

Multicentered Audit of Compliance to WHO Surgical Safety Checklist and Wrong-Site Surgery & Anesthesia in Thailand: The Perioperative and Anesthetic Adverse Events Study in Thailand (PAAd Thai) Study

Somchat C, MD¹, Cholitkul S, MD², Charuluxananan S, MD³, Lapisatepun W, MD⁴, Luanpholcharoenchai J, MD⁵, Sattayopas P, MD⁶, Dechasilaruk S, MD⁷, Ariyanuchitkul T, MD⁸, Tanutanud D, MD⁹, Lawthaweesawat C, MD¹⁰

¹ Department of Anesthesiology, Lamphun Hospital, Lamphun, Thailand

² Department of Anesthesiology, Chiang Rai Prachanukroh Hospital, Chiang Rai, Thailand

³ Department of Anesthesiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

⁴ Department of Anesthesiology, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

⁵ Department of Anesthesiology, Faculty of Medicine, Srinakharinwirot University, Bangkok, Thailand

⁶ Department of Anesthesiology, Nakornping Hospital, Chiang Mai, Thailand

⁷ Department of Anesthesiology, Buddhachinaraj Hospital, Pitsanulok, Thailand

⁸ Department of Anesthesiology, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand

⁹ Department of Anesthesiology, Lampang Hospital, Lampang, Thailand

¹⁰ Department of Anesthesiology, Bumrungrad International Hospital, Bangkok, Thailand

Background: The Royal College of Anesthesiologists of Thailand (RCAT) hosted the Perioperative and Anesthetic Adverse events in Thailand (PAAd Thai) study perioperative adverse events in 2015.

Objective: To investigate the compliance to World Health Organization (WHO) surgical safety checklist among patients with incident reports and the incidence of wrong patient, wrong site or wrong side of surgery or anesthesia.

Materials and Methods: After approval of the Institutional Ethical Committee, informed consent was waived due to the observational study design. Anesthesia providers and site managers of 22 hospitals, including eight medical schools and 14 service-based hospitals, across Thailand were requested to fill-in a structured incident reporting form of the RCAT (both closed-ended and opened-ended) regarding several occurrences such as cardiac arrest, difficult intubation, esophageal intubation, and wrong-site surgery. Three senior anesthesiologists reviewed the incident reports. Any discrepancy was resolved by discussion to reach consensus.

Results: Among 2,206 incident reports of any adverse events during the 12-month period in 2015, there were high compliance of patient identification (80%), use of pulse oximeter (92%), anesthesia checklist completion (92%), and drug allergy inquiry (79%). Low compliance items were site marking (44%), prophylactic antibiotics before incision (52%), post-operative care planning (47%), and communication of possible post-operative problems (48%), according to WHO surgical safety checklist. Among the 333,219 anesthesia undergoing surgeries, there were six cases (two wrong persons, two wrong side, and two wrong side anesthetic procedure) with an incidence of 0.18 (95% CI 0.04 to 0.32) per 10,000. The six cases (100%) were human error and included five incidents (83%) that were system related such as inadequate personnel, lack of guidance for ultrasound guided nerve block etc., five incidents (83%) that could not prevented by the WHO surgical safety checklist, and two (33%) that were near-miss events.

Conclusion: Despite moderate to high compliance of WHO SSC in Thai hospitals, wrong-site-surgery or anesthetic procedure still occurred. Most of the incidents were due to human error. A systemic approach to improve communication, identify adequate personnel, and adhere to the pre-procedural specific checklist, such as guidance for ultrasound guided nerve block, are suggested.

Keywords: Error, Mistake, Communication, Wrong-site surgery, Checklist

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Correspondence to:

Charuluxananan S.

Department of Anesthesiology, Faculty of Medicine, Chulalongkorn University, Rama IV Road, Pathumwan, Bangkok 10330, Thailand.

Phone: +66-2-2564215, +66-2-2564295, Fax: +66-2-2541931

Email: somratcu@hotmail.com

Patient safety is the primary focus, particularly among anesthesiologists and surgical healthcare personnel. Early on, technological improvement and pharmaceutical advances allowed for complex

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procedures. However, in the last decade or so, perioperative patient safety has become widely acknowledged as a key factor in successful surgery outcomes. This spotlight on safety has warranted the development of incident reporting systems, often adapted from other high-risk specialties such as aviation, as the World Health Organization (WHO) Surgical Safety Checklist and improvement of communication guidelines.

Currently, there is evidence that overall incidence of adverse events in hospitals is about 10%⁽¹⁾ and half of them are considered as preventable events⁽²⁾. To reduce this, the WHO introduced its “Safe Surgical Saves Lives” campaign^(3,4). Several countries have adapted and introduced the checklist. In the United Kingdom, the national patient safety agency made it mandatory for all National Health Service (NHS) Trusts to implement the checklist⁽⁵⁾. The use of such surgical safety checklist required changes in organizational culture and teamwork in operating rooms. In Thailand, the WHO’s surgical safety checklist was introduced in 2013. Several crucial steps in the checklist such as patient identification, site, and procedure are communicated through the three stages of sign in time out and sign out, which is observed and recorded.

In 2014, the Royal College of Anesthesiologists of Thailand (RCAT) hosted the Perioperative and Anesthetic Adverse Events Study Thailand (PAAad Thai) to investigate perioperative adverse events including wrong patient, wrong site, and wrong surgery or procedure. The study also monitored compliance of the WHO Surgical Safety Checklist.

Materials and Methods

A multi-center study, among Departments of Anesthesiology in 22 hospitals across Thailand, was conducted in a prospective observational fashion during the 12 months period (between January and December 2015). In addition to the monthly statistics of main anesthetics, each institution agreed to send incident reports of the PAAad Thai Study using structured case report forms and open-ended questionnaires to describe what, when, where, how, and why the incidents occurred.

The protocol for PAAad Thai Study was modified from the previous Thai Anesthesia Incident Monitoring Study (Thai AIMS)⁽⁶⁾ and approved by the Institutional Review Board of the participating hospitals. Informed consent was waived due to observational study design of the PAAad Thai Study. Details of the case record form were described⁽⁶⁾. Data were expressed in

frequency, percentage. Chi-square test, and t-test were used for comparing categorical and continuous data statistics were analyzed by using SPSS for Windows, version 22. A p-value of less than 0.05 was considered significant. Incident reports of interest were sent to three senior anesthesiologists for review. Any discrepancy was discussed to achieve a consensus.

Results

During the 12-month period, there were six incident reports regarding wrong patient, wrong site, or wrong surgery in the database of PAAad Thai study, with 333,219 cases overall. Among the 2,206 incident reports sent to the data management unit at Faculty of Medicine, Chulalongkorn University, the compliance of the surgical safety checklist is shown in Table 1. Proportion of all items in WHO surgical safety checklists were higher in eight medical schools comparing to those in the 14 service-based hospitals ($p < 0.001$), except comparable rates of pre-anesthetic monitoring with pulse oximeter.

Among the six critical incident reports, five (83.5%) were male gender, two (33.3%) and four (66.6%) were classified as American Society of Anesthesiologists (ASA) physical status II and III, respectively. Age of patients varied from 3 to 70 years old. All cases were elective surgery. There were two cases (33.3%) and four cases (66.6%) of wrong patients and wrong side procedures, respectively.

Wrong patients

Case I: A 66 years old male patient set for aneurysmectomy (vascular surgery) under general anesthesia was called for elective procedure by surgical resident. In the pre-anesthetic assessment, the anesthesia resident found that the patient had ischemic heart disease waiting for coronary bypass surgery prior to this specific surgery and discussed this with the surgical resident. After signing in, the attending surgeon realized it was the “wrong patient” and the operation was cancelled.

Cases II: A female patient aged 70 years old was scheduled for embolization (intervention surgery) with pre-anesthetic assessment of ASA physical status II. The electrocardiograph during the pre-anesthetic assessment was considered unremarkable. After induction and intubation with 120 mg propofol intravenous (IV) and atracurium 50 mg IV, the patient developed atrial fibrillation with heart rate of 130 per minute, treated with esmolol, then observed in the intensive care unit. The critical incident resolved with complete recovery. Post-anesthetic cardiac

Table 1. Compliance to WHO surgical safety checklist (2,206 incident reports)

	Medical school (n=1,165)	Service based hospitals (n=1,041)	Total (n=2,206)	p-value
Sign in				
Patient identification	88.4%	72.3%	80.8%	<0.001
Mark site	56.7%	30.7%	44.5%	<0.001
Evaluation for difficult airway	80.7%	59.1%	70.5%	<0.001
Anticipate pulmonary aspiration	77.3%	44.1%	61.6%	<0.001
Anticipate >500 cc blood loss	64.2%	35.1%	50.5%	<0.001
Ask for drug allergy	85.4%	73.6%	79.8%	<0.001
Pulse oximeter	92.8%	92.9%	92.8%	0.99
Complete anesthesia checklist	91.7%	92.5%	92.1%	<0.001
Time out				
Patient identification	89.8%	64.8%	78.0%	<0.001
Operation/site	86.7%	55.6%	72.0%	<0.001
Anticipate anesthesia incident	58.4%	33.9%	46.8%	<0.001
Anticipate surgical incident	56.3%	28.2%	41.6%	<0.001
Expected duration	52.1%	27.4%	40.4%	<0.001
Expected much blood loss	46.4%	27.6%	37.5%	<0.001
Prophylactic antibiotics				<0.001
• No	11.6%	26.1%	18.4%	
• Before skin incision	62.6%	40.8%	52.3%	
• After skin incision	2.1%	1.1%	1.6%	
• After delivery	0.8%	2.1%	1.4%	
• N/A	21.1%	28.6%	24.7%	
Sign out				
Equipment/gauze count	82.7%	66.5%	75.0%	<0.001
Review of intraoperative event	67.5%	35.4%	52.4%	<0.001
Postoperative care planning	65.8%	26.1%	47.1%	<0.001
Estimated blood loss	81.4%	46.7%	65.0%	<0.001
Communicate possible problem	65.2%	28.9%	48.1%	<0.001

N/A=not applicable

reviewer and consultation revealed incorrect patient electrocardiography in her medical records.

Wrong side surgery

Case III: A 3 years old boy was scheduled for redo modified Blalau-Taussig's shunt (left side). The patient developed shunt stenosis on both sides. The attending surgeon recorded admission for left side redo operation. The WHO surgical checklist complied during sign in and time out. The attending surgeon reported that he had changed the side of operation from left to right side without changing the outpatient

medical file records. Therefore, the side of operation was changed prior to skin incision.

Case IV: A 15 years old male patient was scheduled for emergency craniectomy (left side) for removal of epidural hematoma. The surgical resident marked the side in the surgical ward. After signing in and time were completed, the surgical procedure was performed according to marked site in the surgical ward, and the wrong side surgery was diagnosed after skin incision. The incision on the opposite side was made once epidural hematoma could not be found after the first skin incision.

Table 2. Patients and surgical characteristics of wrong patient, wrong side procedure

Case	Wrong	Characteristics	Anesthesia	Compliance		
				Surgical safety checklist		
				Sign in	Time out	Sign out
1	Patient	Abdominal aortic aneurysmectomy 66 years, ASA PS III Vascular surgery	GA	✓	-	-
2	Patient	Embolization 70 years, ASA PS II Intervention (wrong electrocardiography in medical record)	GA	✓	✓	✓
3	Side of surgery	Redo modified Blalaug Taussig's shunt 3 years, ASA PS III cardiothoracic scheduled for left side surgery, changed to right side surgery	GA	✓	✓	✓
4	Side of surgery	Craniotomy for removal of epidural hematoma 15 years, ASA PS III E (wrong mark site at ward)	GA	✓	✓	✓
5	Side of anesthesia	Surgery of femur (right) 56 year, ASA III Orthopedic	PNB with ultrasound	✓	✓	✓
6	Side of anesthesia	Correction osteotomy	Brachial plexus block with ultrasound	✓	✓	✓

GA=general anesthesia; PNB=peripheral nerve block; ASA PS=American Society of Anesthesiologists physical status; E=emergency

Wrong side anesthetic procedure

Case V: A 56 years old male with ASA physical status III was scheduled for open reduction and internal fixation at right side femur. After signing in and time, steps of WHO surgical safety checklist were completed, anesthesia personnel prepared peripheral nerve block procedure under ultrasonography for the left side. An anesthesia resident was called from another operation theatre for the nerve block procedure. The anesthesia resident rechecked the side of procedure by asking the sedated patient. The surgical nurse detected this wrong side incident. The patient received spinal anesthesia for the intended operation.

Case VI: A 70 years old male with ASA physical status II was scheduled for correction osteotomy of the right humerus. Signing in and time steps were done. Anesthesiologist performed the left side brachial plexus block using an ultrasound guided technique. Self-detection of wrong side procedure was realized by the surgeon performing the surgery. Therefore, general anesthesia of total IV anesthesia was used for the entire duration of the operation.

A complete summary of cases is shown in Table 2.

Discussion

In the present multi-center PAAAd Thai Study, there were six cases of wrong patients, wrong site, or wrong procedure regarding surgical and anesthetic procedures, despite moderate to high compliance of the WHO surgical safety checklist. These cases revealed very rare occurrences among the 333,219 anesthesia undergoing surgeries in the 22 participating hospitals with an incidence rate of 0.18 (95% CI 0.04 to 0.32) per 10,000 cases⁽⁷⁾.

The modified WHO surgical safety checklist was introduced to the Thai hospitals in 2012. The present study revealed high compliance for patient identification, using of pulse oximeter, complete anesthesia checklist, and drug allergy inquiry. Specification of operation and site of surgery, evaluation for difficult airway, anticipation for pulmonary aspiration, and sign out steps such as equipment or gauze count and estimated blood loss were considered as moderate compliance. The potential items for improvement of quality and safety of anesthesia and surgery service were marked site, prophylactic antibiotics, post-operative care planning and communication of possible post-operative

Table 3. Contributing factors, outcomes, and preventability by surgical safety checklist

Case	Surgical factors	Anesthesia factors	System factors	Outcomes	Preventability by surgical safety checklist
1	Communication between surgeon and surgical resident	Partial	Communication Intradepartmental Interdepartmental	Cancellation	No
2	-	-	Hierarchy of staff Wrong electrocardiography in medical record	Supraventricular Tachycardic Unplanned ICU admission Resolved	No
3	Communication attending surgeon changed decision without notice in medical record	-	-	Change side of surgery before start of operation	No
4	Wrong side marking at ward by resident	-	Shortage of resident fatigue	Change side of craniotomy after first side operation	No
5	-	Change of anesthesiologist Shortage of anesthesiologist Resident recheck by asking sedated patient	Inadequate personnel No specific guidance for procedure	Proceed operation under spinal anesthesia	No (partial)
6	-	Nurse anesthetist set ultrasound at wrong site No recheck	No specific guidance for procedure	Proceed operation with GA: TIVA	Yes (partial)

ICU=intensive care unit; GA=general anesthesia; TIVA=total intravenous anesthesia

problems. All items except usage of pulse oximeter was considered statistically higher compliance in medical schools than in service-based hospitals. This confirmed the successful strategy of the RCAT in launching the mandatory use of pulse oximeter in all anesthetic cases since 2007 after determining feasible compliance according to Thailand's readiness for monitoring standard improvement. The mandatory use of capnography has also been launched by the RCAT in 2015 during the period of data collection of the present study.

The WHO surgical safety checklist as part of the "Safe Surgery Saves Lives" campaign focuses on enhancing communication and teamwork of surgical teams. A multi-national study accessing the WHO surgical safety checklists revealed that mortality and adverse events decreased by 48% and 37%, respectively^(8,9). The present study suggested that the WHO surgical safety checklist should be encouraged for higher compliance in Thailand. Percentage of compliance might be suggested as one organization monitoring indicators. Among the six cases of wrong patients, wrong site or side, wrong surgery or procedure in the present study, one-third of the cases were anesthesia related error of wrong side regional anesthetic procedure using

ultrasound guided technique. These errors suggested procedure specific guidance such as pre-procedural checklist for ultrasound guided procedure. This was in accordance to the strategic prevention of wrong site surgery in otolaryngology-head and neck surgery that includes standardized protocol to confirm imaging accuracy, procedure-specific checklist, and standardized alternative to site marking when marking is impractical⁽¹⁰⁾. In ophthalmology, safety in surgery involving intraocular lens (IOL) placement can also be enhanced by IOL-specific time-out⁽¹¹⁾.

Among the two cases of wrong patients, one case was due to both intra-departmental (attending surgeon and surgical resident) and inter-departmental (surgical resident and anesthesia resident) miscommunication. In the United Kingdom, the content of communication curricula for medical students emphasized more on the doctor-patient relationship⁽¹²⁾ but very little on the interaction between doctors⁽¹³⁾. Moreover, hierarchy of staff was also considered as a contributing factor. The surgical residents did not inform higher level staff despite being informed of the severity of the underlining condition of the patient by the anesthesia resident. Communication problems were considered two-thirds among this case series according to peer review. The other was wrong patient's pre-anesthetic

electrocardiography leading to misinterpretation as normal electrocardiograph in medical records, which could not be prevented by the WHO surgical safety checklist. This case was also considered as a systematic cause that medical record systems should be improved in the institution. The wrong side procedures in the present study were also considered systematic causes. One case was due to wrong marking site in the ward by a resident who was fatigued due to personnel shortage. The other wrong side case was due to the change of operative side by attending surgeon, which necessitated a system to record of any changes of decision making and clear communication to the surgical team. Therefore, systematic factors and communication failures played a major role in these cases of wrong patients, wrong major role of these wrong patients, wrong side or site surgery, and wrong procedures.

There are some limitations of the present study such as 1) underestimation of the number of cases with wrong patients, wrong side surgery, and procedure, 2) inadequate details of context of error leading to mistake provided by anesthesia provider or site-manager, 3) lack of denominator according to specific types of procedures or surgeries. However, anesthesia providers in participating hospitals were familiar with the study's incident report forms as it was based from the form generated by the RCAT.

In conclusion, there were six reported cases of wrong patients, wrong side surgery, and wrong side anesthetic procedures, which were very rare and mostly caused by human error. Communication failures and systematic errors were considered as major contributing factors. The WHO surgical safety checklist was moderately complied to in participating hospitals and further improvement for higher compliance is needed. The WHO surgical safety checklist could prevent only one out of six incidents. Improvement of communication, systematic factors such as adequate personnel, appropriate working hour of trainee to prevent fatigue, and procedure specific guidance, are suggested strategies.

What is already known on this topic?

The WHO's World Alliance for Patient Safety host the Safe Surgery Save Lives campaign, which has developed surgical safety checklist. Compliance to the checklist varies among different countries.

What this study adds?

Compliance to WHO surgical safety checklist in Thailand varied from moderate to high. The incidence

of wrong site-surgery or anesthetic procedure was rare, and most incidents could not be prevented by the surgical checklist.

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Conflicts of interest

The authors declare no conflict of interest.

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