ANNUAL REPORT ON SENTINEL AND SERIOUS UNTOWARD EVENTS

1 October 2009 – 30 September 2010

HOSPITAL AUTHORITY HONG KONG

January 2011

醫院管理局
HOSPITAL AUTHORITY

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ACKNOWLEDGEMENT

We would like to express our deepest appreciation of the unfailing support from all frontline colleagues, hospital risk managers, clinicians, executives of hospitals, and colleagues of cluster quality and risk management departments in improving patient safety. We would also like to thank them for their invaluable feedback and contributions in the publication of this report for learning and sharing.

Patient Safety and Risk Management Department
Quality & Safety Division

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Hospital Authority (HA) has implemented the Sentinel Event Policy since 1 October 2007 to enhance the reporting, response and management of sentinel events (SE). Two years after implementation, the policy was reviewed and revised and became "The Sentinel and Serious Untoward Event Policy" (The Policy) on 1 January 2010. It now requires also the reporting of Serious Untoward Events (SUEs) relating to patient misidentification and medication incidents. It aims at raising awareness of clinical risk among colleagues and stimulates their innovative thinking for safe designs and processes so as to improve patient safety.

2. The Policy defines SE as an "unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof", and SUE as an "unexpected occurrence which could have led to death or permanent harm". This annual report covers the reported sentinel and serious untoward events occurring from 1 October 2009 to 30 September 2010. A total of 33 SEs and 81 SUEs were reported during this period.

3. "Retained instruments or other material after surgery / interventional procedure" ranked top among all categories (12 out of 33 cases or 36.4%). The second most common category of SE was "death of an inpatient from suicide (including home leave)" (11 cases; 33.3%). This was followed by "surgery / interventional procedure involving the wrong patient or body part" (5 cases; 15.2%).

4. Out of the 33 reported SEs: (i) 15 were classified as having "extreme consequences" and the patient involved died. These included 11 cases of patient suicide; 2 maternal deaths associated with deliveries; 1 death caused by medication error; and 1 unexpected death resulting from an adverse event; (ii) 9 were classified as having "major" or "moderate" consequences; and (iii) another 9 as "minor" or "insignificant".

5. Among the 81 reported serious untoward events, 72 (88.9%) were related to medication error and 9 (11.1%) to patient misidentification. Sixty-two cases (76.5%) had "minor" or "insignificant" consequences and 19 (23.5%) "moderate" or "major".

6. A Root Cause Analysis (RCA) Panel was set up for each SE/ SUE to identify the root causes and make recommendations for improvement and risk management. The HA had shared the lessons learnt from root cause analysis as well as the recommendations on preventing recurrence of these events with all staff in the half yearly Patient Safety Forum and bi-monthly "HA Risk Alert" (HARA) Newsletter. To facilitate access to such information, the HARA Newsletters are available on the designated HA intranet and internet web pages.

7. There was a 17.5 % decrease in the occurrence of SEs in 2009/10, namely 33 SEs compared with 40 in 2008/ 09. The reduction is mainly attributed to the drop of cases in "surgery on wrong patient or body part" (5 cases less than 2008/09) and "patient suicide" (4 cases less than 2008/09).

8. By conducting RCA of individual sentinel events, we can identify the risks and contributing factors which can facilitate management at all levels to develop strategies and means to mitigate, control or manage the risk. Since risks are inherent in our complex hospital environment, working in collaboration with cluster executives, managers and frontline staff is paramount to the continuous nurturing of safety culture.

9. This report represents the conjoint efforts of colleagues in the frontline and hospital management, as well as executives in quality and risk management department of hospitals, clusters and the Head Office.

CHAPTER 1 – INTRODUCTION

10. **"First do no harm"** is the fundamental principle of all healthcare organizations. The HA's strategic intent of **"better service quality and safer service"** is also in line with this principle. Harm could be caused by clinical risks hidden in the process of delivering patient care and by environmental hazards. They must be avoided, minimized or controlled. It is imperative to adopt and reinforce a proactive approach to manage risk before it results in harm to patients.

11. In line with the worldwide healthcare trend, HA is placing increasing emphasis on open, transparent and learning culture in its effort to promote continuous quality improvement. HA has therefore adopted the proactive policy of incident reporting and open disclosure in its management of near misses and adverse events. Incident reporting and management facilitates appropriate investigation, improvement, learning and sharing. It also provides the "soil" for patient safety culture to flourish. Open disclosure protects the right of a patient to know about his own health conditions and serves as a vital communication tool to enhance patient trust. It remains as a key element for patient-centered care.

12. The Sentinel Event Policy, implemented on 1 October 2007, had guided all HA hospitals to focus on patient safety and to undertake thorough evaluation of patient care systems and processes for risk control and quality outcomes. It was revised to become the Sentinel and Serious Untoward Event Policy (The Policy) since January 2010. The Policy broadens the scope of risk identification and strengthens

incident reporting by adding on a category of Serious Untoward Events (SUEs). This category applies to incidents which are unexpected occurrence and could have led to death or serious physical or psychological injury. Under these criteria, an incident which arises from medication error or patient misidentification must be mandatorily reported as SUE.

13. To heighten staff awareness and nurture the patient safety culture, it is essential to share and disseminate the lessons learnt from root cause analysis through staff forums and publications such as the HA Risk Alert and its Half-yearly and Annual Reports. These lessons are imperative to the success of sustaining continuous improvement on quality, incident reporting and management, and patient safety.

14. This Annual Report is a summary of all sentinel and serious untoward events reported by HA hospitals from 1 October 2009 to 30 September 2010. The Report has included a review of all reported events, risks, improvement opportunities and learning points identified through root cause analysis. It has also documented risk reduction measures taken or planned to prevent the reoccurrence of such events.

CHAPTER 2 – SENTINEL AND SERIOUS UNTOWARD EVENT POLICY

15. The Policy (Annex I), effective on 1 January 2010, supersede the Sentinel Event Policy issued in October 2007. Category 2, 3 and 9 of SEs have been updated and two categories of SUEs added to the Policy, namely, medication error and patient misidentification. Under this Policy, SE is defined as an "unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof", and SUE as an "unexpected occurrence which could have led to death or permanent harm".

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 (excluding complications) resulting in permanent loss of function or death
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

16. The Policy provides a framework for reporting, responding and

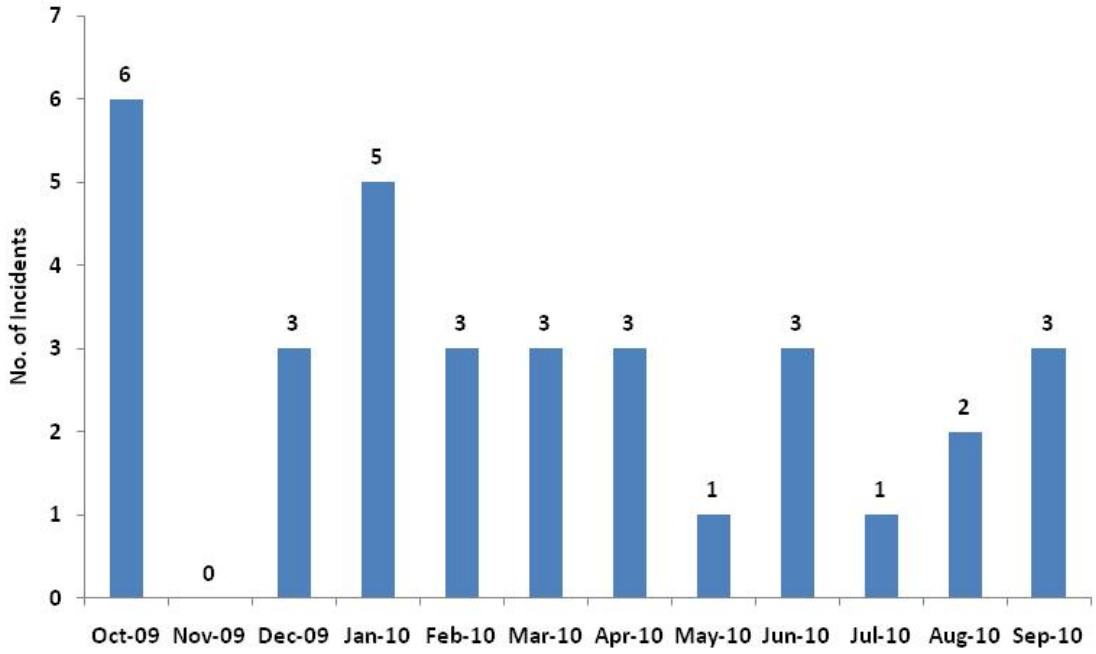
management of reported SEs and SUEs. The hospital management is required to report SEs and SUEs and the Head Office (HAHO) will appoint a RCA panel to investigate the event and recommend improvements. The hospitals are required to implement the improvement measures and report progress to HAHO.

CHAPTER 3 – SENTINEL EVENTS REPORTED FROM 1 OCTOBER 2009 TO 30 SEPTEMBER 2010

Frequency of Reportable SEs

17. A total of 33, 40, and 44 SEs were reported from 1 October 2009 to 30 September 2010, 1 October 2008 to 30 September 2009 and 1 October 2007 to 30 September 2008 respectively. The number of reportable SEs by month is shown in Figure 1.

Figure 1: Reportable Sentinel Events by Month

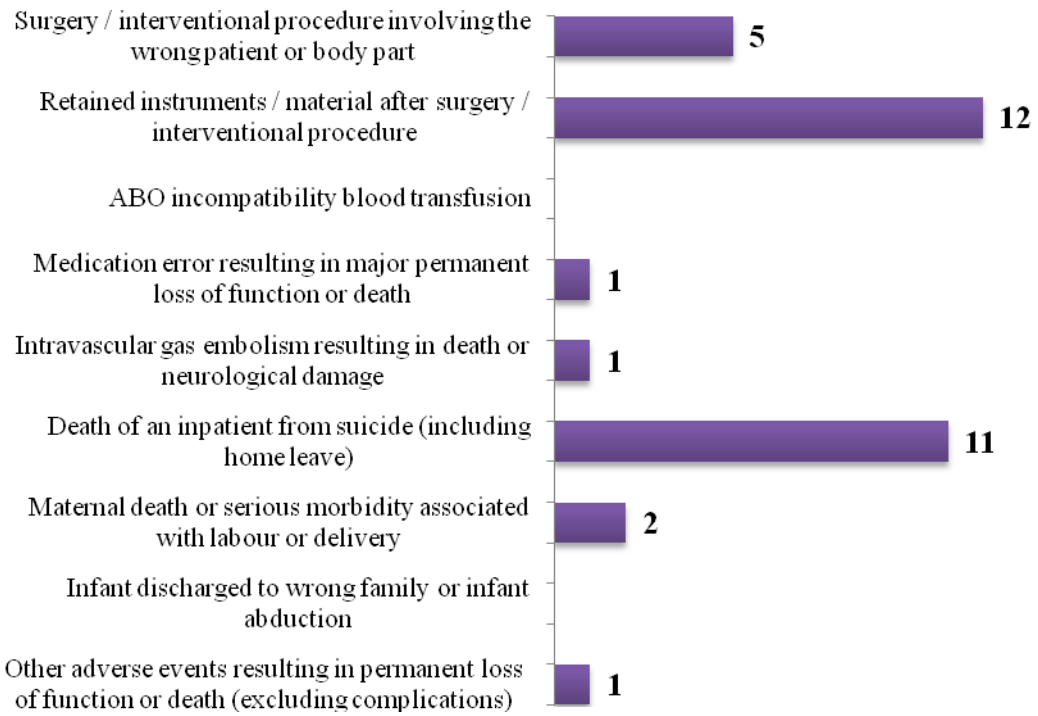


The incidence rate of reportable SEs was 2.0, 2.4 and 2.7 per 1,000,000 episodes of patient discharges and deaths / attendances for 12 months from 1 October 2009 to 30 September 2010[1], 1 October 2008 to 30 September 2009 and 1 October 2007 to 30 September 2008 respectively.

Breakdown of Reportable SEs by Category

18. A breakdown of the frequency of SEs by category from 1 October 2009 to 30 September 2010 is shown in Figure 2, and the distribution of SEs presented as percentages of each category is shown in Figure 3.

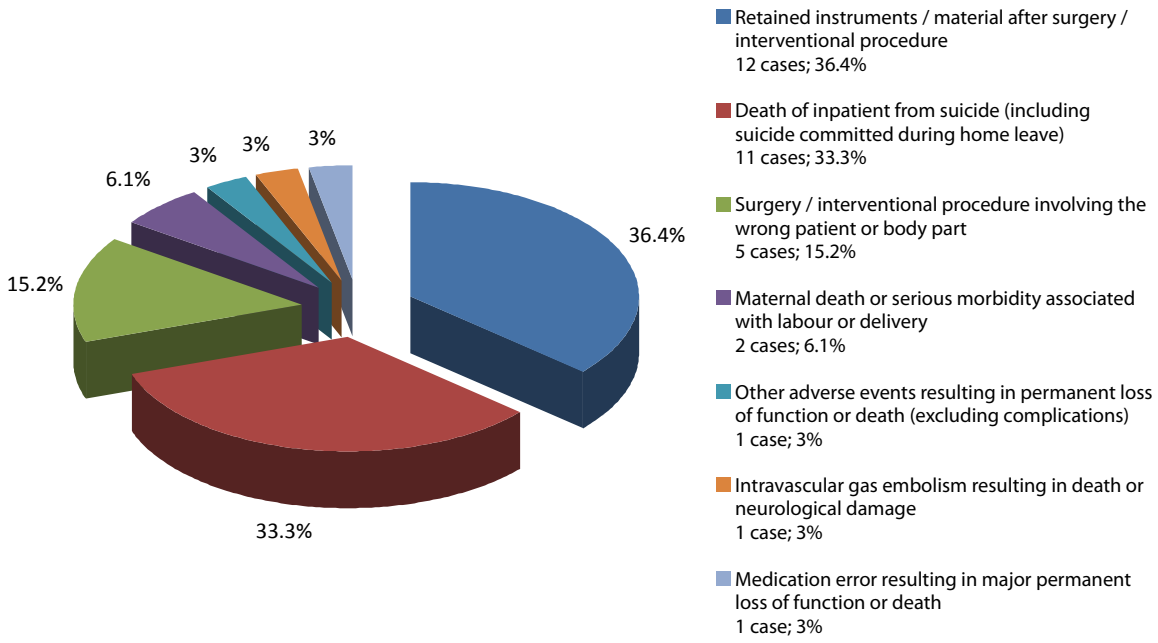
Figure 2: Breakdown of Sentinel Events by Category



[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.

19. The most commonly reported category of SEs, with a total of 12 incidents (36.4%), was "retained instrument / material after surgery / interventional procedure". The second most commonly reported category was "death of an inpatient from suicide (including home leave)" with a total of 11 incidents (33.3%). The third commonly reported SE was "wrong surgery / interventional procedure involving the wrong patient or body parts" and 5 (15.2%) incidents were reported.

Figure 3: Distribution of Sentinel Events from 1 October 2009 to 30 September 2010



- **Retained instruments or other material after surgery / interventional procedure: 12 cases (36.4%)**
  - Retention of intravascular guide wire: 3 cases;
  - Retention of surgical gauze: 4 cases; and

- Retention of instrument or other material (retractor, broken tip of scalpel, a fragment of Foley catheter, a segment of suction catheter and a segment of naso-gastric tube): 5 cases.

- **Death of an inpatient from suicide (including home leave): 11 cases (33.3%)**
  - 5 patients (45.5%) committed suicide during home leave and 6 patients (54.5%) committed suicide while staying in the hospital; and
  - 6 patients had mental illness and 5 had malignancies or chronic illnesses.

- **Surgical or interventional procedures involving the wrong patient or body part: 5 cases (15.2%)**
  - 2 cases of spinal surgery were performed at a wrong level;
  - An incorrect operation (laparoscopic hysterectomy and bilateral salpingo-oophorectomy instead of laparoscopic hysterectomy) was performed;
  - An unnecessary operation on left calcaneum was performed; and
  - Pleural paracentesis was performed on the wrong side.

- **Maternal death or serious morbidity associated with labour or delivery: 2 cases (6.1%)**
  - 1 case of intrauterine death was due to suspected amniotic fluid embolism and/ or cardiac arrhythmia; and
  - 1 case of maternal death was due to postpartum haemorrhage with liver failure.

- **Medication error resulting in major permanent loss of function or death: 1 case (3%)**
  - A patient was given an under-dose of warfarin resulted in mortality.

- **Intravascular gas embolism resulting in death or neurological damage: 1 case (3%)**
  - Improper removal of central venous catheter resulted in intravascular gas embolism and ischaemic stroke.

- **Other adverse events resulting in permanent loss of function or death (excluding complications): 1 case (3%)**
  - Omission of antiviral therapy before chemotherapy resulted in mortality.

Outcome of Reported Sentinel Events

20. The outcome of reported events was as follows:

- Minor or significant consequence: 9 cases (27%);
- Major / moderate consequence: 9 cases (27%);
- Extreme consequence (i.e. death): 15 cases (46%)
  - Patient suicide: 11 cases;
  - Maternal death associated with labour or delivery: 2 cases;
  - Medication error: 1 case; and
  - Other adverse event: 1 case.

Hospital Setting where Sentinel Events Occurred

21. Out of all reported SEs in the reporting period, 91% occurred in general hospitals (Table 1).

Table 1: Setting Where Sentinel Events Occurred

Setting	No. of SEs (%)
Acute general hospitals	27 (82%)
Psychiatric units within general hospital	3 (9%)
Psychiatric hospitals	3 (9%)

22. The occurrence of SE in the past 36 months is depicted in Table 2.

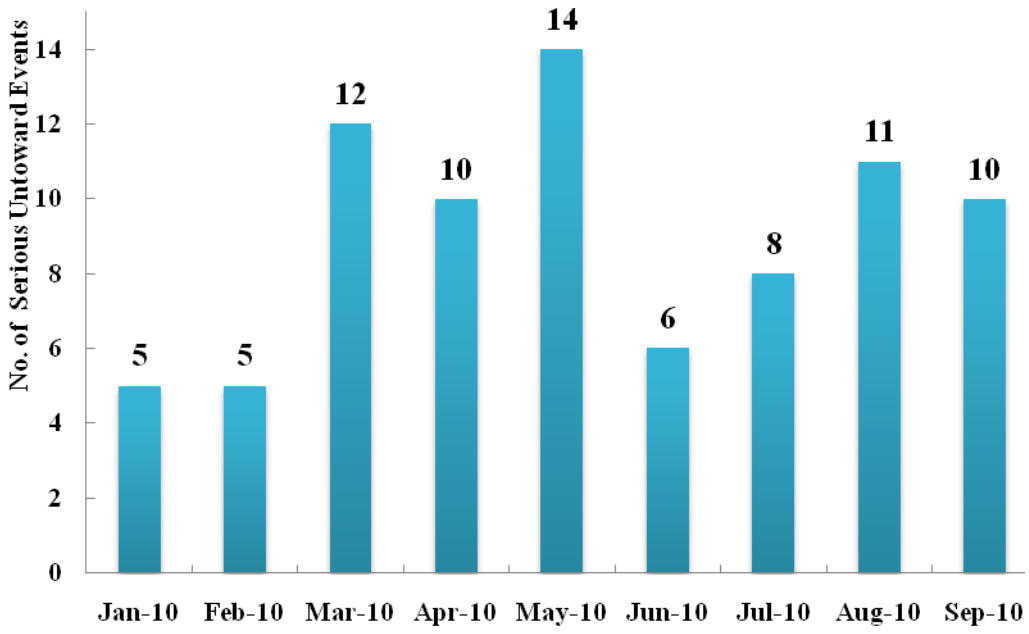
Table 2: Comparison of Occurrence of Sentinel Events in the Past 36 Months

Reportable Sentinel Events	1-Oct-07 to 30-Sep-08	1-Oct-08 to 30-Sep-09	1-Oct-09 to 30-Sep-10	Total number
Surgery / interventional procedure involving the wrong patient or body part	5	10	5	**20**
Retained instruments or other material after surgery / interventional procedure	10	13	12	**35**
ABO incompatibility blood transfusion	1	0	0	**1**
Medication error resulting in major permanent loss of function or death	0	0	1	**1**
Intravascular gas embolism resulting in death or neurological damage	0	0	1	**1**
Death of an inpatient from suicide (including home leave)	25	15	11	**51**
Maternal death or serious morbidity associated with labour or delivery	1	2	2	**5**
Infant discharged to wrong family or infant abduction	1	0	0	**1**
Other adverse events resulting in permanent loss of function or death (excluding complications)	1	0	1	**2**
Total Number	**44**	**40**	**33**	**117**

CHAPTER 4 – SERIOUS UNTOWARD EVENTS REPORTED FROM 1 JANUARY 2010 TO 30 SEPTEMBER 2010

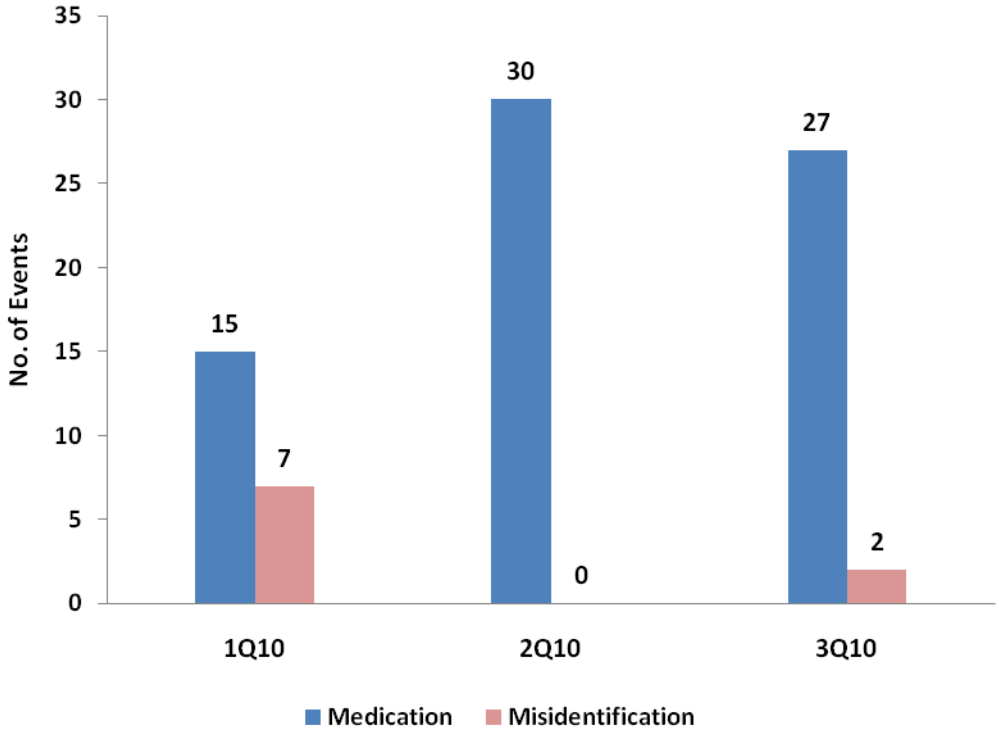
23. A total of 81 SUEs were reported from 1 January 2010 to 30 September 2010. The number of reported SUEs by month is shown in Figure 4.

Figure 4: Monthly Number of Reported Serious Untoward Events



24. A breakdown of reported SUEs revealed that 72 cases (88.9%) were due to medication error and 9 cases (11.1%) patient misidentification (Figure 5).

Figure 5: Breakdown of Serious Untoward Events from 1 January 2010 to 30 September 2010

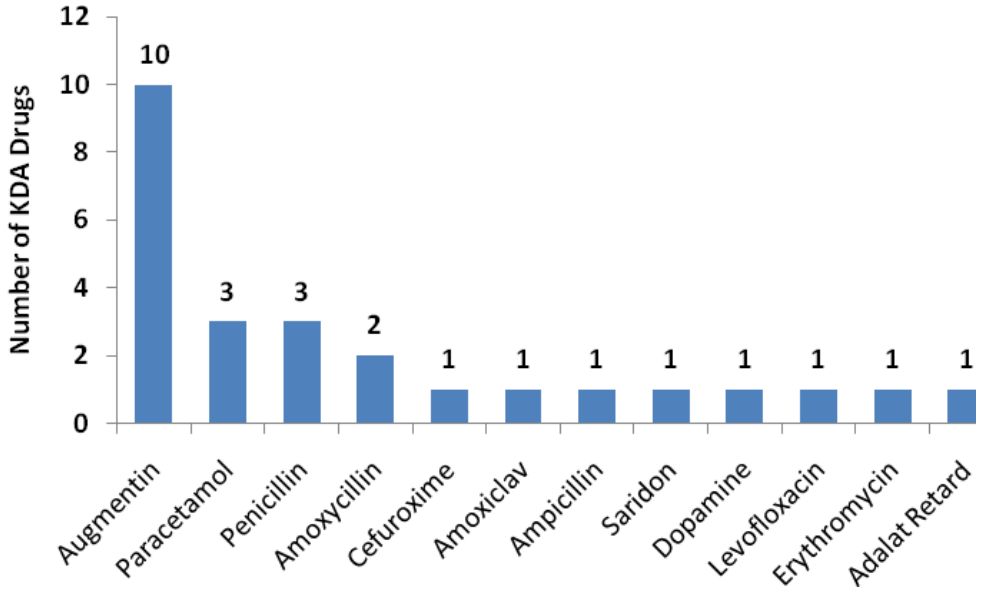


SUEs from Medication Error

25. The commonly reported SUEs due to medication error, with a total of 26 (36.1%) cases, were related to the prescription or administration of "Known Drug Allergy" (KDA) drugs. This was followed by medication error involving "dangerous drugs" (21 cases; 29.2%), "hypoglycaemic agents" (7 cases; 9.7%), "anticoagulants" (6 cases; 8.3%), "vasopressors" (4 cases; 5.6%) and other medications (8 cases; 11.1%).

26. The most common KDA prescribed and / or administered was Augmentin (10 cases; 38.5%), followed by Paracetamol (3 cases; 11.5%) and Penicillin (3 cases; 11.5%). Almost 50% of the KDA incidents were related to the penicillin group. The number of KDA drugs involved is depicted in Figure 6 below:

Figure 6: Distribution of Prescribed or Administered KDA Drugs



27. The majority of patients who were prescribed or administered with "KDA" drugs had no allergic symptoms. A few patients presented with mild rashes after taking these drugs.

SUE from Patient Misidentification

28. A total of 9 SUEs due to patient misidentification were reported. These included incidents of misidentification of patients in the clinical systems and misfiling

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

Table 3: Distribution of Misidentification Incidents

Description	1Q10	2Q10	3Q10
Misidentification of patient during dispensing	1	0	0
Misidentification of patient in clinical systems e.g. Clinical Management System (CMS), Corporate Drug Dispensing History(CDDH)	5	0	1
Misfiling of patient's laboratory report leading to inappropriate or unnecessary treatment	1	0	1

Outcome of Reported Serious Untoward Events

29. Out of the 81 reported SUEs, 62 (76.5%) cases had "minor or insignificant" consequences, 14 (17.3%) "moderate" consequences (required higher level of care) and 5 (6.2%) "temporary major" consequences (including temporary bradycardia and hyperkalaemia, hypoglycemia, hypotension, mild bleeding and drug over-dosage).

CHAPTER 5 – ACTIONS TAKEN AND DISCUSSION

Analysis of Reported Sentinel Events

Sentinel Event Reporting

30. A total of 33 SEs was reported in the past 12 months (October 2009 to September 2010) within the Hospital Authority. 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 on the Accreditation of Healthcare Organizations (JCAHO) received 968 reports of SEs in 2009[4]. Since there is currently no international benchmarking for an 'appropriate' or 'acceptable' level of sentinel event reporting, the above figures on SEs reported in different jurisdictions is for information only.

31. Compared with previous years, a decreasing trend in occurrence of SE in HA is observed. There were 44 cases of sentinel events reported from October 2007 to September 2008, 40 cases from October 2008 to September 2009, and 33 from October 2009 to September 2010.

[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 September 30, 2010.

Types of Sentinel Events Reported

32. "Retained instruments or other material after surgery/ interventional procedure" was the most commonly reported SEs (12/33 cases; 36.4%). "Death of an inpatient from suicide (including home leave)" was the second most commonly reported SEs (11/33 cases; 33.3%), while "surgery / interventional procedure involving the wrong patient or body part" was the third (5/33 cases; 15.2%). There was also a downward trend in occurrence of inpatient suicide in the past 36 months.

33. "Retained instruments", "inpatient suicide", and "wrong patient or site operated" were also the most common SEs reported to JCAHO, 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 suicide. It should be pointed out that there are differences in criteria for reportable suicides amongst Hong Kong, Victoria, and Western Australia. In Hong Kong, reportable inpatient suicides include also suicides committed during home leave whilst in Australia only suicides committed in inpatient units are to be reported.

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

[5] World Health Organization: suicide prevention (SUPRE).

11.8 per 100,000 population in 1995 to 15.2 in 2006[6].

Contributing Factors for Sentinel Events

35. 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 SEs in future. In the Victoria Department of Health Service of Australia and the Western Australia Department of Health, the top contributing factors were policies / procedures, human factors and communication. Despite the small number of SEs reported in HA, ineffective or inadequate communication was identified as an important factor in causing these events. The key contributing factors for each category of incidents are summarized below:

- **Key contributing factors for "retained instruments or material"**
  - Ineffective communication between team members;
  - Unclear role delineation among the team members;
  - Insufficient documentation of counting and checking of instruments, consumables and used devices;
  - Failure to detect the retained instruments or material;
  - Failure to check the integrity of medical devices/ consumables after operation or procedure;
  - Failure to check the number of gauzes intentionally packed and removed;
  - Difficulty in checking the integrity of a blood-soaked gauze;

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

- Problem with quality of raytec gauze; and
- Lack of a robust system to ensure no retention of used devices.

- **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 the chronic or terminal illnesses), the following are other factors that may have contributed in varying degrees to a patient's suicide:

  - Sudden and unpredicted change of mental conditions and behavior of patients;
  - Change of the psychological conditions in patients with terminal illnesses; and
  - Inadequate supporting services for patients on home leave.

- **Key contributing factors for "surgery/ interventional procedure involving the wrong patient or body part"**

  - Insufficient attention to anatomical variations of patients;
  - Failure to match the pre-operative imaging with the intra-operative imaging;
  - Failure to retrieve the correct source image for CT image reconstruction;
  - Failure to correlate image findings with clinical conditions and X-ray findings;
  - Failure to mark and identify the correct site before performing an operation; and
  - Ineffective communication among team members.

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

- **Key contributing factors for "medication error resulting in major permanent loss of function or death"**
  - Unfamiliarity with the complex "advance order" of the CMS Medication Order Entry and the wordings of complex prescription; and
  - Inadequate communication with relative on the dosage adjustment.

- **Key contributing factors for "intravascular gas embolism resulting in death or neurological damage"**
  - Lack of requisite experience for the procedure; and
  - Unawareness of the risk related to the procedure.

- **Key contributing factors for "other adverse events resulting in permanent loss of function or death"**
  - Incorrect interpretation of the patient's negative laboratory result; and
  - No checklist was used for comprehensive checking of the patient's critical clinical information prior to commencement of chemotherapy.

Risk reduction programmes

36. The HAHO has collaborated with clusters and hospitals to improve and

redesign the healthcare systems and work processes to prevent recurrence of SEs. Examples of risk reduction programmes introduced are outlined below:

- **Retained instruments or other material after surgery/ interventional procedure**
  - Adopt the principle of Surgical Safety Checklist for procedures performed in ward;
  - Count and verify used devices immediately and upon removal from the patient;
  - Record and check the integrity of the gauze / instrument / material after use or removal;
  - Restrict the number of staff involved in the surgery/ interventional procedure and define the role of each staff member in the counting process;
  - Report defective medical devices / consumables to procurement unit / department for investigation;
  - Perform digital examination for removal of gauze from vagina if indicated;
  - Alert staff of possible product defects; and
  - Provide appropriate training and supervision for junior staff on critical procedures.

- **Death of an inpatient from suicide (including home leave)**
  - Use standardized checklist for suicide risk assessment to enhance early identification of patients at risk of suicide;
  - Redesign facilities and/ or environment to improve patient safety;
  - Multidisciplinary assessment and intervention before home leave; and

- Explore the feasibility of outreach team providing support to mentally ill patients during home leave on weekends and public holidays.

- **Surgery / interventional procedure involving the wrong patient or body part**
  - Implement the Surgical Safety Policy by adopting a checklist and team approach to ensure that the correct patient receives the right operation at the correct site;
  - Repeat the "Time-out" process to reaffirm the intended operation when a new member joins the operating team;
  - Match the pre-operative imaging with the clinical findings and intra-operative image;
  - Use a radio-opaque marker and intra-operative X-rays to reconfirm the spinal level in a spine surgery; and
  - For post CT scanning reconstruction, use anatomical landmarks to identify the laterality on the image and source image with bilateral structures for image retrieval and cropping.

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

  Hospitals should be vigilant when providing obstetric care to pregnant patients as obstetric emergencies could occur at anytime.

- **Medication error resulting in major permanent loss of function or death**
  - Enhance staff training on using the computerized prescription system for complex prescription; and
  - Check for correctness of prescription before handing the prescription sheet

to the patient.

- **Intravascular gas embolism resulting in death or neurological damage**
  - Enhance supervision when the procedure is performed by junior staff; and
  - Increase staff awareness of potential risks of the procedure.

- **Other adverse events resulting in permanent loss of function or death (excluding complications)**

  A standardized protocol and checklist for chemotherapy should be used to ensure comprehensive checking of critical clinical information prior to commencement of chemotherapy.

Analysis of Reported Serious Untoward Events

37. Out of 81 SUEs reported from 1 January 2010 to 30 September 2010, 72 cases (88.9%) were related to medication error and 9 (11.1%) misidentification of patient or patient record / report leading to inappropriate treatment.

38. Of the 72 medication error cases, 26 were related to prescription and administration of "Known Drug Allergy" drug to patients. There were no adverse consequences in these cases except only minor reactions in one patient. The key contributing factors were:

- Failure to refer to the patient's drug allergy history and remain alert during prescription, dispensing or administration of drugs;
- Failure to recognize that the prescribed drug belonged to the same drug group to which the patient was allergic (e.g. Augmentin belongs to the penicillin group);

- Bypassing the pharmacy checking system by using ward-stock drugs, left-over drugs from discharged patients or borrowed drugs from other inpatients in the ward.

39. Seven cases of SUEs were related to medication error involving hypoglycaemic agents such as oral hypoglycaemia drugs and subcutaneous insulin. The key contributing factors were:

- Inappropriate administration of oral hypoglycaemia drugs;
- Unsupervised intake of medications;
- Failure to communicate causing misunderstanding of drug dose.

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

- Incorrect input of data on the control keypad of the infusion device;
- Failure to check the infusion rate;
- Proximity of the storage bins of look-alike-sound-alike (LASA) drugs.

41. Twenty-one cases of SUEs were related to medication error arising from administration of dangerous drugs (extra dose, wrong rate and wrong drug), of which 4 were related to the use vasopressors and 8 to other medications. The key contributing factors were:

- Failure to properly conduct “3 Checks 5 Rights” during drug administration;
- Inadequate communication in verbal order;
- Wrong administration of medication and failure to identify error before administration;

- Wrong calculation of drug dose.

42. Nine cases of SUEs were related to misidentification of a patient or a patient's record / laboratory report leading to prescription of inappropriate or unnecessary treatment to patients. The key contributing factors were:

- Failure to verify the identification of the patient;
- Failure to verify correct patient record / laboratory report with the correct patient.

Learning and Sharing

43. To promote learning and sharing, salient information on all reported SEs and SUEs, contributing factors and learning points have been shared in the 'HA Risk Alert' (HARA), a bimonthly newsletter published since November 2007. Abstracts of local and global healthcare risk alerts are also included in each publication of HARA to raise staff awareness on patient safety.

CHAPTER 6 – CONCLUSION

44. Since the implementation of the Sentinel Event Policy in 2007, HA has been promoting an open and transparent policy to incident reporting, risk identification and management. By so doing, HA is able to sustain the momentum for continuous system improvement so as to better manage inherent and hidden clinical risks as well as mitigate avoidable or unnecessary risks.

45. To err is human. System improvement should be targeted at being risk-proof, so that the effect of human factor could be controlled and minimized. Yet, in order to ensure safe patient care in an increasing complex healthcare environment, system improvement alone is not enough. In our journey for quality and patient safety, building up a patient safety culture is the key. Let us work together to cultivate a patient safety culture by proactively nurturing and supporting the practice of near miss / incident reporting and sharing in accordance with the Sentinel and Serious Untoward Event Policy.

CHAPTER 7 – THE WAY FORWARD

46. The following measures and activities will be introduced to further enhance patient safety:

(a) To implement the principles of "surgical safety policy" to bedside procedures;

(b) To develop effective team communication and clinical risk awareness through crew resources management program; and

(c) To implement Patient Safety WalkRounds in clinical areas to facilitate executives and managers in collecting feedback on patient safety direct from frontline staff.

ANNEX I

HA SENTINEL AND SERIOUS UNTOWARD EVENT POLICY

1. Purpose

The Sentinel and Serious Untoward Event Policy defines the process for identification, reporting, investigation and management of Sentinel Events (SE) and Serious Untoward Events (SUE) in the Hospital Authority.

2. Scope

This Policy applies to sentinel and serious untoward events related to care procedures.

3. Objectives

- To increase staff's awareness to SE and SUE.
- To learn from SE and SUE through Root Cause Analysis (RCA), with a view to understand the underlying causes and make changes to the organization's systems and processes to reduce the probability of such an event in the future.
- To have positive impact on patient care and services.
- To maintain the confidence of the public and regulatory / accreditation bodies.

4. Definition of Mandatory Reporting Events

4.1 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 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).

4.2 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.

5. Management of SE and SUE

5.1 Immediate response upon identification of an SE or SUE

5.1.1 Clinical Management Team shall assess patient condition and provide care to minimize harm to patient.

5.1.2 Attending staff shall notify senior staff of Department without delay (even outside office hours). Hospitals should establish and promulgate a clear line of communication for SE and SUE to all staff.

5.1.3 Department and hospital management shall work out an immediate response plan, including

- Disclosure to patient / relatives
- When to notify HAHO
- Public relation issues and media handling, (making reference to HAHO Corporate Communication Section's protocol / advice); and
- Appropriate support / counseling of staff.

5.2 Reporting (within 24 hours)

5.2.1 Hospitals must report SE and SUE through the Advance Incident Report System (AIRS) within 24 hours of their identification, to

- Provide an initial factual account
- Mark the case as "SE" or "SUE" in AIRS accordingly.

5.2.2 Hospitals shall consider additional reporting requirements as indicated, for example, to Coroner in accordance to statutory requirement.

5.3 Investigations

5.3.1 Within 48 hours

5.3.1.1 For SE, HAHO shall appoint an RCA Panel, composing of members from hospital RCA team, respective COCs, external senior clinicians, HAHO coordinator and / or lay persons from Hospital Governing Committee, to evaluate the event reported.

5.3.1.2 For SUE, the RCA Panel shall be formed by respective hospital.

5.3.2 Hospitals shall submit a detailed factual account to HAHO in 2 weeks.

5.3.3 The RCA Panel shall submit an investigation report to the Hospital Chief Executive in 6 weeks.

5.3.4 Hospital shall submit the final investigation report to HAHO in 8 weeks.

5.4 Follow-up (post 8 weeks)

5.4.1 Implicated departments shall implement the action plan as agreed in the RCA report, and risk management team / personnel shall monitor compliance and effectiveness of the measures in due course.

5.4.2 The RCA panel in the HAHO shall review RCA reports to identify needs for HA-wide changes, and to share the lessons learned through Safety Alert, HA Risk Alert (HARA), Patient Safety

Forum, SE and SUE Half-year Report (to public) and follow-up visits.

5.4.3 The HAHO would visit respective hospitals for the implementation of improvement measures.

ANNEX II

SUMMARY OF INDIVIDUAL SENTINEL EVENTS AND RECOMMENDATIONS FOR IMPROVEMENT

Category 1: Surgery / interventional procedure involving the wrong patient or body part

WRONG LEVEL SPINAL SURGERY

Case 1:

A patient with prolapsed L4/5 disc had an operation for lumbar discectomy and anterior spinal fusion. Tactile confirmation of the operating lumbar level was performed. The Surgeon reviewed the post-operative X-ray and noticed the operation was performed at L5/S1. L4/5 disectomy and anterior spinal fusion was subsequently performed for the patient. The patient had recovered uneventfully.

Case 2:

A patient with herniated and prolapsed L2-L5 disc confirmed by MRI underwent emergency laminectomy and discectomy at L4/5 level. The operating site was identified by X-ray imaging before skin incision. The patient had increasing bilateral foot numbness after the operation. The Surgeon reviewed the post-operative X-ray and noted the patient had sacralisation and the operation was performed at L3/4 level. A revision operation for L4/5 level was performed. The patient had recovered uneventfully.

Key contributing factors:

1. Patient factor: Anatomical variations; and
2. Failure to match the pre-operative imaging with the intra-operative X-rays.

Key recommendations:

1. Match MRI and X-ray before operation to ensure accuracy in level identification for spinal surgery; and
2. Use a radio-opaque marker and intraoperative X-rays to reconfirm levels on the site of operation before skin incision is more accurate.

PATIENT UNDERWENT NON-CONSENTED OPERATION

A patient with suspected endometrial carcinoma was advised to have total hysterectomy and bilateral salpingo-oophorectomy. The patient consented to laparoscopic hysterectomy only on the understanding that a second operation would be required to remove her ovaries should carcinoma be confirmed. The O& G team used the "Surgical Safety Checklist" prior to operation. A senior doctor was called in to assist because of difficulties encountered during the operation. The team concentrated on the difficult surgery. The senior doctor was not reminded of the patient's request to preserve her ovaries. In addition to laparoscopic hysterectomy, bilateral salpingo-oophorectomy was performed. Endometrial carcinoma was subsequently confirmed. The patient received adequate surgical treatment and a second operation was not required.

Key contributing factor:

Ineffective communication between team members.

Key recommendations:

1. Adhere strictly to the consent obtained from the patient; and
2. Repeat the "Time-out" process to reaffirm the intended operation when a new member joins the operating team.

UNNECESSARY OPERATION ON LEFT CALCANEUS

A patient injured his Right and Left feet after jumping from height. CT scan was performed to examine the injury. The image of the Right calcaneus was mistakenly labeled as Left calcaneus during post–scanning image reconstruction. The surgeon reviewed the CT images and noted significant fractures of both calcaneus. Open reduction and internal fixation for both calcaneal fractures was planned. During the operation, the surgeon found the injury to Left calcaneus not compatible with the CT image. Intra-operative X-ray showed insignificant fracture of the Left calcaneus. The surgeon closed the skin incision of the Left heel and continued with the operation on the Right heel. The patient had made good recovery from the operation and injury.

Key contributing factors:

1. Retrieval of incorrect source image for CT image reconstruction; and
2. The surgeon did not correlate image findings with clinical conditions of the patient and X-ray findings.

Key recommendations:

1. Correlate the CT images and X-ray images with clinical conditions of the patient;
2. Study bilateral images of the patient on the scan;
3. Use anatomical landmarks to identify the laterality during image reconstruction; and
4. Use the source image with bilateral structures for image retrieval and cropping during image reconstruction.

WRONG-SIDED PLEURAL PARACENTESIS

A patient was admitted for investigation of pleural effusion. His chest X-ray and CT scan revealed a massive LEFT pleural effusion. The patient consented to LEFT pleural paracentesis. The doctor performed percussion at the back of the patient to establish the position for aspiration and marked a site at the RIGHT side of the back of the chest. The other team members did not notice the incorrect site marking. The doctor could only aspirate air from the RIGHT side of the patient's chest. The patient's clinical condition was stable. The doctor proceeded to perform aspiration on the LEFT side of the patient's chest. Pleural fluid was aspirated. The post-procedure chest X-ray revealed a RIGHT apical pneumothorax. The patient was treated conservatively and his condition remained stable.

Key contributing factors:

1. Human factor: Incorrect marking of the site for aspiration; and
2. Team factor: Failure to identify the correct site before performing the procedure.

Key recommendations:

1. Develop and implement a "Time-out" practice to verify the correct patient and correct site for bedside invasive procedure; and
2. Consider the use of bedside ultrasound guidance for chest tapping procedure.

Category 2: Retained instruments or other material after surgery / interventional procedure

RETAINED INTRAVASCULAR GUIDE WIRE

Case 1:

A central venous catheter was inserted for a patient in the Intensive Care Unit for renal replacement therapy. Resistance to injection was encountered in one of the lumens of the catheter which was resolved by flushing with normal saline. A guide wire was noted on the Chest X-ray 6 days later. The guide wire was retrieved under fluoroscopy guidance.

Case2:

A junior doctor performed the procedure to insert a central venous catheter. He experienced difficulty with the insertion of the guide wire and was assisted by his supervisor. After the guide wire was inserted, the junior doctor inserted the catheter by threading it over the guide wire. After the insertion, there was difficulty in flushing the lumen of the catheter. A post-procedure Chest X-ray revealed a guide wire in the inferior vena cava. The guide wire was retrieved via endovascular approach.

Case 3:

A patient was admitted to the Intensive Care unit in status epilepticus at 4 am. A specialist required two attempts at femoral venous catheterization to insert a central venous line for infusion of anti-convulsant and inotropic drugs. The assisting nurse was busy in resuscitating and preparing medications for the patient during the procedure. A post-procedure X-ray revealed a retained guide wire in the inferior vena cava. The guide wire was then removed.

Key contributing factors:

1. The staff member involved lacked experience and competence, and was unaware of inadvertent retention of guide wire;
2. Ineffective communication between team members;

3. Patient was in critical condition, requiring rapid intervention (procedure); and
4. Lack of a robust process to ensure that the guide wire was not retained.

Key recommendations:

1. Adopt a robust process to prevent retention of guide wire and keep track of the tail-end of the guide wire throughout the procedure;
2. Count and verify the guide wire immediately after insertion of the central venous catheter and removal of the guide wire from the patient;
3. Provide appropriate training and supervision for junior staff on insertion of central venous catheter;
4. Recognize and promote the removal of guide wire as a "critical point" in the procedure, preferably requiring simultaneous checking by the doctor and the nurse; and
5. Ensure proper documentation of the procedure, including the number of guide wire used and removed.

RETAINED GAUZE AFTER OPERATION / PROCEDURE

Case 1:

A woman was noted to have some vaginal bleeding after normal delivery of a baby girl. Doctor A examined the patient and found a bleeder in the vagina. One pack of raytec gauze was used to control the bleeding. Counting of raytec gauze was done by Doctors A and B during the process. No final gauze counting was performed after completion of the procedure when the delivery set was checked and counted. Ten days later, the patient experienced perineal discomfort and 1 month after delivery, the patient complained of discomfort and attended follow-up. A raytec gauze was found retained in the patient's vagina.

Case 2:

A diabetic patient was admitted thrice for unhealed right heel abscess. On each admission, incision and drainage (I&D) was performed (once in the ward and twice in the operating theatre). Wound packing and dressing was performed by the nursing staff during her hospital stay and by community nurses after discharge. During the third I&D, a retained piece of plain gauze was found deep inside the wound and was removed. The heel abscess subsequently healed up well.

Case 3:

An operating theatre had just adopted a new "counting away" method for used gauzes for infection control purpose. During an elective thymectomy operation, 5 nurses took part in the operation because of shift changeover. Gauze count was reported to be correct prior to wound closure. Post-operative CXR showed a piece of retained gauze. Recounting of used gauzes in the operating theatre revealed that one piece was missing.

Case 4:

A patient attended the Accident and Emergency Department (A&E) with referral letter for continuous vaginal bleeding from a suspected cervical cancer. The attending doctor was not aware that 4 pieces of gauze were packed in the patient's vagina which was delineated in the referral letter. The doctor performed vaginal examination with speculum, removed 2 pieces of gauze from the patient and found the bleeding was stopped. The patient was then referred to the gynaecology clinic for further management of her suspected cervical cancer. Two days later, the patient felt discomfort in her genitalia and re-attended A&E. Two residual pieces of gauze were removed upon digital examination.

Key contributing factors:

1. Lack of system to record supplementary items added to the delivery set or the number of gauzes during I&D procedure in ward;
2. Failure to detect the retained gauze and difficulty in seeing blood-soaked gauzes during vaginal examination and clinical procedures;
3. Failure to check the number of gauzes intentionally packed and removed;
4. The new "counting away" practice may have compromised visual tracking of the number of gauzes used; and
5. Unclear role delineation among the team members.

Key recommendations:

1. Establish an accurate counting process both at the start and end of delivery;
2. Adopt the principle of Surgical Safety Checklist for procedures performed in ward;
3. Standardize the documentation of counting (worksheet / whiteboard);
4. Count and record the number and types of gauze used for wound packing

procedures performed and removed from inside the body;

5. Revise the new "counting away" practice to preserve the visual checking in order to account for all used gauzes;
6. Explore the use of "sponge counter bag" for "counting away";
7. Restrict the number of staff involved in each procedure and define the role of each staff member in the counting process; and
8. Perform digital examination for removal of gauzes from vagina if indicated.

RETAINED PART OF INSTRUMENT / MATERIAL IN PATIENT AFTER OPERATION OR PROCEDURE

Case 1: Fragment of Urinary Catheter

A patient had urinary catheter insertion during an operation which had to be retained postoperatively. The patient became confused later and pulled violently at the catheter which eventually slipped out. The patient had haematuria and cystitis 6 months later and was admitted to another hospital. He claimed that he had passed out a plastic band. Cystoscopy was performed during which a fragment of urinary catheter was removed.

Case 2: Segment of Naso-gastric Tube

A patient requiring long term naso-gastric (NG) tube feeding was admitted because of fresh hematemesis and was scheduled to undergo endoscopic examination. The NG tube was removed prior to endoscopic examination. The endoscopist found a broken piece of NG tube inside the patient's hiatus hernia. The broken piece of NG tube was removed with forceps.

Case 3: Broken Scalpel Tip

A patient underwent an uneventful K-wire fixation for fracture humerus. Post operation X-ray showed a foreign body suspected to be a fragment of the implanted "K-wire". During removal of "K-wire", the retrieved foreign body was confirmed to be a small broken scalpel tip.

Case 4: Segment of Suction Catheter

An acute stroke patient required post-operative ventilation after a burr hole operation. A naso-gastric tube was inserted for feeding. Suction for sputum was performed via oral endotracheal tube and later tracheotomy. The patient was transferred to a convalescent hospital for rehabilitation on Day 23. During the transfer, the patient pulled out the naso-gastric tube. He was assessed by a speech

therapist in the ward and a segment of suction catheter was found at the back of the patient's throat.

Case 5: Malleable Copper Retractor

A patient underwent an elective Whipple's operation. Prior to wound closure, the first "counting away" for instruments and gauzes was completed and the operating team was aware that some instruments were still in use. A scrub nurse commenced the second "counting away" but was not able to finish the process before the end of the operation. Both the anaesthetist and surgeon were not aware of the "unfinished" second count. The scrub nurse assisted the patient's reversal from anaesthesia. The patient was discharged to the recovery room. On completion of the second "counting away", a malleable copper retractor was found missing. An X-ray showed a retained retractor in the patient's abdomen. An emergency operation was performed to remove the retractor.

Key contributing factors:

1. The "unfinished" second count was not made known to all members of the operating team (surgeon and anaesthetist);
2. Difficulty in managing patient was confused with violent behavior; and
3. Failure to check the integrity of medical devices/ consumables after operation or procedure.

Key recommendations:

1. Staff conducting counting should clearly communicate to the operating team upon completion of the second count;
2. The other team members should confirm completion of the second count before formally finishing the operation;
3. Time should be allowed for an accurate and timely second count;
4. Methods such as progressive counting away technique should be adopted to ensure an accurate and timely second count;
5. Check the integrity of medical devices / consumables after use;
6. Report defective medical devices/ consumables to the procurement team for investigation; and
7. Alert staff of possible product defects.

Category 4: Medication error resulting in major permanent loss of function or death

An elderly patient with hypertension, diabetes and chronic rheumatic heart disease was on warfarin, 2mg on even days and 2.5mg on odd days. At the out-patient clinic, Dr. A intended to adjust the warfarin dosage to 2mg daily according to the latest INR blood test result. Dr. A amended the warfarin dosage via the "advance order" of CMS's Medication Order. The order line "warfarin 2.5 mg daily (on odd day)" was deleted. The other order line for warfarin (which was for even day) was not changed – as Dr. A. noted the dosage was 2.0 mg daily but unfortunately did not note the "Suppl. Frequency" which was "on even day". As a consequence, the prescription "warfarin 2 mg daily (on even days)" was dispensed accordingly. The patient received 2 mg warfarin only on even days. Two weeks later, the patient was admitted with an ischaemic stroke. Her condition further deteriorated with medical problems and subsequently passed away.

Key contributing factors:

1. Unfamiliarity with the complex "advance order" of the CMS Medication Order Entry and the wordings of complex prescription; and
2. Inadequate communication with relative on the dosage adjustment.

Key recommendations:

1. Enhance staff training on using the computerized prescription system for complex prescription; and
2. Check for correctness of prescription before handing the prescription sheet to the patient.

Category 5: Intravascular gas embolism resulting in death or neurological damage

A junior doctor removed a jugular catheter which was inserted for dialysis in a 70 years old patient. The doctor instructed the patient to sit still and removed the catheter gently and smoothly. With the use of gauze, pressure was quickly and firmly applied to the wound for bleeding control. Soon after removal of the catheter, the patient complained of dizziness, generalized numbness and left side weakness. Urgent CT scan revealed air embolism with tiny air pockets seen at both carotid arteries. The patient was given hyperbaric oxygen therapy at Recompression Treatment Centre on the same day. He made a good recovery with rehabilitation and was subsequently discharged.

Key contributing factors:

1. The staff member involved was inexperienced in removing jugular catheter. The patient should "lie down" or keep a "head down" position during the removal procedure; and
2. The staff member was unaware of the risk related to removal of jugular catheter.

Key recommendations:

1. Enhance supervision when procedure is performed by junior staff;
2. Develop and implement a guideline on "safe removal of central catheter"; and
3. Enhance staff awareness of potential risks of central catheter removal.

Category 6: Death of an inpatient from suicide (including home leave)

Out of the 11 suicide cases, 6 patients committed suicide while in hospital and 5 during home leave; 6 patients had mental illnesses while 5 had malignancies or chronic diseases.

Key contributing factors:

Apart from the underlying medical conditions of the patients and their mental health conditions (e.g. depression from the chronic or terminal illness), the following are other factors that may contribute in varying degrees to patients' suicides:

1. Sudden and unpredicted change in patient's mental conditions and behavior;
2. Change of the psychological conditions in patients with terminal illnesses;
3. Unawareness of environmental risks that may facilitate suicidal acts; and
4. Inadequate supporting services for home leave patients.

Key recommendations:

1. Use standardized checklist for suicide risk assessment to enhance early identification of patients at risk of suicide;
2. Redesign facilities and/ or environment to improve patient safety;
3. Multidisciplinary assessment and intervention before home leave; and
4. Explore feasibility of outreach team providing support to mentally ill patients during home leave on weekends and public holidays.

Category 7: Maternal death or serious morbidity associated with labour or delivery

Case 1:

A woman with twin pregnancy at 37-week gestation presented with a 2 day history of decreasing fetal movement, yellowish discoloration of skin and tea coloured urine. Ultrasound revealed intrauterine death of twin II and surviving twin I. Emergency Caesarean section was arranged immediately and laboratory result revealed that the patient had grossly abnormal liver and renal functions with clotting problem. Massive blood loss was encountered during the Caesarean section. Despite massive blood therapy, the patient's condition deteriorated and she was certified dead several hours after operation.

Case 2:

A pregnant woman at 28-week gestation was diagnosed to have intrauterine fetal death by ultrasound examination. Induction for labour was started with good progress. The patient's condition was stable. On arrival at the labour room, the patient suddenly became unresponsive. Resuscitation was immediately performed and the abortus was extracted manually. The patient did not regain consciousness and CT brain showed hypoxic brain damage. The patient died 11 days after delivery. The RCA panel considered that possible causes of the patient's death included amniotic fluid embolism or cardiac arrhythmia.

Conclusion:

In these two cases of maternal deaths, no specific contributing factors could be identified. The treatment and care provided to the two patients were found to be timely and appropriate.

Learning Point:

Obstetric emergencies can occur at anytime. Hospitals should be vigilant when providing obstetric care to pregnant patients.

Category 9: Other adverse events resulting in permanent loss of function or death (excluding complications)

A lymphoma patient was scheduled for chemotherapy. As part of the standard pre-chemotherapy workup, the patient's hepatitis B (HBV) status was checked. The result which was positive was noted (screened and signed) by Doctor A. Subsequently, Dr A prescribed chemotherapy for the patient and in the process, he inadvertently assumed the patient's HBV status to be "Negative". Hence, prophylactic anti-viral therapy was not prescribed. Four months later (after the 5th course of chemotherapy), the patient's liver function became abnormal. On reviewing the case, the previous result of "positive" HBV status was noted. The patient was immediately started on anti-viral therapy for acute hepatitis due to reactivation of HBV. Despite aggressive anti-viral therapy and intensive medical support, the patient developed acute liver failure and died four weeks later.

Key contributing factors:

1. Human factor: Inadvertent assumption of the result of the patient's HBV status by the staff member (not referring to the actual laboratory report); and
2. System factor: No checklist was used to ensure comprehensive checking of the patient's critical clinical information prior to commencement of chemotherapy.

Key recommendations:

1. A standardised protocol and checklist for chemotherapy should be used to ensure comprehensive checking of critical clinical information prior to commencement of chemotherapy; and
2. The patient's HBV status should be ascertained and appropriate pre-emptive anti-viral therapy should be given according to the recommendations of the HA Central Oncology Committee.

Published by the Patient Safety and Risk Management Department
Hospital Authority
Hong Kong

January 2011

Available from www.ha.org.hk/visitor