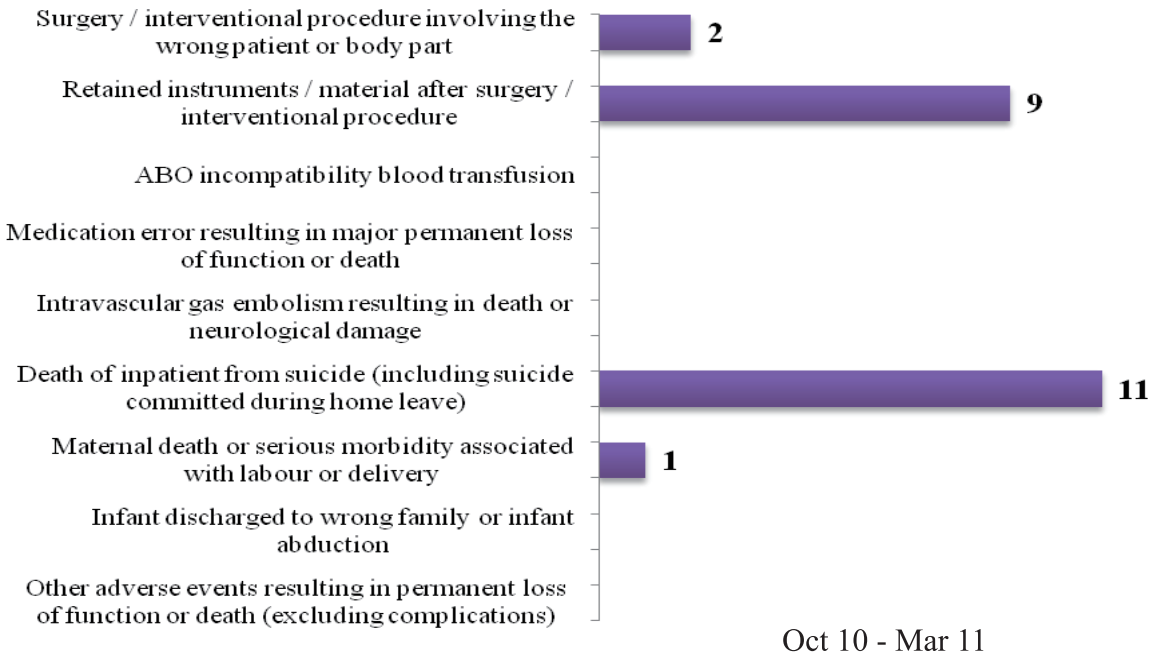
The rate of reportable SEs for these 6 months was 1.9 per 1,000,000 episodes of patient discharges and deaths / attendances[1].

[1] Including total inpatient and outpatient discharges as well as deaths and ambulatory service attendances as defined in the HA Controlling Officer's report: Vol. 1B, 2010-2011.

Breakdown of Reportable SEs by Category

15. A breakdown of the number of SEs by category in these 6 months is shown in Figure 2, and the SEs are presented as percentages in Figure 3.

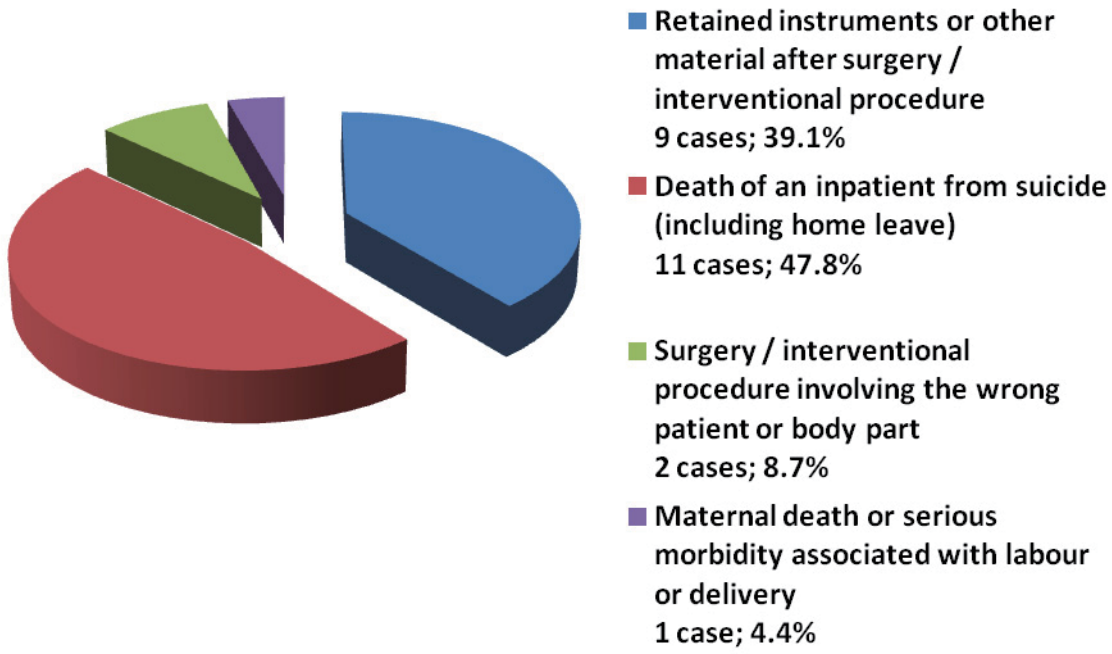
Figure 2: Breakdown of Sentinel Events by Category



16. The most commonly reported category of SEs, making a total of 11 incidents (47.8%), was "death of inpatient from suicide (including suicide committed during home leave)". The second most commonly reported category was "retained instruments or material after surgery / interventional procedure" with a total of 9 incidents (39.1%). The third most commonly reported SE was "surgery / interventional procedure involving the wrong patient or body part" and 2 incidents

(8.7%) were reported.

Figure 3: Distribution of Sentinel Events from 1 October 2010 to 31 March 2011



- **Death of an inpatient from suicide (including home leave): 11 cases (47.8%)**
  - 5 patients (45.5%) committed suicide during home leave, 5 (45.5%) committed suicide while staying in hospital and 1 missing patient (9%) committed suicide outside hospital compound; and
  - 8 out of the 11 patients had terminal cancer or chronic illnesses and 3 had mental illness.

- **Retained instruments or other material after surgery / interventional procedure: 9 cases (39.1%)**
  - Retention of surgical gauzes or fragments of sponge: 3 cases;
  - Retention of segment of tubing: 1 case;

- Retention of mini-vessel clip: 1 case; and
- Retention of instrument or other material (a fragment of suture shuttle needle, broken tip of screw holder, a segment of Sagittal Saw Blade, a segment of radio-opaque material): 4 cases.

- **Surgery or interventional procedure involving the wrong patient or body part: 2 cases (8.7%)**
  - Local anaesthetic was injected into the wrong eye; and
  - Catheterization was performed on the wrong patient.

- **Maternal death or serious morbidity associated with labour or delivery: 1 cases (4.4%)**
  - One case of maternal death (massive acute intracranial haemorrhage) associated with labour or delivery.

Outcome of Reported Sentinel Events

17. The outcome of reported events was as follows:

- Minor or insignificant consequence: 10 cases (43.5%);
- Major / moderate consequence: 1 cases (4.4%);
- Extreme consequence (i.e. death): 12 cases (52.1%);
  - Patient suicide: 11 cases; and
  - Maternal death associated with labour or delivery: 1 case.

Hospital Settings where Sentinel Events Occurred

18. Of all reported SEs in the reporting period, 86.9% occurred in general hospitals (Table 1).

Table 1: Setting Where Sentinel Events Occurred

Setting	No. of SEs (%)
General hospitals	20 (86.9 %)
Psychiatric units within general hospital	2 (8.7 %)
Psychiatric hospitals	1 (4.3 %)

19. The occurrence of SEs in the past three and half years from 1 October 2007 to 31 March 2011 is depicted in Table 2.

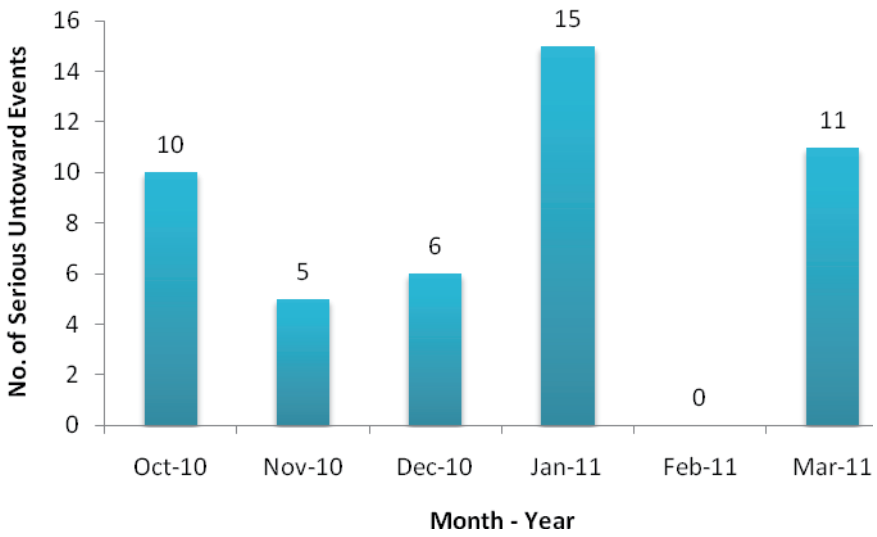
Table 2: Comparison of Occurrence of Sentinel Events from 1 Oct 07 to 31 Mar 11

Category of Sentinel Events	1-Oct-07 to 31-Mar-08	1-Apr-08 to 30-Sep-08	1-Oct-08 to 31-Mar-09	1-Apr-09 to 30-Sep-09	1-Oct-09 to 31-Mar-10	1-Apr-10 to 30-Sep-10	1-Oct-10 to 31-Mar-11	Total number
1. Surgery / interventional procedure involving the wrong patient or body part	3	2	5	5	3	2	2	22
2. Retained instruments or other material after surgery / interventional procedure requiring re-operation or further surgical procedure	5	5	7	6	10	2	9	44
3. ABO incompatibility blood transfusion	0	1	0	0	0	0	0	1
4. Medication error resulting in major permanent loss of function or death	0	0	0	0	0	1	0	1
5. Intravascular gas embolism resulting in death or neurological damage	0	0	0	0	0	1	0	1
6. Death of an in-patient from suicide (including home leave)	12	13	11	4	5	6	11	62
7. Maternal death or serious morbidity associated with labour or delivery	1	0	2	0	2	0	1	6
8. Infant discharged to wrong family or infant abduction	1	0	0	0	0	0	0	1
9. Other adverse events resulting in permanent loss of function or death (excluding complications)	1	0	0	0	0	1	0	2
Total Number	**23**	**21**	**25**	**15**	**20**	**13**	**23**	**140**

CHAPTER 4 – SERIOUS UNTOWARD EVENTS REPORTED FROM 1 OCTOBER 2010 TO 31 MARCH 2011

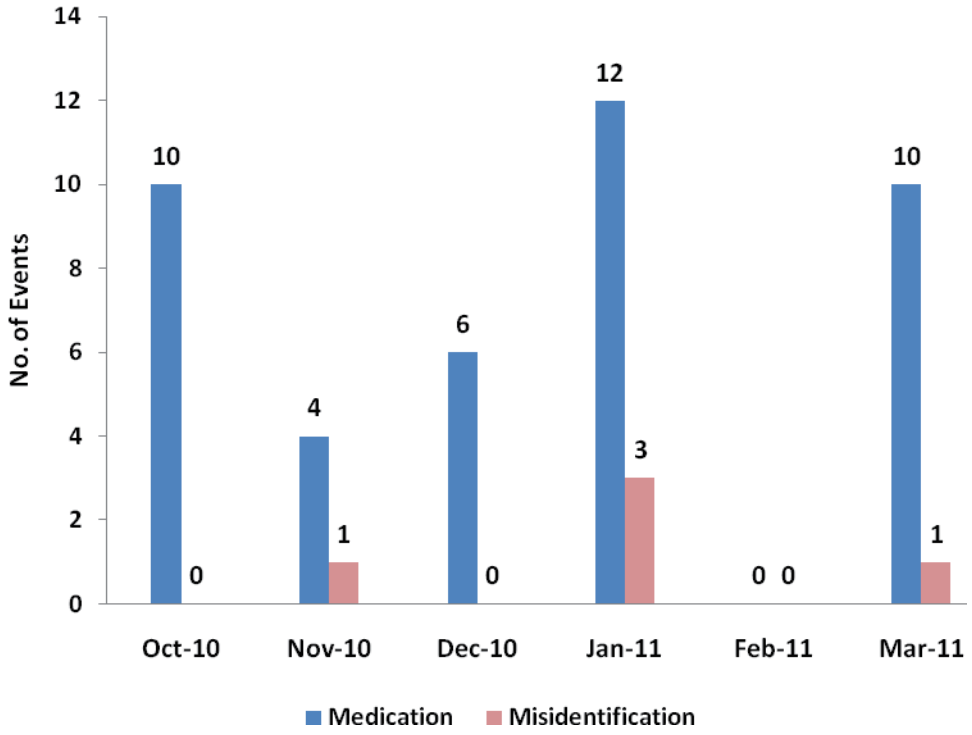
20. A total of 47 SUEs were reported from 1 October 2010 to 31 March 2011. The number of reported SUEs by month is shown in Figure 4.

Figure 4: Monthly Number of Reported Serious Untoward Events



21. A breakdown of reported SUEs revealed that 42 cases (89.4%) were due to medication error and 5 (10.6%) patient misidentification (Figure 5).

Figure 5: Breakdown of Serious Untoward Events from 1 October 2010 to 31 March 2011



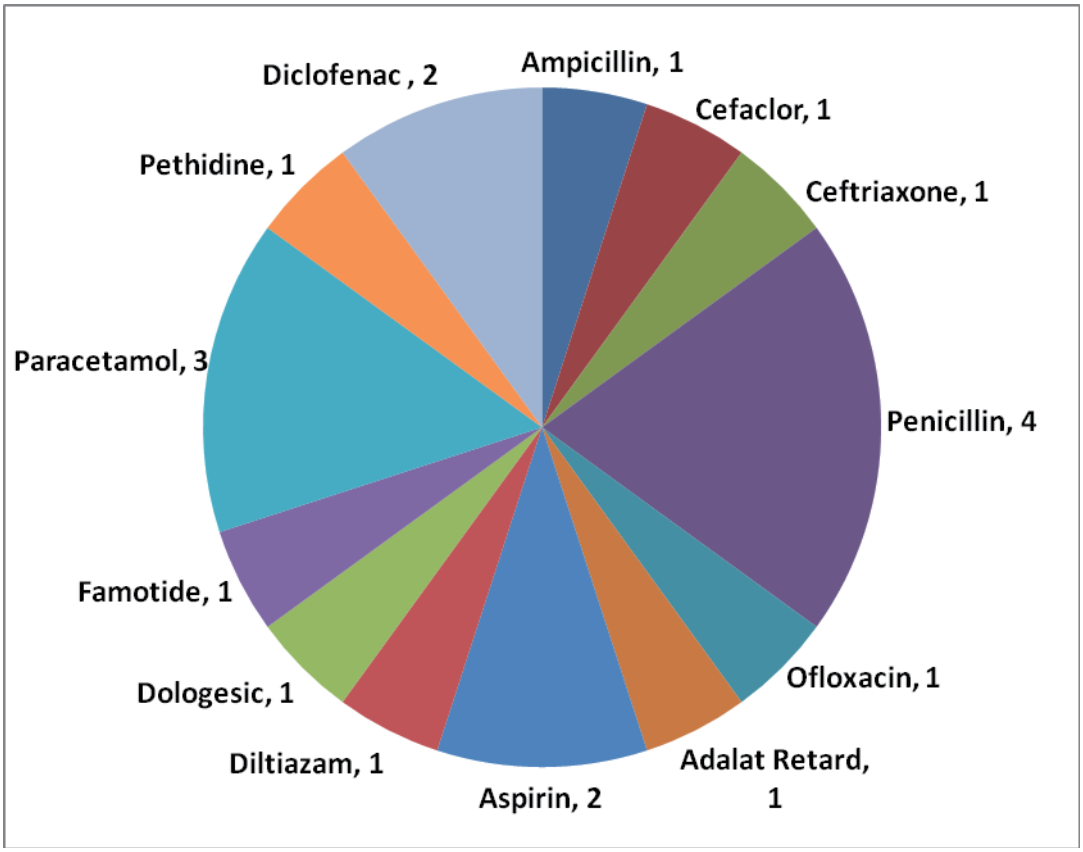
SUEs from Medication Error

22. Of the most commonly reported SUEs due to medication error (42 cases), 20 cases (47.6%) were related to the prescription or administration of "Known Drug Allergy" (KDA) drugs. This was followed by medication error involving "dangerous drugs" (10 cases; 23.8%), "anticoagulants" (5 cases; 11.9%), "hypoglycaemic agents" (3 cases; 7.1%) and other medications (4 cases; 9.5%).

23. Out of the 20 cases related to KDA drugs, the most commonly involved drugs were: (i) Penicillins (4 cases; 20%); (ii) Dologesic / Paracetamol (4 cases; 20%); (iii) Diclofenac (2 cases; 10%); and (iv) Aspirin (2 cases; 10%). Almost 60% of the total

KDA incidents were related to the penicillin group and analgesics agents. The number of KDA drugs involved is depicted in Figure 6 below:

Figure 6: Distribution of Prescribed or Administered KDA Drugs



24. The majority of patients who were given "KDA" drugs had no allergic symptoms. A few patients presented with mild rashes after taking these drugs.

SUEs from Patient Misidentification

25. A total of 5 SUEs due to patient misidentification were reported. These included incidents of misidentification of patients in the clinical management systems or

misfiling of laboratory results in patients' notes leading to prescription of inappropriate treatment. The types of patient misidentification incidents are summarized in Table 3 below:

Table 3: Distribution of Misidentification Incidents

Description	4Q10	1Q11
Misidentification of patient during dispensing	1	0
Misidentification of patient during drug administration	0	1
Misidentification of patient in clinical systems e.g. Corporate Drug Dispensing History(CDDH), Electronic Patient Record (ePR) summary	0	2
Misfiling of patient's laboratory report leading to inappropriate or unnecessary treatment	0	1

Outcome of Reported Serious Untoward Events

26. The outcome of reported events was as follows:

- Minor or insignificant consequence: 37 cases (78.7%);
- Moderate consequence (required higher level of care): 8 cases (17%);
- Temporary major consequence (including hypotension and hypoglycemia): 2 cases (4.3%).

CHAPTER 5 – ACTIONS TAKEN AND DISCUSSION

Analysis of Reported Sentinel Events

Sentinel Event Reporting

29. A total of 23 SEs were reported in the past 6 months (1 October 2010 to 31 March 2011) within the HA. In Australia, the Victorian Department of Health Services received 68 reports of SEs in 2008-2009[2]. The Western Australia Department of Health received 47 reports of SEs in 2009 – 2010[3]. In the United States, the Joint Commission received 802 reports of SEs in 2010[4]. Though there is currently no international benchmarking for an 'appropriate' or 'acceptable' level of sentinel event reporting, the number of SEs reported in our series is similar to overseas healthcare systems serving population of similar size.

Types of Sentinel Events Reported

30. "Death of an inpatient from suicide (including home leave)" was the most commonly reported SEs (11/23 cases; 47.8%). "Retained instruments or other material after surgery / interventional procedure" was the second most commonly reported SEs (9/23 cases; 39.1%) while "surgery / interventional procedure involving the wrong patient or body part" ranked third (2/23 cases; 8.7%) and "maternal death or serious

[2] The Victorian Department of Health Service, sentinel event program, annual report 2008-09.
[3] The Western Australia Department of Health, sentinel event report 2009-2010.
[4] The US Joint Commission, sentinel event statistic: as of 31 December, 2010.

morbidity associated with labour or delivery" ranked fourth (1/23 case; 4.4%).

31. "Retained instruments", "inpatient suicide", and "wrong patient or site operated" were also the most common SEs reported to the Joint Commission, the Victoria Department of Health Service of Australia, and the Western Australia Department of Health. In Victoria, 7 out of 68 (10.3%) SEs were inpatient suicides and 3 (4.4%) were retained instrument or material. In Western Australia, 4 out of 47 (8.5%) SEs were retained instrument or material and 3 (6.4%) were inpatient suicides. There are, however, differences in criteria for reportable suicides in Hong Kong, Victoria and Western Australia. In Hong Kong, reportable inpatient suicides include suicides committed during home leave whilst in Australia only suicides committed in inpatient units are to be reported.

32. According to the World Health Organization (WHO), approximately one million people died from suicide with a global mortality rate of 16 per 100,000 populations in the year 2000[5]. In Hong Kong, the suicide rate has increased from 11.8 per 100,000 populations in 1995 to 15.2 in 2006[6].

Contributing Factors for Sentinel Events

33. The HAHO appoints a Root Cause Analysis Panel for every SE to conduct investigation and analysis, identify root causes and contributing factors as well as recommend appropriate improvement measures to prevent recurrence of similar SEs in future. In the United States of America, Victoria and Western Australia, the top

[5] World Health Organization: suicide prevention (SUPRE).
[6] World Health Organization: suicide rates, by gender, China, Hong Kong SAR, 1995-2006.

contributing factors were policies / procedures, human factors and communication. Despite the small number of SEs reported in HA, ineffective or inadequate communication and failure to comply with guidelines and policies were identified as important factors in causing these events. The key contributing factors for each category of incidents are summarized below:

- **Key contributing factors for "death of an inpatient from suicide (including home leave)"**

  Apart from the underlying medical conditions of patients and their mental health conditions (e.g. depression from terminal or chronic illnesses) which are the most important factors, the following are other factors that may have contributed in varying degrees to a patient's suicide:

  - Sudden change of a patient's mental conditions and behavior;
  - Change of the psychological conditions in patients with terminal illness;
  - Inadequate patient suicidal risk assessment;
  - Inadequate awareness of the psychological needs of high risk patients; and
  - Existence of environmental risks which may facilitate patients' suicidal acts.

- **Key contributing factors for "retained instruments or material"**

  - Difficulty in detecting tiny dislodged fragment of instrument;
  - Integrity checking was not performed when disassembling instruments before wound closure;
  - The number of soaked sponge prepared and applied to the operation site might be counted inaccurately due to difficulty in counting wet sponge;
  - The number and type of gauzes put into the wound cavity were not

documented;

- Inadequate communication on the number and type of gauzes used;
- Inadequate awareness of the risk that Raytec gauze could stick to cement and detach during removal; and
- Insufficient communication when encountering difficulty in gauze removal.

- **Key contributing factors for "surgery / interventional procedure involving the wrong patient or body part"**
  - The surgeon was distracted by activities between the time-out procedure and the operation; and
  - Patient identification procedure was not performed before intervention.

- **Key contributing factors for "maternal death"**
  - No specific contributing factors could be identified in the reported case of maternal death.

Risk reduction measures

34. The HAHO has collaborated with clusters and hospitals to redesign relevant healthcare systems and work processes to prevent recurrence of SEs. The risk reduction measures introduced are outlined below:

- **Death of an inpatient from suicide (including home leave)**
  - Enhance suicidal risk assessment and staff awareness of patient suicide in hospital;

- Strengthen communication with patients' family members on suicidal precaution during hospitalization;
- Conduct environmental scanning and modify facilities and environment to reduce suicidal risks;
- Enhance control of patient access at ward entrance or exit;
- Encourage appropriate referral of patients to clinical psychologists or psychiatrists for early intervention and risk mitigation; and
- Explore appropriate community support for home / day leave patients.

- **Retained instruments or other material after surgery / interventional procedure**
  - Change clinical practice of wound packing by using gauze roll instead of individual piece of gauze and leaving a tail of the gauze outside the wound after wound packing to facilitate subsequent gauze removal;
  - Reinforce the standard counting procedures and surgical safety policy;
  - Complete the final count of all accountable items before patients leave the operating room;
  - Strengthen the sign out process of the Surgical Safety Checklist;
  - Verify instrument integrity both before and after each operation;
  - Alert staff on the possibility of instrument breakage;
  - Consider sourcing an alternative model of sagittal saw hand piece and blade;
  - Use a designated container to hold sponges prepared for eye operation and count them when they are dry.
  - Count both the used and unused sponges after the operation for verification against the total number of sponges prepared for the operation;

- Reinforce proper documentation of the number and type of gauzes packed into and removed from a wound cavity;
- Enhance training and bedside supervision of doctors and nurses on documentation of wound management;
- Explore suitable product to replace the use of Raytec gauze in preventing seepage of cement during orthopaedic operation; and
- Intensify gauze integrity verification when using gauze in the presence of cement.

- **Surgery / interventional procedure involving the wrong patient or body part**
  - Reconfirm the site of procedure when there are distractions or extended time lapse between the time-out procedure and the operation / procedure.
  - Reinforce patient identification before performing a procedure; and
  - Check patient's identity with open-end questions.

- **Maternal death or serious morbidity associated with labour or delivery**

  Hospitals should be vigilant of and should take appropriate measures to prevent, detect and manage potential major obstetric complications for women with high risk pregnancy.

Analysis of Reported Serious Untoward Events

35. Out of the 47 SUEs reported from 1 October 2010 to 31 March 2011, 42 cases (89.4%) were related to medication error and 5 (10.6%) misidentification of patient or

patient's record / report leading to inappropriate treatment.

36. Of the 42 medication error cases, 20 were related to prescription and administration of (KDA) drugs to patients. There were only minor consequences in these cases. The key contributing factors were:

- The patient's allergy history was not verified against CMS during prescription and administration;
- The pharmacy checking system was bypassed by administering ward-stock drugs, left-over drugs from discharged patients;
- Illegible writing of allergy drug items;
- The practice of drug administration was not performed according to the drug administration policy; and
- The prescribed drug was not recognized as the same drug group (e.g. Ciprofloxacin and Ofloxacin; Toradol and Diclofenac) to which the patient was allergic.

37. Four cases of SUEs were related to medication error involving hypoglycaemic agents. The key contributing factor was:

- Failure to comply with the standard checking procedures during dispensing and drug administration.

38. Five cases of SUEs were related to medication error resulting from the use of anticoagulants. The key contributing factors were:

- Preparing the incorrect strength of drug for infusion;
- Failure to check the infusion rate;
- Failure to communicate on the drug used for administration; and

- Transcription error and staff being un-familiar with the operation of Medication Order Entry (MOE).

39. Ten cases of SUEs were related to medication error arising from administration of dangerous drugs (extra dose, wrong rate and wrong drug), and 4 other medications. The key contributing factors were:

- Failure to properly conduct "3 Checks 5 Rights" during drug administration;
- Inadequate communication in verbal order;
- Incomplete checking / reviewing of drug infusion in duty hand-over;
- Incomplete counter-checking of intravenous infusion; and
- Failure to confirm the exact dose to be administered.

40. Five cases of SUEs were related to misidentification of a patient or a patient's record / laboratory report leading to prescription of inappropriate or unnecessary treatments. The key contributing factors were:

- Failure of the Critical Result Alert System to retrieve the patient's latest demographics from the Patient Master Index;
- Inadequate communication between nursing staff in duty hand-over;
- Failure to verify the identification of the patient; and
- Failure to match correct patient record / laboratory report with the correct patient.

Learning and Sharing

41. To promote learning and sharing, salient information on all SEs and SUEs, contributing factors and learning points have been shared in the HARA, a newsletter first published in November 2007 which became a quarterly publication since January 2011. Abstracts of local and global healthcare risk alerts are also published in each issue of HARA to raise staff awareness and promote patient safety.

CHAPTER 6 – CONCLUSION

42. The consequences of serious incidents to patients, their relatives, and healthcare workers could be devastating and long lasting. It is therefore HA's priority to promote and sustain a safe healthcare environment for both our patients and staff.

43. The quest for quality and patient safety is challenging yet rewarding. Concerted effort by multi-disciplinary and inter-disciplinary teams of staff with the common goal of striving for better quality and greater safety is of utmost importance in building a safe environment in HA hospitals. Let us work together to cultivate a patient safety culture, to enhance our healthcare systems by supporting the practice of reporting and managing near misses / incidents, and share lessons learned in accordance with the Sentinel and Serious Untoward Event Policy.

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