# An Analysis of The Drug Error Problem in the Thai Anesthesia Incidents Study (THAI Study)

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**Objectives :** To analyze the problem of drug error related to anesthesia in Thailand including nature, contributing factors and preventive strategies.

*Material and Method :* We prospectively recorded anesthesia-related drug error incidents for 18 months in 20 studied hospitals in Thailand. Types of errors and their outcomes were recorded. All data were analyzed to identify contributing factors and preventive strategies.

**Results :** Forty-one drug error incidents were reported in 40 out of 202,699 anesthetized cases or 1: 4,943 in this study. The most common type of error was wrong drug (20 incidents; 48.8%). No relationship between anesthetic techniques and the incidents except for a combined general and epidural technique. The errors were most commonly occurred during induction of anesthesia(26 out of 41; 63.4%) and muscle relaxants were most commonly involved(13 out of 41; 31.7%). The majority of incidents (26 out of 41; 63.4%) caused no adverse effect. However 14 incidents (34.1%) caused transient mild to severe physiological effects, of which 13 had complete recovery but one died. Haste and lack of recheck were two common contributing factors which were minimized by high awareness and double check prior to drug administration. Main strategies suggested to prevent the incidents included specific guideline development whereas the incidents did not effectively decrease by increasing of manpower.

**Conclusion :** The incidence of drug error in our study was 1 : 4,943. It can cause morbidity and mortality during anesthesia. Practitioners should be aware of these potential incidents and strictly follow the guideline for drug administration.

Keywords : Anesthesia , Drug error, Ampoule, Syringe, Incidence, Multi-center study

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Human error is an important contributing factor of adverse events in anesthetic practice<sup>(1-9)</sup> and critical care<sup>(10)</sup>. Drug error during anesthesia is also a part of human error. The incidence of drug error is not rare, its outcomes may be harmful to the patients, raised the medical expenses and could be a cause of closedclaims . In 2001, Webster et al <sup>(11)</sup> reported incidents of drug error during anesthesia in two studied hospitals based upon self-reporting and found the incidence of 1 : 133 or 0.75 percent from 7,794 studied cases. This number of incidence was greater than that reported by Fasting and Gisvold<sup>(12)</sup> whose study was done in 55,426 anesthetized cases and 63 cases was reported to have drug error problems (0.11% or 1:880). Recently in 2004, the Japanese study group<sup>(13)</sup> analyzed the critical incidents from 4,291,925 anesthetic cases and found that the drug administration error was only 1: 5,475. There were many types and causes of drug errors reported from many studies<sup>(1-13)</sup>. In 1995, systems analysis of adverse drug events was published by Leape et al<sup>(14)</sup>. They found that the most common type of drug error in adult intensive care units and adult non-obstetric general care units at the two studied tertiary hospitals was

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wrong dose error (28%). However, in the anesthetic practice, Currie et al <sup>(15)</sup>found that the wrong drug error was most common. This character was also found in many studies<sup>(1, 4, 11, 12, 15-20)</sup>.

In Thailand, the study of drug error problem during anesthesia has not been performed. In order to analyze the nature, contributing factors and preventive strategies of drug error during anesthesia,the Thai Anesthesia Incidents Study (THAI Study) group decided to study this problem.

#### **Material and Method**

The Thai Anesthesia Incidents Study (THAI Study) is the multi-center study included 7 university hospitals,5 tertiary care hospitals,4 secondary care hospitals and 4 primary care hospitals. This study aimed to monitor the incidence of adverse events from February 1, 2003 to July 31, 2004. THAI Study was approved by Institutional Ethical Review Board. Details of preanesthetic condition, anesthetic management, intraoperative events and perioperative complications within 24 hours of consecutive patient had been recorded in standardized record forms.

Drug error problem in this study was defined as any undesirable event during anesthesia that caused or led to inappropriate drug use or patient harm. The error was recorded until 24 hours postoperatively.

Details of drug error event were recorded on a standardized form by attending or nurse anesthetists and verified by the site manager. These included type of hospital classified by the number of patient beds, ASA physical status, emergency state, anesthetic technique, error drug and its type of error, involving personnel, causes of event and its outcomes. Then the recorded data were reviewed by 3 peer reviewers to identify clinical risk factors, contributing factors and corrective or preventive strategies.

Data was analyzed by using descriptive statistics. We used a Fisher s Exact test or Chi-square test with Yate s correction for statistical analysis of frequency differences. Statistically significant was considered if P value < 0.05.

#### Results

There were 202,699 anesthetized cases included in this study. Incidents of drug errors were reported in 40 cases. Of these,one case in general hospital had 2 events so that there were 41 drug error incidents which were approximated to 1 per 4,943 or 0.02%.

Characteristics of the patients (ASA physical status, emergency state) who had drug error incidents

as well as anesthetic techniques and types of hospital are summarized in table 1.

Table 2 shows the type and frequency of the drug errors, the majority of events were related to wrong drug (48.8%) and incorrect dose (29.3%). Each type of errors was further categorized as actual error and near error. The actual error was defined as an error drug was actually given to the patient whereas the near error drug was detected early before administration. The total incidents of actual error and near error were 37 of 41 cases (90.2%) and 4 of 41 cases (9.8%) respectively.

Table 3 summarizes groups of error drugs and the occurrence period of time involved in the incident. Muscle relaxant group was the most common drug that caused the error (13/41; 31.7 %) and the second most common agent was opioids (11/41; 26.8%). These error drugs were most frequently taken unintentionally from correctly labeled syringes or syringe swaps (29/41;70.7%) and wrong selected ampoules or ampoule swaps (7/41; 17.1%). The most common occurrence time of the error was induction period (26/41; 63.4%)

**Table 1.** Patient characteristics and anesthetic technique in relation to frequency of incidents

Characteristics	Frequency of incidents
Type of hospital :	
University	19
Regional	17
General	4
District	-
ASA physical status :	
ASA 1	18
ASA 2	20
ASA 3	2
ASA 4	-
ASA 5	-
Emergency state	
Emergency case	15
Elective case	25
Anesthetic technique :	
General anesthesia	27
Spinal anesthesia	6
Combined general with epidural *	5
Total intravenous anesthesia (TIVA)	1
Monitor anesthesia care (MAC)	1

\* Significantly high occurrence ratio in comparison with other techniques

 Table 2. Classification of drug error incidents showing types of error, frequencies of actual error, near error and adverse effects.

Types of error	Frequencies			
Types of error	Actual error	Near error Total number		Adverse effects
Wrong drug	19	1	20	8
Incorrect dose	12	-	12	6
Wrong route	3	-	3	-
Drug omission	1	1	2	-
Wrong concentration	-	1	1	-
Wrong label	-	1	1	-
Wrong time	1	-	1	-
Wrong patient	1	-	1	-
Total	37 ( 90.2% )	4 (9.8%)	41(100%)	14(34.1%)

**Table 3.** Types of error, drug group, drug container involved and the occurrence period of time involved in the incidents

Error groups , container involved, and occurrence time	Number of incidents( % ) N = 41
Drug groups involved :	12 (21 7 0/)
- Muscle relaxants (suxamethonium,	13 (31.7 %)
atracurium, pancuronium, vecuronium	
- Opiods (fontanyl morphing pathiding)	11 (26.8%)
<ul><li>(fentanyl, morphine, pethidine)</li><li>Volatile (halothane, sevoflurane)</li></ul>	3 (7.3%)
- Antibiotic	3 (7.3%)
(cloxacillin, bleomycin, cefazolin)	5 (7.570)
<ul> <li>Vasopressor (adrenaline)</li> </ul>	3 (7.3%)
- Intravenous induction	2 (4.9%)
(thiopentone, propofol)	2 (1.970)
- Anticolinesterase (neostigmine)	2 (4.9%)
- Anticoagulant (heparin)	2 (4.9%)
- Combination of bupivacaine	2 (4.9%)
and morphine	_ (, , ,)
Drug containers involved :	
- Syringe swaps	29 (70.7%)
- Ampoule swaps	7 (17.1%)
- Vaporizer errors	3 (7.3%)
- Intravenous fluid bottle errors	2 (4.9%)
Occurrence time :	
- Induction	26 (63.4%)
- Maintenance of anesthesia	9 (22.0%)
- Extubation and emergence	3 (7.6%)
- Recovery	2 (4.9%)
- 24 hours postoperatively	1 (2.4%)

 Table 4. Relationships between the anesthetic personnel and frequency of incidents

Relationships between anesthetic personnel and incidents		
Relationships	Frequency of incidents	
Drug administer and person who prepared drug : - Same person - Different personnel	20 21	
Drug administer and error detector : - Same person - Different personnel	18 23	

followed by maintenance of anesthesia (9/41; 22.0%) and extubation and emergence (3/41; 7.3%).

The anesthetic team comprised of attending anesthesiologists, nurse anesthetists, anesthesia residents, anesthesia nurse trainee and medical students. Every case, except one in a secondary hospital, was anesthetized by an attending anesthesiologist who acted as a leader of the team. Two or more anesthesia person-nel were involved in the anesthetic team. Everybody in the team was responsible to prepare or administer any kinds of anesthetic drugs depended on hospital policy. The error drugs were prepared by nurse anesthe-tists (16/41; 39.0%), attending anesthesiologists (8/41; 19.5%), anesthesia residents (3/41; 7.3%), anesthesia nurse trainee (7/41; 17.1%), medical students (2/41; 4.9%) and unknown (5/41; 12.2%). These error drugs were administered by nurse anesthetists (15/41; 36.6%), attending anesthesiologists (13/ 41; 31.7%), anesthesia residents (3/41; 7.3%), ward nurses (1/41; 2.4%), anesthesia nurse trainee (2/41; 4.9%), medical students (2/41; 4.9%) and unknown (5/41; 12.2%). The personnel who detected the incidents were nurse anesthetists (21/41; 51.2%), attending anesthesiologists (14/41; 34.1%), aneshesia residents (3/41; 7.3%), surgeons (2/41; 4.9%) and ICU nurses (1/41; 2.4%). There were no relation-ships between incidents and anesthetic personnel involving in drug preparation, and administration and error detection; as shown in table 4.

The patient outcomes resulting from the incidents varied from no effect to serious harm or even life-threatening. The majority of incidents (26/41; 63.4%) caused no adverse effects but the other 14 (34.1%) did. In the adverse effect group, 13 had transient effects. These included 2 cases of hypotension from morphine given instead of ephedrine and 8 % sevoflurane administered at the end of anesthesia, 1 case of severe tachy-cardia from adrenaline given instead of ergonovine, 1 case of severe bradycardia from neostigmine given instead of atracurium, 2 cases of hypoventilation from

atracurium given instead of fentanyl and repeated dose of epidural morphine, 2 cases of apnea from atracurium given instead of fentanyl and pancuronium given instead of ergonovine and 5 cases of prolonged emergence / apnea from succinylcholine given instead of neostigmine, overdosage of atracurium, pancuronium instead of fentanyl, halothane and sevoflurane continuing at the end of anesthesia. The most serious outcome occurred in a congenital heart disease underwent cardiac surgery with a massive overdose of heparin resulting in severe coagulopathy and cardiac arrest unresponsive to cardio-pulmonary resuscitation.

The only main cause of all incidents was anesthesia-related. Table 5 summarizes the risk factors contributed to be the causes of incidents which were categorized as skill-based , rule-based , knowledgebased and system-based errors. One to several contributing factor(s) was/were found in each error. Also shown in table 5 are the lists of factors suggested to minimize the incidents. Again, one to several factor(s) was/were reported to minimize the incident in each case. Haste (19/65; 29.2%) and lack of recheck prior to drug administration (19/65; 29.2%) were the two most common contributing factors which were minimized by high awareness (29/75; 38.7%) and double check sys-

Contributing factors <sup>a</sup>		Factors minimizing incidents <sup>b</sup>	
Categories of error	Number	Categories of error	Number
Skill-based :		Skill-based :	
- Haste	19	- High awareness	29
- Careless/inattention	3		
		Rule-based :	
Rule-based :		- Double check prior to	18
- Lack of recheck prior	19	drug administration	
to drug administration		- Staff change	1
Knowledge-based :		Knowledge-based :	
- Inexperience	9	- Prior experience	5
- Lack of knowledge	5	- Additional training	1
- Error of judgment	2		
		System-based :	
System-based :		- Skilled assistant	7
- Communication problem	7	- Improved communication	7
- Unclear drug label	1	- Improved drug labeling	5
-		- Improved supervision	1
		- Additional equipment	1
Total	65	Total	75

Table 5. Contributing factors and factors minimizing the incidents

<sup>a,b</sup> More than one categories/factors may have been reported per incident.

**Table 6.** Preventive strategies of drug error incidents.

Suggested preventive categories	Frequency <sup>a</sup>
Rule-based :	
Specific guideline / protocol development	21
Improved communication	11
Knowledge-based :	
Quality assurance activity	11
Additional training	7
System-based :	
Improved supervision	6
More manpower	2
Total	58

<sup>a</sup> More than one categories may have been suggested per incident.

tem prior to drug administration (18/75; 24.0%).

All drug error incidents were preventable. Pre-ventive strategies were suggested and summarized in table 6. Specific guideline or protocol development for drug administration during anesthesia was the most frequent suggestion (21/58; 36.2%) whereas more manpower was the least (2/58; 3.4%).

#### Discussion

#### Incidence and nature :

In our study, there were 41 drug error events in phase I and phase II of the Thai Anesthesia Incidents Study (THAI Study)<sup>(21)</sup> reported. This is comparable to 0.8 % reported by Fasting and Gisvold (12), 1.5 % reported by Cohen et al. (22) and 2.4 % reported by Spittal et al.<sup>(23)</sup> The frequency of drug error per any type of anesthetic in our study was 1: 4,943 (0.02%). This incidence was greater than that reported from Irita et al. s study (1: 5475)<sup>(13)</sup> but much less than those reported from the studies of Webster et al. (11) (1:133) and Fasting and Gisvold (1: 880).<sup>(12)</sup> In the study of Irita et al.<sup>(13)</sup>, data were obtained from annual surveys of 4,291,925 anesthetized cases conducted by Japanese Society of Anesthesiologists and found 1: 5,475 drug error incidence. It was also noted in the Japanese study that 88 percent of drug ampoule or syringe errors occurred in patients with ASA physical status class I or II who did not seem to require complex anesthetic management. In the study of Webster et al.<sup>(11)</sup>, the obtained 7,794 data from 10,806 anesthetics at two hospitals were analyzed and found a high incidence of drug error (1: 133). This incidence was greater than that reported from the study Fasting and Gisvold<sup>(12)</sup> who prospectively recorded anesthesia-related information from all anesthetic cases for 36 months, totally 55,426 procedures. This study was divided into 2 periods, 18 months before and 18 months after implementation of the color coded syringe labels. They found that the overall incidence was 1:880 and the color coding of syringe labels did not eliminate syringe swaps which occurred most often between syringes of equal size. In addition, they found no difference between the two periods except for decreased number of ampoule swaps. Interestingly, there was a high number of drug errors reported in obstetric anesthesia. Yentis and Randall<sup>(18)</sup> conducted a national survey to find drug errors in obstetric anesthesia and found that of the 179 out of 240 maternity units in the United Kingdom, 70 units (39%) had at least one drug error during the last year. Though it was unable to estimate an incidence of drug error from this study, the reporters believed that drug error problem was relatively widespread in obstetric anesthesia. In fact, Sinclair et al.<sup>(19)</sup> found that wrong drug errors were over-represented in obstetric cases compared with non-obstetric ones. From all of these reports, we have found large variations in drug error incidences varied from 1: 5475 to 1:133. These might be due to the differences in study designs, definitions of drug errors and methods of data collection. Though the incidence of drug error in our study was lower than in previous reports(11, 12), we believed that it was under-reported from our results for four reasons. First, some minor drug errors did not cause any physiological effects therefore possibly undetected or unaware. Second, it is the human nature not to report his/her error because of feeling of shame, embarrassment, fear of medico-legal problems and others. Third, method of data collection in our study was based on anonymously submitted written report of any incident after the anesthetic team has agreed to report. The researchers did not retrospectively inspect in anesthetic chart and therefore some minor or near errors might be missed. And finally, some incidents occurred during critical periods of time or occurred in such busy days that no one could remember to report.

Concerning the occurrence time of errors, Short et al.<sup>(3)</sup> reported 125 critical incidents from a total of 16,379 anesthetics and found that most incidents occurred during induction or maintenance of anesthesia. Similarly in our study, the drug error incidents oc-curred mostly during induction of anesthesia (26/41; 63.4%). The reason was many kinds of drug were given steps by steps in a short period of time.

Surprisingly in our study, there was no increased risk of drug error in association with emergency state as well as the ASA physical status. This was different from the study in 1,000 anesthetic incidents by James<sup>(17)</sup> who found that the number of incidents involving emergency cases was probably slightly disproportionately high and predominated in ASA 1 patients. However in his study, there was no comparison of incident cases with the total number of anesthetized ones. In aspect of anesthetic technique, we found in our study that most of errors (27/40;67.5%) occurred in general anesthesia. However, when comparing with nonerror data, we found that types of anesthetic technique did not contribute to the likelihood of errors except for a combined general and epidural technique which its occurrence ratio was highest, therefore possibly increased the chance of risk (table 1). In this combined technique, nearly all incidents (4 of 5 incidents) resulted from infusions of premixed epidural solutions into intravenous lines for post-operative epidural pain control.

#### Drugs involved and outcome :

Actual errors was reported in 37 incidents (90.2%) but only 14 cases had adverse effects. The most common type of drug error in our study was wrong drug. It constituted 20 of 41 cases (48.8%) which was similar to most studies<sup>(1, 4, 11, 12, 15-20)</sup>. The second common type of error was incorrect dosage (12 of 41; 29.3%). These types of errors were clinically important because they caused minor to major adverse effects to patients and one case with heparin overdose died.

Muscle relaxant group was the most common erroneous drug which was found in the same manner as reported in many studies<sup>(1, 7, 12, 15, 16)</sup>. Opioid group was also common. Both muscle relaxant and opioid were at risk of errors because they were used frequently, drawn up in the equal size of syringes and were placed side by side on anesthetic carts. These drugs especially muscle relaxants were given in hurry when patients moved. Adverse effects of these two drug groups were hypoventilation and apnea. Fortunately, these events were early detected and promptly managed without long-term adverse outcomes. However, anesthesia personnel must realize the frightening experiences and psychic trauma caused by erroneous drugs given to awake patients. Examples of these in our study included one case suffered from adrenaline induced severe tachycardia and two cases of rapidly progressive paralysis from muscle relaxants given unintentionally which resulted in endotracheal intubation and artificial ventilation.

Serious outcomes of drug error incidents can bring to closed malpractice claims. In 2004, Orser and Byrick <sup>(24)</sup> mentioned that a single most common cause of malpractice action against Canadian anesthesiologists who were members of the Canadian Medical Protection Association (CMPA) was medication related event which occurred in 120 out of 232 closed legal actions or 52% of claims during the period from 1998 to 2002. This percentage of claims was much higher than that of the previous report of the ASA Close Claims Project<sup>(25)</sup> which occurred approximately 4% for the 1980s and 1990s. In addition, Bates et al<sup>(24)</sup>. reported the annual costs of drug-related errors was estimated to be approximately 2.8 million dollars for a 700-bed teaching hospital. Therefore all anesthesiologists should be aware of all error incidents in their practices.

#### Hospitals and personnel involved :

Because our study was done in 20 hospitals which were different in facilities, numbers and experiences of anesthetic teams and nature of patients, we decided to find the relationships between the incidents and hospitals or personnel involved. In comparison with the total number of anesthetized cases in each hospital group, there was no any difference in the comparison amongst university, regional, general and district hospitals (table 1).

We can not report the risk of drug errors in association with anesthetic personnel because we did not record the details of personnel who prepared and administered drugs in all cases including in our study. However, we have analyzed the relationships between the 41 error incidents and involving personnel and found that there was no any difference amongst the person who prepared, administered and error detected (table 4). From this data, we conclude that the prevention of communication problems by permitting only one person in performing of drug preparation and administration provided no guarantee of safety. The increasing in the number of manpower for effective awareness as seen in the different personnel involving in drug preparation and administration did not decrease the risk as well. We also noted that a moderate number of personnel involved in drug preparation and drug administration was trainees(12 out of 41 prepared drugs and 7 out of 41 administered drugs). These trainees included anesthesia residents, anesthesia nurse trainee and medical students. In teaching hospital, the trainees are allowed to both prepare and administer drugs

under supervision but only anesthesia residents detect the incidents. Some rules should be developed in order to reduce the risks.

For the error detection, we found that not only the same person who administered drug and detected the error afterward but also the different ones did (table 4). This also reconfirmed that using one or more personnel provided no guarantee of safety. In fact, most anesthesiologists experienced at least one actual or potential drug error<sup>(27, 28)</sup>. Therefore, it should be recommended that all anesthesia personnel have to do a double check of drugs immediately before giving and observe clinical signs after administration.

#### **Contributing factors :**

The only main cause of all incidents was anesthesia-related. More than one contributing factors invol-ved in some events. The two most common contribut-ing factors in our study were haste and lack of recheck prior to drug administration. These consisted of equal number of frequency (19 of 65 or 29.2% each). The factors of haste, lack of recheck, fatigue, carelessness, inattention, judgment error, forgetfulness and communication problem have previously been identified as potential causes of errors<sup>(5, 15-17, 20)</sup>. Though many recommendations or preventive systems have been developed for years, the incidents still occur. These confirm the philosophy of human behavior that the error making is an inherent part of human psychology and activity and no ones can eliminate it from their lives but possibly only be reduced<sup>(29, 30, 31)</sup>.

The errors can be categorized as human and system errors<sup>(5, 31, 32)</sup>. Human error is further classified as knowledge-based, rule-based, skill-based and technical errors. We found that human error was a major cause of drug errors in our study (table 5). It composed of 57 of 65 or 88% which was similar to most of previous studies<sup>(1-5)</sup>.

The error drugs in this study were taken mostly from correctly labeled syringes which were placed nearby the intended syringes. This was called as syringe swaps . Some errors caused by taking wrong ampoules which looked similar to the correct ampoules. This was called ampoule swaps . In our study, we found syringe swaps more common than ampoule swaps (70.7% versus 17.1%) which was similar to the previous studies of Fasting <sup>(12)</sup>, Currie <sup>(15)</sup> and Orser <sup>(27)</sup> who analyzed drug error incidents from the Norwegian study, the Australian Incident Monitoring Study (AIMS) and the Canadian Study respectively. Recently in 2005, Abeysekera et al. <sup>(16)</sup> reviewed 896 incidents relating to drug errors reported to the AIMS between 1988 and 2001. They found that ampoule identification errors were more common than syringe swaps which contrasts to Currie s original study<sup>(15,16)</sup>. Because the architecture and labeling of drug ampoules used in anesthesia are non-standardized and different amongst drug manufacturers, these lead to increase the risk especially in a hurried situation.

In our study, the common factors for minimization of incidents were high awareness (29/75 or 38.7%) and double check prior to drug administration (18/75 or 24.0%) which correlated to the two most common contributing factors mentioned above. We also found only one case of unclear drug labeling in syringe swaps group. Thus the labeling system played only a minor role in our study. Indeed Fasting and Gisvold <sup>(12)</sup> reported that syringe swaps occurred most often between syringes of equal size and were not eliminated by color coding of labels. Therefore it is strongly recommended that the label on any drug ampoule or syringe should be read carefully before a drug is drawn up or injected<sup>(33)</sup>.

#### **Preventive strategies :**

Because critical incidents including drug error were mostly caused by human error<sup>(1-10)</sup> and the most common type of drug error in anesthetic practice was wrong drug error related to syringe swaps<sup>(12, 15, 27)</sup>. Therefore many studies have been designed with the aim of reducing errors during anesthesia<sup>(12,34-36)</sup>. Fasting and Gisvold<sup>(12)</sup> reported that color syringe labels did not eliminate syringe swaps. They strongly recommended to do double checking of ampoule as the drug was drawn up into the syringe and checking the label on the syringe as the last procedure before drug administration.

In 2001, Merry et al<sup>(34)</sup>. introduced a new drug administration system including trays, color and barcoded labeling of syringes pre-filled with desired drugs and automatic audio-visual- verification of the syringe labels by computer just before each drug administration. They evaluated this new system in an anesthetic simulator and found that it was compared favorably with conventional methods in aspects of safety, clinical acceptability and time consumption in the preparation of drugs both before and during anesthesia<sup>(35)</sup>. This was later confirmed in clinical trial by Webster CS et al<sup>(36)</sup>. However, this new system is associated with some costs additional to those of conventional drug administration. Theses include the hardware, the software, the labels, the preparation of pre-filled syringes and the trays. The limitation of this system in authors opinion is that it can not reduce risk of wrong preparation, wrong route, drug omission or inappropriate administration time. In addition, the system provides anesthesia safety in aspect of reductions in syringe swaps and ampoule errors but not judgment error in drug selection. Therefore, additional special preventive measures should be developed.

Recently in 2004, Jensen et al<sup>(33)</sup>. developed an evidence-based recommendation for the minimization of errors in intravenous drug administration from a systematic review of the 98 reference reported from 1978 to 2002. All evidences were ranked by using a points system, validated the recommendations and identified additional recommendations from the incident data. In their summary, one general and five specific strong recommendations were generated. These included 1) systematic countermeasures against drug error, 2) carefully read the label on any drug ampoule or syringe before a drug is drawn up or injected, 3) standardization of the legibility and contents of labels ampoule or syringes, 4) labeling of all syringes, 5) formal organization of drug drawers and workspaces and 6) double check of labels with a second person or a device before a drug is drawn up or administered.

In our study, specific guideline or protocol development for drug administration in anesthesia was mainly recommended to prevented drug error incidents. Improved communication and quality assurance activity was also important. For the errors in the trainees, additional training and improved supervision were helpful. We believe that more manpower is not a main role for the reduction of incidents. The reason is that the more people the more communication error.

#### **Suggested strategies :**

Because the implementation of universal color and bar coding of drugs both in standardized ampoule and syringe or the new drug administration system designed by Merry et al<sup>(34-36)</sup>. are not settled worldwide, we develop a simple specific protocol to prevent the incidents as follows :

1. All practitioners should always be cautious about preparation and administration of all anesthetics. This should be done routinely.

2. Carefully read the label on any ampoule before a drug is drawn up in a syringe. Then label the syringe clearly with name and concentration of drug. And recheck the empty ampoule before placing it aside or discarding it.

3. Carefully read the label on any syringe and re-

confirm with the person who has prepared drug before injection.

4. Every change in drug formula or package should always be informed before implementation.

5. Use new prepared drugs in each. For any multidosage vial such as thiopentone, carefully read the label of drug s name, its concentration and date of preparation

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#### References

- Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthetic mishaps: a study of human factors. Anesthesiology 1978;49: 399-406.
- Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. Anesthesiology 1984;60: 34-42.
- Short TG, O Regan A, Lew J, Oh TE. Critical incident reporting in an anaesthetic department quality assurance programme. Anaesthesia 1993;48: 3-7.
- Kumar V, Barcellos WA, Mehta MP, Carter JG. An analysis of critical incidents in a teaching depart-ment for quality assurance. A survey of mishaps during anaesthesia. Anaesthesia 1988; 43: 879-83.
- Williamson JA, Webb RK, Sellen A, Runciman WB, Van Der Walt JH. Human failure: An analysis of 2000 incident reports. Anaesth Intens Care 1993;21: 678-83.

- 6. Davies JM, Strunin L. Anesthesia in 1984 : how safe is it? Can Med Assoc J 1984; 131 : 437-41.
- 7. Sigurdsson GH, McAteer E. Morbidity and mortality associated with anaesthesia. Acta Anaesthesiol Scand 1996; 40: 1057-63.
- 8. Katz RI, Lagasse RS. Factors influencing the reporting of adverse perioperative outcomes to a quality management program. Anesth Analg 2000; 90 : 344-50.
- 9. Khan FA, Hoda MQ. Drug related critical incidents. Anaesthesia 2005; 60 : 48-52.
- Dochin Y, Gopher D, Olin M, Badihi Y, Biesky M, Sprung C, et al. A look into the nature and causes of human errors in the intensive care unit. Crit Care Med 1995; 23 : 294-300.
- Webster CS, Merry AF, Larsson L, McGrath KA, Weller J. The frequency and nature of drug administration error during anaesthesia. Anaesth Intens Care 2001;29: 494-500.
- 12. Fasting S, Gisvold SE. Adverse drug errors in anes-thesia, and the impact of coloured syringe labels. Can J Anaesth 2000;47: 1060-7.
- Irita K, Tsuzaki K, Sawa T, Sanuki M, Makita K, Kobayashi Y, et al. Critical incidents due to drug administration error in the operating room: an analysis of 4,291,925 anesthetics over a 4 year period. (Japanese) Masui 2004 ;53: 577-84.
- Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systemic analysis of adverse drug events. JAMA 1995; 274: 35-43.
- Currie M, Mackay P, Morgan C, Runciman WB, Russell WJ, Sellen A, et al. The wrong drug problem in anaesthesia : an analysis of 2000 incident reports. Anaesth Intens Care 1993;21: 596-601.
- 16. Abeysekera A, Bergman IJ, Kluger MT, Short TG. Drug error in anaesthetic practice: a review of 896 reports from the Australian Incident Monitoring Study database. Anaesthesia 2005; 60: 220-7.
- 17. James RH. 1000 anaesthetic incidents: experience to date. Anaesthesia 2003 ;58 :856-63.
- Yentis SM, Randall K. Drug errors in obstetric anaesthesia: a national survey. Int J Obstet Anesth 2003 ;12 :246-9.
- 19. Sinclair M, Simmons S, Cyna A. Incidents in obste-tric anaesthesia and analgesia: an analysis of 5000 AIMS reports. Anaesth Intens Care 1999; 27:275-81.
- 20. Liu EH, Koh KF. A prospective audit of critical inci-dents in anaesthesia in a university teaching

hospital. Ann Acad Med Singapore 2003 ; 32 : 814-20.

- Charuluxananan S, Punjasawadwong Y, Suraseranivongse S, Srisawasdi S, Kyokong O, Chinachoti T, et al.The Thai Anesthesia Incidents Study (THAIS) anesthetic outcomes : II Anesthetic Profiles and Adverse Events. J Med Assoc Thai 2005 ; 88 (Suppl 7) : 14-29.
- Cohen MM, Duncan PG, Pope WD, Wolkenstein C. A survey of 112,000 anaesthetics at one teaching hospital (1975-83). Can Anaesth Soc J 1986;33:22-31.
- 23. Spittal MJ, Findlay GP, Spencer I. A prospective analysis of critical incidents attributable to anaes-thesia. Int J Qual Health Care 1995 ;7 : 363-71.
- Orser BA, Byrick R. Anesthesia-related medication error: time to take action. Can J Anesth 2004; 51: 756-60.
- 25. Bowdle TA. Drug Administration Errors From the ASA Closed Claims Project. ASA Newsletter 2003; 67: 11-13.
- 26. Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA, et al. The costs of adverse drug events in hospitalized pa-tients. Adverse Drug Events Prevention Study Group. JAMA 1997; 277: 307-11.
- Orser BA, Chen RJB, Yee DA. Medication errors in anesthesia practice: a survey of 687 practitioners. Can J Anesth 2001; 48 : 139-46.
- Merry AF, Peck DJ. Anaesthetists, errors in drug administration and the law. N Z Med J 1995; 108 : 185-7.
- 29. Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human : Building a Safer Health System. Washington, DC : National Academic Press, 2000.
- 30. Leape LL. Error in medicine. JAMA 1994; 272 :1851-7.
- Runciman WB, Sellen A, Webb RK, Williamson JA, Currie M, Morgan C, et al. The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice. Anaesth Intens Care 1993 ;21:506-19.
- 32. Runciman WB, Webb RK, Lee R, Holland R. The Australian Incident Monitoring Study. system failure: an analysis of 2000 incident reports. Anaesth Intens Care 1993; 21:684-95.
- 33. Jensen LS, Merry AF, Webster CS, Weller J, Larsson L. Evidence-based strategies for preventing drug administration errors during anaesthesia. Anaes-thesia 2004; 59 : 493-504.

- 34. Merry AF, Webster CS, Mathew DJ. A new, safety-oriented, integrated drug administration and automated anesthesia record system. Anesth Analg 2001; 93 : 385-90.
- 35. Merry AF, Webster CS, Weller J, Henderson S, Robinson B. Evaluation in an anaesthetic simulator of a prototype of a new drug administration

system designed to reduce error. Anaesthesia 2002; 57 : 256-63.

36. Webster CS, Merry AF, Gander PH, Mann NK. A prospective, randomised clinical evaluation of a new safety-oriented injectable drug administration system in comparison with conventional methods. Anaesthesia 2004; 59 : 80-7.

## การวิเคราะห์ปัญหาความผิดพลาดจากการให้ยา การศึกษาภาวะแทรกซ้อนทางวิสัญญี่ใน ประเทศไทย

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**ที่มาและเหตุผล**: เพื่อวิเคราะห์ปัญหาความผิดพลาดที่เกิดจากการให้ยาในระหว่างการให้ยาระงับความรู้สึก ในประเทศไทย ในด้านลักษณะของปัญหา ปัจจัยเสี่ยง และการป้องกันเชิงระบบ

**วัสดุและวิธีการ:** เป็นการศึกษาเซิงพรรณนาชนิดไปข้างหน้า แบบคัดกรองอุบัติการณ์ในผู้ป่วยที่ได้รับยาระงับ ความรู้สึกในโรงพยาบาล 20 แห่ง ในประเทศไทย และนำอุบัติการณ์ของการเกิดความผิดพลาดในการให้ยามาศึกษา ปัจจัยเกี่ยวข้อง และหาแนวทางแก้ไข

**ผลการศึกษา:** พบความผิดพลาดในการให้ยาจำนวน 41 อุบัติการณ์ จากจำนวนผู้ป่วยที่มารับการให้ยาระงับความ รู้สึก ทั้งสิ้นจำนวน 202,699 ราย คิดเป็น อุบัติการณ์เท่ากับ 1: 4,943 ส่วนใหญ่ (ร้อยละ 48.8) เป็นการให้ยาผิด ยาที่พบว่าให้ผิดมากที่สุดได้แก่ ยาหย่อนกล้ามเนื้อโดยพบทั้งสิ้นร้อยละ 31.7 ช่วงเวลาที่เกิดเหตุการณ์มากที่สุด ได้แก่ ช่วงนำสลบ เทคนิคที่เพิ่มความเสี่ยงในความผิดพลาดต่อการให้ยาได้แก่ การให้ยาระงับความรู้สึกแบบทั่วไป ร่วมกับแบบ epidural ส่วนใหญ่ของความผิดพลาดในการให้ยานี้ไม่มีผลต่อผู้ป่วย ยกเว้น 14 อุบัติการณ์ที่ก่อให้เกิด ปัญหากับผู้ป่วยโดยมี 1 รายที่เสียชีวิต ปัจจัยที่ทำให้เกิดปัญหาความผิดพลาดในการให้ยาที่พบบ่อย ได้แก่ ความรีบเร่ง และการขาดการอ่านฉลากยาซ้ำก่อนให้ยา ซึ่งสามารถป้องกันโดยการปฏิบัติตามแนวทางเกี่ยวกับการให้ ยาอย่างเคร่งครัด

**สรุป:** อุบัติการณ์ของความผิดพลาดในการให้ยาที่เกิดขึ้นในระหว่างการให้ยาระงับความรู้สึกในการศึกษานี้คือ 1: 4,943 ซึ่งมีความสำคัญ คือ เป็นสาเหตุของภาวะแทรกซ้อนหรือการตาย ดังนั้น จึงควรให้ความระมัดระวัง และปฏิบัติตาม แนวทางที่กำหนดอย่างเคร่งครัด