The Thai Anesthesia Incident Monitoring Study (Thai AIMS) of Anesthetic Equipment Failure/Malfunction: An Analysis of 1996 Incident Reports

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Background: The present study is a part of the multi-centered study of model of anesthesia relating adverse events in Thailand by incident report (The Thai Anesthesia Incident Monitoring Study or Thai AIMS). The objective was to identify the frequency distribution, contributing factors, and factors minimizing incident of equipment failure/malfunction.

Material and Method: As a prospective descriptive research design, anesthesia providers reported the data as soon as the incidents of equipment failure/malfunction occurred. Standardized forms of incident report were then mailed to the center at Chulalongkorn University and three anesthesiologists reviewed the data. *Results:* Ninety-two cases of equipment failure/malfunction were reported from 51 hospitals across Thailand. Between January and June 2007, 92 incidents of equipment failure/malfunction were reported out of 1996 anesthesia-related incidents (4.6%). Failed/malfunctioned equipment included anesthetic circuit (17.4%), anesthesia machine (15.2%), capnography (15.2%), laryngoscope (15.2%), ventilator (12%), pulse oximeter (8.7%), vaporizer (4.3%), endotracheal tube (3.3%), sodalime (3.3%), and electrocardiogram (2.2%). All 16 anesthetic circuit incidents (100%) were detected by clinical signs whereas five incidents (31.3%) were detected firstly by monitors. All 14 laryngoscope malfunction (100%) were detected solely by clinical signs. Only one out of eight (12.5%) of pulse oximeter incidents was detected by clinical signs before the pulse oximeter itself. Three out of four (75%) incidents of vaporizer were detected by clinical signs before monitors. The majority of equipment malfunction was considered as related to anesthetic (69.6%) and system factors (69.6%) and 71.7% of incidents were preventable. Seventy-four incidents (80.4%) were caused by human error and, specifically, rule-based error in three fourths.

Conclusion: Contributing factors were ineffective equipment, haste, lack of experience, ineffective monitors, and inadequate equipment. Factors minimizing incidents were equipment maintenance, pre-use equipment checking, vigilance, prior experience, and compliance to guidelines. Suggested strategies were quality assurance activity, training, and improvement of supervision.

Keywords: Anesthesia, Incidence, Incident report, Complication, Equipment failure, Human error, System error, Monitoring

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Anesthesia incidents, as reported elsewhere, can range from hazards to personnel to patient morbidity and mortality. At the present, anesthesia involves the use of various equipment; some of which are functionally or structurally complex. It is inevitable that some of them will be subject to failure or malfunction. In 2005, the Royal College of Anesthesiologists of Thailand conducted The Thai Anesthesia Incidents Study (THAI Study) among 20 hospitals across Thailand aiming to study the incidences and risk factors of anesthetic adverse outcomes in a registry design^(1,2). The THAI Study group also reported the occurrence of 90 equipment malfunctions or failure among 202,699 given anesthesia as an incidence of 0.04% or 1:2252⁽³⁾. In 2007, the Royal College of Anesthesiologists of Thailand conducted the Thai Anesthesia Incident Monitoring Study (Thai AIMS), with a voluntary and anonymous basis, among 51 hospitals from all regions of Thailand^(4,5). This national anesthesia incident reporting system also includes equipment malfunction or failure as primary outcome. Unlike the Australian Incident Monitoring Study (AIMS), the present study includes malfunction incidents that are subject to a specific pre-use check, misconnections, disconnections, and system leakage.

Material and Method

Between January and June 2007, the Royal College of Anesthesiologists of Thailand conducted a prospective multi-centered study of incident reports of anesthesia related adverse events among 51 hospitals across Thailand. The present study was a sub-study of the Thai AIMS.

Incident reporting forms were distributed to participating hospitals. These hospitals were asked to fill in the forms as soon as an incident occurred and, collectively, send to Chulalongkorn University monthly. In the first part of the forms, details of the incidents were given in terms of what and how it had happened, and what management had been done in response to the incidents. They were also asked to check which category was the incidents. The present study includes the incidents that were checked as "equipment failure/ malfunction". The latter part required the participants to state whether the incidents could be detected by clinical signs and/or monitoring devices, the incidents were related to patient factors, surgical factors, anesthetic factors, or system factors, the incidents caused any immediate and long-term outcomes, and the relationship between the incidents and contributing factors, factors minimizing the incidents, and suggested corrective strategies. All incident reports were reviewed by three anesthesiologists. Data management was performed using SPSS program version 12. Descriptive statistics were used.

Results

Among 1996 incident reports sent to the data management unit, 104 reports were preliminarily checked in the "equipment failure/malfunction" category. These 104 incidents were subsequently reviewed by the authors of the present study to validate the data. Twelve incidents that were not related to equipment failure/malfunction were excluded from the present study. The remaining 92 incidents were then analyzed. Table 1 shows equipment-related incidents ranked by frequency of occurrence. According to the type of anesthetic equipment, circuit failure/ malfunction has the highest frequency (17.4%), which were detectable by clinical signs and monitors. It was noted that clinical signs could detect anesthetic circuit failure/malfunction before the monitor in 11 out of 16 incidents (68.7%). Monitors failed to detect anesthetic circuit malfunction in six incidents (37.5%).

According to the opinions of reviewers, the equipment failure/malfunction was considered as caused by patient, surgical, anesthetic, and/or system (management) factors. The characteristics of occurrence are shown in Table 2. The incidents were mostly related to anesthetic and system/management factors (69.6% each) while patient or surgical factors were 5.4 and 7.6% respectively. This equipment failure/ malfunction was considered preventable in 71.7% of the total incidents whereas 28.3% was spontaneously and incidentally unpreventable. Of 92 incidents, 74 incidents were considered to be related to human error (80.4%). These errors can be classified into rule-based (58.7%), skill-based (1.1%), and knowledge-based (20.7%) as shown in Table 3.

Five incidents (5.4%) led to minor physiological changes such as tachycardia (heart rate more than 120 per min), hypercapnea, and hypotension. Four incidents (4.3%) caused major physiologic changes including hypoxia, oxygen desaturation, and brain edema. There was one fatal case possibly caused by malfunction of a syringe pump containing epinephrine. This incident occurred in a patient with preoperative American Society of Anesthesiologist Physical Status (ASA PS) of 4E.

Contributing factors that led to equipment failure/malfunction were ineffective equipment, haste, lack of experience, ineffective monitor, inadequate

	No. of incidents (%)	Undetectable by clinical signs	Detectable by	y clinical signs	Undetectable by monitors	Detectable by monitors
	incluents (70)	by enniear signs	Before monitors	After monitors	by monitors	
Anesthetic circuit	16 (17.4)	-	11	5	6	10
Anesthetic machine	14 (15.2)	4	10	-	6	8
Capnography	14 (15.2)	8	-	6	-	14
Laryngoscope	14 (15.2)	-	14	-	14	-
Ventilator	11 (12)	-	5	6	2	9
Pulse oximeter	8 (8.7)	4	1	3	1	7
Vaporizer	4 (4.3)	-	3	1	3	1
Endotracheal tube	3 (3.3)	-	1	2	1	2
Sodalime	3 (3.3)	3	-	-	-	3
ECG	2 (2.2)	2	-	-	2	-
NIBP	1 (1.1)	1	-	-	-	1
Syringe pump	1 (1.1)	-	-	1	-	1
IBP transducer	1 (1.1)	-	-	1	-	1
Total (%)	92 (100%)	22 (23.9%)	45 (48.9%)	25 (27.2%)	35 (38.0%)	57 (62.0%)

Table 1. Equipment failure/malfunction and methods of incident detection

NIBP = non-invasive blood pressure

IBP = invasive blood pressure

Table 2.	Types of equipment failure/malfunction and		
	characteristics of incident according to opinions of		
	anesthesia reviewers $(n = 92)$		

Characteristics*	n	%
Patient factors	5	5.4
Surgical factors	7	7.6
Anesthetic factors	64	69.6
System factors	64	69.6
Preventable	66	71.7
Non preventable	26	28.3
(spontaneously, incidentally)		

* Data are not mutually exclusive

 Table 3. Characteristics of 74 cases of equipment failure/ malfunction related to human error

Human error	Incidents (n = 72)	% of human error (n = 92)	% of all incidents
Rule-based	54	73.0	58.7
Knowledge-based	19	25.7	20.7
Skill-based	1	1.3	1.1

equipment, and poor decision making in 50.0%, 32.6%, 16.3%, 14.1% and 10.9% respectively. Factors that may minimize the incidents were equipment maintenance, equipment checking prior to use, vigilance, prior experiences, compliance to existing guidelines, and adequate equipment in 60.9%, 58.7%, 40.2%, 28.3%, 19.6%, and 9.8% respectively. Suggested corrective strategies included quality assurance activity, equipment maintenance, clinical practice guidelines, and more equipment in 72.8%, 69.6%, 36.9% and 13.0% respectively. Details of contributing factors, factors minimizing incidents and suggested corrective strategies are shown in Table 4-6 respectively.

Discussion

Equipment failure/malfunction is another anesthesia-related incident that has been previously reported elsewhere⁽¹⁻⁶⁾. The incidence varies depending on study methodology and reporting system. The Thai Anesthesia Incidents Study (THAI Study) reported 90 incidents in 202,699 cases⁽³⁾. The present study categorizes neither the types of failure/malfunction nor the types of equipment. In the Australian Incident Monitoring Study (AIMS) the types of failure/malfunction involves 1) the equipment that fails to perform the way it was manufactured and

Factors*	n	%
Ineffective equipment	46	50.0
Haste	30	32.6
Lack of experiences	15	16.3
Ineffective monitor	13	14.1
Inadequate equipment	10	10.9
Poor decision making	6	6.5
Lack of knowledge	4	4.3
Emergency condition	3	3.3
Communication failure	2	2.2
Fatigue	2	2.2
Lack of monitoring devices	2	2.2
Insufficient manpower	1	1.1
Unfamiliarity to workplace and environment	1	1.1

Table 4. Contributing factors of equipment failure/ malfunction (n = 92)

* Data are not mutually exclusive

Table 5. Factors minimizing equipment failure/malfunction(n = 92)

Factors*	n	%
Equipment maintenance	56	60.9
Equipment checking prior to use	54	58.7
Vigilance	37	40.2
Prior experiences	26	28.3
Comply to existing guidelines	18	19.6
Adequate equipment	9	9.8
Experienced assistants	5	5.4
Staff change	3	3.3
Presence of diagnostic monitor	3	3.3
Good communication	2	2.2
Improved training system	1	1.1

* Data are not mutually exclusive

Table. 6Suggest corrective strategies for equipment failure/
malfunction (n = 92)

Suggested strategies*		%
Quality assurance activity	67	72.8
Equipment maintenance	64	69.9
Clinical practice guidelines	34	36.9
More equipment	12	13.0
Additional training	7	7.6
Improved supervision	7	7.6
More manpower	2	2.2
Improved communication	2	2.2

* Data are not mutually exclusive

2) the equipment that may or may not need pre-use check⁽⁶⁾. Additionally, the types of equipment include anesthesia equipment, airway equipment, monitoring equipment and theater equipment.

Among 92 incidents, anesthetic circuit failure was the most common (17.4%) followed by machine, capnograph, and laryngoscope (15.2% each). If circuit, machine, ventilator, vaporizer, and sodalime were considered as anesthetic equipment, they would contribute to 52.2% of the incidents, which was comparable to previous studies⁽⁶⁻⁸⁾.

Clinical signs could detect 70 incidents (76.1%) both before and after the monitor whereas are monitor could detect only 57 incidents (62.0%). Incidents involving anesthetic circuits and anesthesia machine were mostly detected by clinical signs before monitors. However, this does not imply that particular alarm setting is not necessary for machine and circuits as standard practices recommend that an alarm system be included in modern anesthesia machines. Furthermore, clinical signs failed to detect four machine incidents and detected five circuit incidents only after detection by monitoring equipment.

Unlike anesthesia machine and circuits, all 14 incidents (100%) of capnography malfunction were detected by the capnogram alarm itself whereas clinical signs failed to detect eight incidents and could detect six incidents after the monitor. An alarm system and capnogram pattern are good parameters to identify perioperative problems although the device needs frequent calibration.

Problems with laryngoscope seemed undetectable by clinical signs because all 14 incidents occurred after pre-use check. It is recommended that another functioning and checked laryngoscope be available in the operating room for immediate replacement⁽⁶⁾.

Eleven ventilator incidents consisted of ventilator malfunction (7 incidents of true ventilator malfunction and 2 incidents of leakage of bellow) and failure to switch on the ventilator (2 incidents). From 11 incidents, the alarm failed to go off on two incidents resulting in desaturation. The other nine incidents were detected by alarm and capnography. Clinical signs could detect all 11 ventilator incidents although six could be detected after the monitors. Therefore, clinical signs are still important in detecting ventilator malfunction and both clinical signs and monitors give a better and reliable parameter.

Among eight incidents involving pulse oximeter, seven incidents (87.5%) were detected by

the monitor itself but four out of eight (50%) were undetectable by clinical signs. Plethysmography is highly sensitive in detecting circulation and oxygenation problems but clinical signs, such as skin color or hemodynamic change, may be of limited use as it takes several minutes to detect such problems. One incident was related to probe malfunction that was resolved by a new probe replacement. Although pulse oximetry is a device that needs no calibration before use, special care is needed for the probe as it might be damaged by accident, secretion, or antiseptic.

Four incidents involving vaporizer were related to leakage of the system at the vaporizer due to changing of vaporizer during and between cases. Clinical signs could detect all four incidents, *i.e.* leakage was heard at the vaporizer or the breathing bag failed to recoil and expand. Monitors could detect only one incident when the ventilator low-pressure alarm went off.

There were three incidents involving endotracheal tubes. Two were due to obstruction and one was from a ruptured endotracheal tube cuff. All were detected by clinical signs but monitors failed to detect one incident where the ventilator bellow kept failing without any alarm from the ventilator.

Three incidents of sodalime exhaustion were detected by monitors but not by clinical signs. This is simply one example of the benefits of capnography when inspired carbon dioxide rises as opposed to checking of sodalime color change because its canister is not located at the eye level.

Electrocardiography (ECG) problems accounted for two incidents as it failed to analyze S-T segment and the monitor alarmed. No clinical change was noted. However, S-T segment analysis is optional in ECG monitoring and must be confirmed by 12-lead reading.

One incident involving non-invasive blood pressure monitoring was due to false reading when the surgeon leaned against the patient's arm and blood pressure cuff. This incident was detected by the monitor when blood pressure reading was spuriously low.

Syringe pump alarm was ignored during patient transfer resulting in one incident of possible drug withdrawal (epinephrine) in a patient with ASA physical status 4E. The patient died 1 hour and 30 minutes later. Even though the patient was critically ill with many anesthetic risks and dependent on high dose vasopressors, it is standard to make sure that all drug delivery devices should be well-maintained to ensure their performance during transfer with built-in battery. Any alarm should be regarded as a threat to drug delivery hence the patient's safety.

One incident was related to invasive blood pressure monitoring when the arterial line waveform was gradually flattened. A leak at the reuse-type dome was noted under the diaphragm and replacement of a new one resolved the problem. The anesthesiologist claimed that the dome was manufactured for multiple uses and that the number of uses was unknown. However, with the increasing risks of blood-borne diseases and incomplete sterilization of the dome, a disposable type is favorable and safer with fewer risks of leakage at the diaphragm.

Of 92 incidents, 66 (71.7%) were preventable and 26 (28.3%) were incidentally unpreventable or spontaneously occurred. Among the unpreventable incidents, 10 were related to laryngoscope failure with device checking prior to use. Although the reasons were not described, this can happen due to inappro- priate contact between handle and blade of the laryngoscope. Additionally, eight incidents were related to capnography failure despite pre-use calibration and only one incident was resolved by sample line replacement due to condensed water in line. The rest were not resolved by filter change or recalibration and a new device replacement was needed.

The anesthetic and system (or management) factors contributed equally (45.7% each) to the 92 incidents. This implied that equipment failure/ malfunction mostly occurred no matter what surgical procedures or how fit the patients were. Rather, they occurred from factors related to anesthetic practice and the organization of anesthetic care, for example, pre-use anesthesia machine checking, anesthesia plan changed during the case or device battery malfunction. However, system failure defined in the present study is different from that described elsewhere⁽⁹⁾. Instead, equipment failure/malfunction incidents were resulting from patient, surgical, anesthetic or system (management) factors (or in combination) regardless of the consideration that they were due primarily to human or system failure. The detail of methodology was elaborated in this symposium(4).

Seventy-four (80.4%) out of 92 were related to human error, which is comparable to a previous study⁽⁷⁾. Among these, 54 (73.0%) were attributable to rule-based, 19 (25.7%) to knowledge-based, and one (1.3%) to skill-based error. Unlike other fields, for

example, engineering where human error accounts for a small percentage, human errors in anesthesia practice contribute to a large proportion of the incidents. According to the study of Runciman et al, rule-based error includes inattention, failure to check equipment, and poor patient preparation and evaluation. Among 54 rule-based errors, 25 (55.6%) resulted from failure to check equipment before use including machine, ventilator, and breathing circuits⁽⁹⁾. A question is raised whether the pre-use protocol of machine checking is complied appropriately in the present practice.

All 92 incidents were checked at least one of contributing factors, factors minimizing the outcome and suggested corrective strategies. The top five common factors contributing to the incidents were ineffective equipment (46, 50%), haste (30, 32.6%), lack of experiences (15, 16.3%), ineffective monitor (13, 14.1%), and inadequate equipment (10, 10.9%). These results support the finding that rule-based error accounted for the highest percentage of all incidents.

Factors minimizing the incidents included proper equipment maintenance (56, 60.9%), equipment checking prior to use (54, 58.7%), vigilance (37, 40.2%), prior experiences (26, 28.3%), and compliance to existing guidelines (18, 19.6%). These results are congruent to the contributing factors described above. Equipment maintenance and equipment checking prior to use are vital to anesthesia practice and involve almost all parts of various procedures. Without such minimizing factors, anesthesia practice is at high risk and may lead to catastrophic outcomes.

Suggested corrective strategies included quality assurance activity (67, 72.8%), equipment maintenance (64, 69.6%), clinical practice guidelines (34, 36.9%), more equipment (12, 13%), additional training (7, 7.6%), and improved supervision (7, 7.6%). It is noted that apart from equipment maintenance, quality assurance activity, for example, morbiditymortality conference, incident report, clinical practice guideline development, or risk management is instrumental to improve anesthesia care and patient safety.

A model of anesthesia related adverse event involving equipment failure/malfunction can be drawn as in Fig. 1. Contributing factors, factors minimizing incident, and suggested corrective strategies characteristically form such a model.

Conclusion

Thai AIMS has reported 1996 incidents involving anesthesia practice across Thailand. Among these, 92 incidents involved equipment failure/malfunction. The most frequent equipment was related to anesthetic circuit followed by anesthesia machine, capnography, laryngoscope, ventilator, and pulse oximeter. While some incidents were "rescued" by monitors and undetectable by clinical signs, more



Fig. 1 Model of anesthesia related adverse events of equipment failure/malfunction

incidents were undetected by monitors. Findings suggested that both clinical signs and monitoring devices should be considered indispensable as it is recommended in ASA standards for basic anesthetic monitoring⁽¹⁰⁾.

The majority of the incidents resulted from anesthetic and system or management factors. Fewer incidents were caused by surgical or patient factors indicating that equipment incidents occurred no matter what the surgical procedure and patient health status were.

Although anesthetic equipment is important in practice, it is unarguable that human factors are also important to patient safety. The present study showed that human error accounted for up to 80% of the incidents. Without vigilance and experienced personnel, safety in anesthesia would be impossible.

In summary, ineffective equipment, haste, lack of experience, ineffective monitors, and inadequate equipment were the most frequent contributing factors to the incidents. In order to minimize the incidents, it is suggested from the present study that proper equipment maintenance, pre-use equipment checking, vigilance, prior experiences, and compliance to existing guidelines be considered. Additionally, quality assurance activity (morbidity-mortality conference, clinical practice guideline development, or risk management), as well as additional training and improved supervision are strategies that would help improve anesthesia practice and patient safety.

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การเฝ้าระวังการเกิดปัญหาเกี่ยวกับเครื่องมือทางวิสัญญี่ในประเทศไทยโดยการรายงานอุบัติการณ์: ผลการวิเคราะห์จาก 1,996 อุบัติการณ์

ชัยพฤกษ์ กุสุมาพรรณโญ, สมรัตน์ จารุลักษณานั้นท์, ดุจเดือน สีละมาด, อักษร พูลนิติพร, วิมลรัตน์ ศรีราช

ภูมิหลัง: การศึกษานี้เป็นส่วนหนึ่งของการศึกษาแบบจำลองการเกิดอุบัติการณ์ทางวิสัญญี ในประเทศไทย โดยการรายงานอุบัติการณ์ (Thai AIMS) ซึ่งมีวัตถุประสงค์ในการศึกษาความถี่ ปัจจัยนำ ปัจจัยลดความรุนแรงของ ปัญหาเกี่ยวกับเครื่องมือทางวิสัญญี

ว**ธิการศึกษา**: เป็นการศึกษาแบบพรรณนาชนิดไปข้างหน้า ผู้ให้การระงับความรู้สึกกรอกแบบรายงานอุบัติการณ์ เมื่อประสบกับภาวะแทรกซ้อนเกี่ยวกับเครื่องมือทางวิสัญญี ข้อมูลได้รับการทบทวนโดยวิสัญญีแพทย์ 3 คน **ผลการศึกษา**: ระหว่างมกราคม ถึง มิถุนายน พ.ศ. 2550 จากฐานข้อมูลทั้งหมด 1,996 รายงาน ของอุบัติการณ์ทาง วิสัญญีพบว่าเกิดอุบัติการณ์เกี่ยวกับเครื่องมือทางวิสัญญี 92 รายงาน (4.6%) ซึ่งประกอบด้วยบัญหาเกี่ยวกับ วงจรดมยาสลบ (17.4%) เครื่องให้ยาระงับความรู้สึก (15.2%) เครื่องวัดระดับควรบอนไดออกไซด์ในลมหายใจออก (12%) กล้องส่องกล่องเสียง (15.2%) เครื่องช่วยหายใจ (12%) เครื่องวัดระดับ ความอิ่มตัวของออกซิเจน (8.7%) เครื่องระเหยยาดมสลบ (4.3%) ท่อหายใจ (3.3%) โซดาไลม์ (3.3%) และเครื่องวัดคลื่นไฟฟ้าหัวใจ (2.2%) ปัญหาเกี่ยวกับวงจรดมยาสลบทั้ง 16 อุบัติการณ์ (100%) สามารถตรวจพบได้จากอาการทางคลินิกขณะที่ 5 อุบัติการณ์ (31.3%) วินิจฉัยได้ก่อนด้วยเครื่องมือเฝ้าระวัง สำหรับกล้องส่องกล่องเสียงทั้ง 14 อุบัติการณ์ (100%) วินิจฉัยได้ด้วยอาการทางคลินิกในจำนวน 8 อุบัติการณ์ ของความผิดปกติเกี่ยวกับเครื่องวัดระดับความอิ่มตัว ของออกซิเจนมีเพียง 1 อุบัติการณ์ (12.5%) ที่สามารถวินิจฉัยทางคลินิกได้ก่อนเครื่องมือเฝ้าระวังร้อยล 75 ของปัญหาเกี่ยวกับ vaporizer สามารถวินิจฉัยได้จากอาการทางคลินิกด้วยเครื่องมือเฝ้าระวัง โดยสรุปปัญหา เกี่ยวกับเครื่องมือทางวิสัญญีเป็นปัญหาเกี่ยวข้องกับบัจจัยทางวิสัญญี (69.6%) บัจฉัยเซิงระบบ (69.6%) เป็นปัญหาที่ป้องกันได้ (71.7%) และเกิดจากความผิดพลาดของมนุษย์ (80.4%) โดยส่วนใหญ่เป็นการไม่ปฏิบัติตาม แนวทางการให้บริการวิสัญญี

สรุป: ปัจจัยนำของการเกิดปัญหาเครื่องมือทางวิสัญญีได้แก่เครื่องมือทำงานไม่มีประสิทธิภาพความรีบร้อน การขาดประสบการณ์ เครื่องเฝ้าระวังไม่มีประสิทธิภาพปัจจัยช่วยลดอุบัติการณ์ ได้แก่ การซ่อมบำรุงเครื่องมือที่ดี การตรวจเครื่องมือก่อนใช้งาน ความระแวดระวัง การมีประสบการณ์มาก่อนและการปฏิบัติตามแนวทางที่มีอยู่ ข้อแนะนำเพื่อลดปัญหาได้แก่กิจกรรมพัฒนาคุณภาพการฝึกอบรมเพิ่มเติมและการปรับปรุงระบบให้คำปรึกษา