Original Article

Medication Errors and Adverse Drug Events: Analysis from Perioperative Anesthetic Adverse Events in Thailand (PAAd Thai Study)

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Objective: Perioperative medication administration can lead to the higher rate and severity of medication errors (MEs). This epidemiological study aimed to assess the current situation in Thailand regarding the frequency, types, severity, contributing factors and suggested corrective strategies of MEs related to anesthesia care.

Materials and Methods: The prospective multi-center observational study was conducted in 22 university and non-university hospitals across Thailand. Data were collected during January 1 and December 31, 2015. MEs incidents were reported and filled out in the standardized incident reporting form on an anonymous and voluntary basis. All completed forms of MEs related to anesthesia were reviewed and discussed by peer reviewers who used the "Medication Error Detection Framework" to identify type of MEs, contributing factors and suggestive prevention strategies.

Results*:* There were 85 relevant reports of MEs from the first 2,206 incident reports (4.25% of all incident reports). Overdosage (25 incidents, 29.4%) was the most frequently found types of error. 10 incidents (40%) occurred in pediatric patients. Wrong drug administration (19 incidents, 22.4%) was the second frequently found type of error including syringe swaps or wrong ampule. Labelling errors were reported for 15 events (17.6%). 16 incidents (18.8%) were caused temporary patient harm or prolong hospital stay. All of the incidents were related to human error and considered preventable.

Conclusion: 4.25% of MEs were reported in our study, which comparable to the previous report from Thailand in 2007. Overdosage was the most frequently found type of errors. Pediatric patients were considered a high risk group. All of the incidents were related to human error and considered preventable. Vigilance and experience were factors that can help to minimize incidents.

Keywords: Medication error, drug error, adverse event, anesthesia, incident report, drug overdose

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Perioperative medication administration is a unique practice, much different from other hospital drug administration setting. It often bypasses standard medication safety checks, such as pharmacy approval or multiple nursing check. Furthermore, the high-stress and time-limited working concurrent with lots of high-alert drugs used can lead to the higher rate and severity of medication errors (MEs)[(1)]. However, the incidence of MEs associated with anesthesia practice is

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not certain. The reported incidence ranges from 1:133 to 1:5475 anesthetics[2-8].

Eighty-two (4.1%) of MEs from 1996 incident analysis were reported in the Thai Anesthesia Incidents Monitoring Study (Thai AIMS) in 2012[9]. After that time, several strategies were applied in anesthesia care system across Thailand, such as using class-specific color labelling and double-checked drug preparation to minimize the perioperative MEs. Despite this, the anesthesia safety incident reporting system has not been yet nationwide established.

With the supports from The Royal College of Anesthesiologists of Thailand (RCAT), we conducted this epidemiological study to assess the current situation in Thailand regarding the frequency, types. severity, contributing factors and suggested corrective strategies of MEs related to anesthesia care.

Materials and Methods

Study Site and Data Collection

The prospective multi-center observational study, a part of the Perioperative and Anesthetic Adverse Events Study in Thailand (PAAd Thai), was conducted in 22 hospitals across Thailand, including university and non-university hospitals. Data were collected during a 12-month period from January 1 and December 31, 2015. The study obtained the approval from each hospital ethical committee.

MEs incidents were reported and filled out in the standardized incident reporting form by anesthesiologists or nurse anesthetists on an anonymous and voluntary basis. Event details included "what", "where", "when" the incident occurred were asked. The information about how the incident was detected, treatment and patient outcome were filled in both close-ended and open-ended research questionnaire. Details regarding the error type, provider type were addressed as well as the freehand section for a narrative describing of the event. Patient factors, surgical factors, anesthetic factors and systematic factors were also recorded on the data record form.

Definition and Event Classification

The definition of medication error (MEs) used in this study is "a failure in the treatment process of mediation that leads to or has the potential to lead to, harm to the patient"[10,11]. It was assumed that the the anesthesia providers failed to give drugs in the ideal fashion.

All of the incidents were classified into potential adverse drug events (potential ADEs) or adverse drug event (ADEs) occurred according to the definition below[12].

"Potential ADE is medication error with the potential to cause an injury but which does not actually cause any injury, either because of specific circumstance, chance or because the error is intercepted and corrected."

"ADEs is an injury due to medication."

Events which not deemed to be MEs and/or potential ADEs and/or ADEs, which occurred in the operating room or in the post-anesthetic care unit (PACU) were excluded. Adverse drug reactions (ADR) which were not due to some type of medication errors, such as anaphylaxis, were also excluded.

All completed forms of MEs related to anesthesia were reviewed and discussed by three peer reviewers, each was a board-certified anesthesiologists and MEs experts. The reviewers used the "Medication Error Detection Framework" to identify type of MEs, contributing factors and suggestive prevention strategies (Figure 1). Severity of MEs and ADEs were classified by The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) medication error index[13], which is categorized from A to I. Categories A to D are relevant to MEs and categories E to I are relevant to ADEs (Figure 2).

Category A: Circumstances or events that have the capacity to cause error.

Category B: An error occurred but the error did not reach the patient.

Category C: An error occurred that reached the patient but did not cause patient harm.

Category D: An error occurred that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.

Category E: An error occurred that resulted in the need for treatment or intervention and caused temporary patient harm.

Category F: An error occurred that resulted in initial or prolonged hospitalization and caused temporary harm.

Category G: An error occurred that resulted in permanent patient harm.

Category H: An error occurred that resulted in near-death event (e.g. cardiac arrest)

Category I: An error occurred that resulted in patient death.

Any disagreement was critically discussed and judged to achieve a consensus. The descriptive statistics were used to analyse the data by using SPSS for Window, version 22.0.

Results

There were 85 relevant reports of MEs from the first 2,206 incident reports (4.25% of all incident reports). Of these events, 35 (41.2%) were MEs without potential harm, 22 (25.9%) were MEs with the potential of ADEs and 28 (32.9%) were MEs that led to an observed ADEs (Figure 2). The age of the patients varied from three hours to 91 years old. One-fourth of the incidents (22 incidents) occurred in pediatric patients under 15 years of age. In addition 11 incidents were found in the infant (less than one year old) (Table 1).

The type of MEs with example of errors and potential ADEs/ADEs are demonstrated in Table 2. Overdosage (25 incidents, 29.4%) was the most frequently found types of error. Among the patients with overdosage of drugs, 10 incidents (40%) occurred in pediatric patients. Some overdosage events caused major ADEs such as alteration of consciousness from neuraxial opioid overdose, seizure and cardiac arrhythmia from local anesthetic toxicity and led to unplanned admission to intensive care unit.

Wrong drug administration (19 incidents, 22.4%) was the second frequently found type of error including syringe swaps or wrong ampule. The main drugs involved in syringe swaps were opioids and neuromuscular blocking agents. The wrong ampule errors were similar to those involved with syringe swaps. The examples of drug substitutions (drug intended to drug given) were fentanyl/pancuronium, atracurium/cis-atracurium, furosemide/metoclopramide, morphine/ephedrine. There was one report of wrong drug caused by problem with communication in which esmolol was substituted by Esmeron® (rocuronium).

Labelling errors were reported for 15 events (17.6%). Most of them were near-miss incidents and detected by re-check process by personnel who were not involved in drug preparation.

Each incident was detected by more than one methods. Some personnel administered medication and detected the incidents by self recall, these were found in 7 incidents (8.3%). Eleven incidents (20%) were detected by clinical findings, 12 incidents (15.3%) by monitoring, 52 incident (61.2%) by re-check drugs on anesthetic table and 9 incidents (10.6%) by re-check document (Table 3). Time of incidents alert and personnel involvement are also demonstrated in Table 3. The people detected the incidents were anesthesiologists, nurse anesthetist and resident 17 incidents (20%), 51 incidents (60%) and 17 incidents (20%) respectively.

MEs events were submitted from 15 from 22 participated hospitals. Events were reported along the year but most frequent in July and none in December

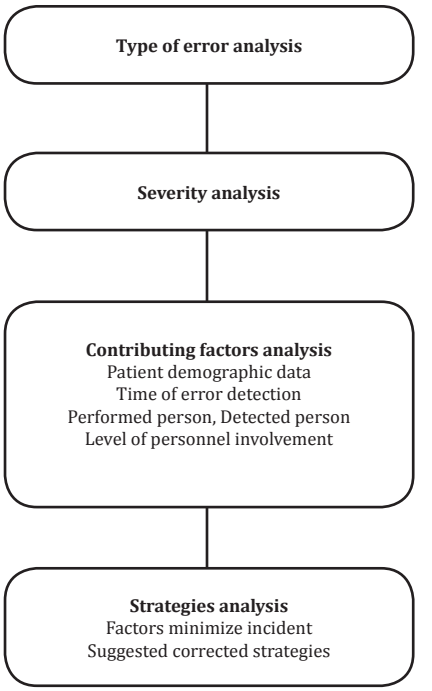


Figure 1. Medication error detection framework.

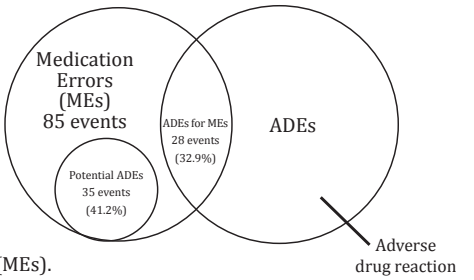


Figure 2. Relationship between adverse drugs events (ADEs), potential ADEs and medication errors (MEs).

Table 1. Age group of patients involved in medication errors

Age (year)	Number of patients	Percentage
< 1	11	12.5
1 - 14	11	12.5
15 - 60	36	40.9
61-80	22	25.0
>80	5	5.7

Table 2. Type of MEs, example of error and associated potential ADEs and ADEs

Type of errors	n (%)	Errors example	Potential ADE / ADE example
Wrong Drug	19 (22.4%)	Morphine-Ephedrine Fentanyl-Pancuronium Atracium-Cistracurium Esmeron®-Esmolol Atropine-Normal saline solution Cistracurium-Morphine Furosemide-Metoclopramide Prostigmine-Methyl Ergonovine maleate Ephedrine-Oxytocin	Hypotension Sedation Delay emergence
Wrong Label	15 (17.6%)	Thiopental 20 mg/ml labelled as 10mg/ml Dopamine 10 mcg/kg/min labelled as 1 mcg/kg/min Fentanyl 5 mcg/ml labelled as10 mcg/ml	
Wrong route	5 (5.9%)	Intravenouns-Invasive arterial blood pressure line	
Wrong document	1 (1.2%)	No concentration document	
Wrong concentration	4 (4.7%)	Dopamine200mg/100ml (100mg/ml) Morphine 1mg/ml (0.9 mg/ml)	Tachycardia
Underdosage	4 (4.7%)	Diazepam 0.75 mg (7.5mg) Cistracurium 1 mg (2mg)	
Overdosage	25 (29.4%)	Spinal morphine 0.5 mg.(0.05mg) 2%lidocaine with adrenaline 30 ml Brachial plexus block Heparin 25,000 unit(5,000unit) Prostigmine 5.0 mg(2.5mg) Protamine 65 mg (50mg)	Alteration of consciousness Seizure Arrhythmia Non ST-elevation myocardial infarction
Omit Dose	5 (5.9%)	Heparin Atracurium	
Omit Record	7 (8.2%)	Prostigmine Atropine	

Table 3. Details of incident alerted*

	Number (n = 85)	Percentage
How the incidents alerted		
Self recall	7	8.3
Detect from clinical	17	20
Detect from monitor	13	15.3
Re-check drugs on the table	52	61.2
Re-chek documents	9	10.6
Phase when incidents alerted		
During anesthesia	59	69.4
After anesthesia ends	26	30.6
Personnel who prepared or administered drugs		
Anesthesiologist	17	20
Nurse anesthetist	38	44.7
Resident	27	31.8
Anesthesia nurse student	3	3.5
Personnel who detected MEs		
Anesthesiologist	17	20
Nurse anesthetist	51	60
Resident	17	20
Anesthesia nurse student	0	0

Data are not mutually exclusive

(Figure 3).

All MEs incidents were classified by severity using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) medication error index. The result of classification was shown in Figure 4. Among the 16 incidents (18.8%) of E and F classes, 12 incidents were overdosages, 3 incidents were wrong drug and one was wrong route administration. None was associated with permanent harm or death.

Among 32 incidents of B class (near-miss), there were 15 incidents (46.8%) of wrong label, 7 incidents (21.8%) of omit document, 5 incidents (15.6 %) of wrong drug, 3 incidents (9.3%) of wrong concentration, one incident of overdose administration and one for wrong document.

The reviewers discussed and classified all MEs basing on a psychological approach (Figure 4). Fifth-teen incidents (17.6%) , 20 incidents (23.5%), 47 incidents (55.3%) and 3 incidents(3.5%) were considered to be knowledge-based, rule-based, action based (slip) and memory based (lapse) respectively. All 85 incidents were considered as preventable. The contributing factors, factors minimizing incidents and suggested corrective strategies for preventing of perioperative medication errors are shown in Table 4.

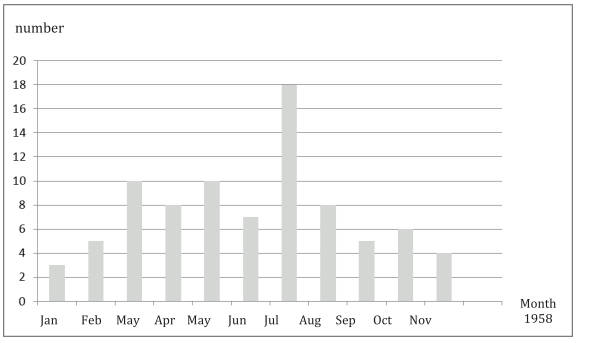
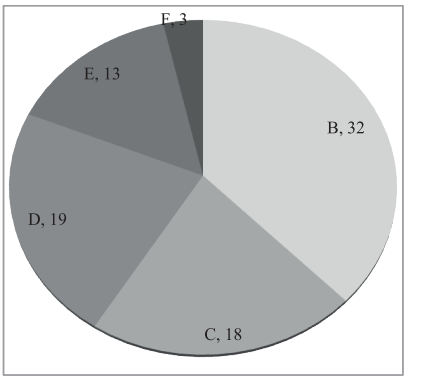


Figure 3. Number of medication error reported by months.



AB : CD : EF = 37.6 : 41.2 :18.9%

Figure 4. Classification of medication errors base on severity among the first 2000 incident reports (number of incidents are shown).

Discussion

In previous studies, MEs rate is sparse. In 2009, R.L. Llewellyn et al. report incidence was 1:274 of drug administration errors[8], while Karen C. Nanji et al. revealed that about 1 in 20 perioperative medication administrations included MEs and/or ADE by prospective observation study[1]. We found that about 4.25% of the incidents of perioperative MEs in PAAd Thai study that was comparable to the 4.1% of Thai AIMS published in 2012 [9]. Differences in study design, data collection and definition of MEs/potential ADEs and ADE may account for the discrepancy.

One-fourth of the incidents (22 incidents) occurred in pediatric patients under 15 years of age and half of those were found in the infant (less than one year old). Pediatric patients are at higher risk of MEs and ADEs for several reasons [14,15]. Dosage calculation is required, based on weight, age or body surface area of the children. Frequently, there is the lack of a formulation for pediatric patient and adult formulation must be diluted for the use in children. These lead to the wrong dose calculation and may harm patients with overdosage[16]. Supporting features such as dose calculators, maximum dose checking or double

Table 4. Analysis of contributing factors, factors minimizing incident and suggested corrective strategies

	Number	Percentage
Contributing factors		
Lack of knowledge	6	7.1
Lack of experience	11	12.9
Haste	53	62.4
Miscommunication	14	16.5
Misjudgement	2	2.4
Problem with labelling	15	17.6
Factors minimizing incident		
Experience	16	18.9
Vigilance	70	82.4
Communication	16	18.9
Training	6	7.1
Suggested corrective strategies		
Practice guideline	9	10.6
Additional training	7	8.3
Improvement of supervision	13	15.3
Improvement of communication	12	14.1
Quality assurance activities	85	100

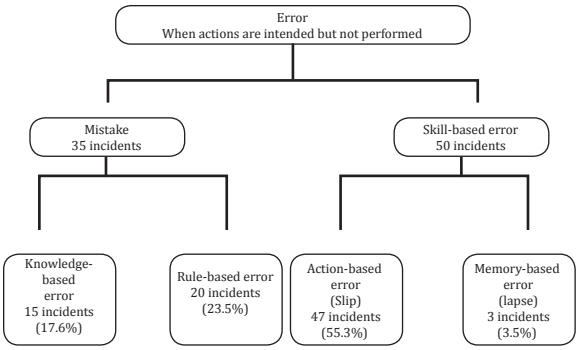


Figure 5. Classification of medication errors based on the psychological approach.

checking by other personnel has the capacity to reduce MEs because of minimizing cognitive overload[1].

We found that overdosage of drugs was the most frequently found type of error. Among these incidents, 40% occurred in pediatric patients who are vulnerable to MEs and ADEs as mentioned above. Two of overdosage incidents caused major ADEs, but one occurred from local anesthetic toxicity administered by surgeon. Communication among the team members was crucial in this case.

Wrong drug administration including syringe swap and wrong ampule was the second most common incident reported to our study (19 incidents, 22.4%). This type of error caused the substitution of drugs as an inter-class pattern, for example substitution of ephedrine with morphine, which was more dangerous than giving the wrong drug in the same class. Data in many previous studies suggest that color-coded labelling reduced the incident of drug error[3,17]. We found that even color-coded labelling system is available in our practice, the incident of wrong drug administration was still high and comparable to the previous study conducted in Thailand when the color-coded labelling was not applied[9]. However, most of the incidents did not cause patient harm, only three incidents were classified in NCC MERP class E and F (temporary harm). Similar labelling of ampules and vials by manufacturers (look-alike) is one of another important risk attributed to this type of error. One incident occurred with the sound-alike drugs, when Esmeron ®(rocuronium) was given instead of esmolol. Strategies to prevent such error include choosing drug with clear font labelling, using generic name rather than trade name, double checking when drawing up drugs and bar-coded system that reveals the drug name after it has been scanned before being drawn up[18,19]. However, there is no bar-coded system in our practice.

The majority of incidents was detected by re-checking drugs on anesthetic table (52 incidents, 61.2%), this revealed that errors were detected by second personnel rather than the practitioners themselves. Thus, supervision or double checking of drugs is crucial to error detection and prevention. Especially in the perioperative period when anesthesiologist or nurse anesthetist often work as a single practitioner and responsible for whole drug administration process.

Our study used voluntary and anonymous reporting system. There were large differences in the degree of compliance as one affiliated hospital reported 34 incidents (40% of overall) and no incidents from 7 out of total 22 hospitals. Furthermore, near-miss incidents reported were only one-third of errors. These variations may depend on awareness of anesthetic personnel, institution policy on drug administration, manpower for supervision and document audit system. The events were reported along the year, but most frequently in July. Anesthesia resident training in the whole country starts in this month of every year. New residents in the anesthesia service were considered to relate with this high incidents of MEs. However, we conducted the study only in the 12-month period, a longer study will be required if this phenomenon is to be observed.

In our study, we preferred to use psychological theory to classify all MEs events as it explains how the events occurred. This approach yields four broad types of medication errors Figure 5. Mistakes can be divided into knowledge-based errors and rule-based errors. Skill-based errors can be divided into slips and lapses. However, the disadvantage of this classification is that it concentrates on human rather than systems source of error[10]. Classification of MEs provides the understanding how medication error occur and how to prevent them. All of the incidents in this study were related to human error and were considered preventable. The majority of incidents were classified into skill-based errors: 47 incidents (55.3%) were classified into action-based errors (slips) and 3 incidents (3.5%) were memory-based errors (lapses). Haste (62.4%), problem with labelling (17.6%) and miscommunication (16.5%) were considered as the contributing factors. Because of more than half of the incidents were classified into skill-based error, we thought that vigilance (82.4%) and experience (18.9%) were considered the most common factors minimizing incidents. We suggested that quality assurance activity such as morbidity-mortality conference and patient

safety round should be done for every incident as corrective strategies to increase the awareness in perioperative MEs.

In 2009, the RCAT enclosed the clinical guidance of using international color-coding for anesthetic drugs for prevention of inter-class MEs[9]. However, we found in our study that the problem with labelling was still high. Computerized system such as bar code scanning was considered to minimize errors.

Conclusion

Medication errors (MEs) in perioperative setting may lead to serious outcome. Investigating the incidence, classification and identifying preventive strategies are crucial to improving the quality of anesthesia. 4.25% of MEs were reported in our study, which comparable to the previous report from Thailand in 2007. Overdosage was the most frequently found type of errors. Pediatric patients were considered a high risk group. All of the incidents were related to human error and considered preventable. Vigilance and experience were factors that can help to minimize incidents.

What is already have known this topic

Medication errors (MEs) were related to human error and preventable. The incident rate is sparse among studies due to the study design, data collection and definition of MEs.

What this study adds?

One-fourth of the incidents occurred in pediatric patients. 40% of overdosage occurred in this group. Dose calculators, maximum dose checking or double checking strategy should be applied to reduce MEs.

Since 2009, color-coded labelling has been applied in our practice, but we found that the incident of wrong drug administration was still high. However, most of the incidents did not cause patient harm. Bar code system should be considered to minimize errors.

The incidents were reported mostly in July when the residency training began. New trainees may be associated with this phenomenon.

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Potential conflicts of interest

The authors declare no conflict of interest.

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