ASSESSMENT OF KNOWLEDGE, ATTITUDES AND BARRIERS TOWARDS MEDICATION ERROR REPORTING AMONG NURSE PRACTITIONERS IN HOSPITAL TENGKU AMPUAN AFZAN KUANTAN MALAYSIA

BY

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A thesis submitted in fulfilment of the requirement for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice)

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ABSTRACT

Background: Nowadays, Medication Errors (MEs) have appealed more interest of health care organizations because of their complications like higher mortality rate and increased health care cost. The MEs are underreported in all countries. This issue compromises the Medication Error Reporting (MER) systems. **Objectives:** This study was aimed to explore the knowledge and attitudes of nurses toward ME reporting. Furthermore, barriers and facilitators towards MER practices among nurses have also been investigated. **Method:** A mixed methodological approach has been adopted to answer the research questions. In the qualitative part, a total of twenty-three nurses were interviewed, using new validated semi structured interview guide. The saturation point was reached after twenty interviews. Three extra interviews were conducted to confirm saturation point. The audio recordings were transcribed verbatim and exposed to thematic content analysis. In order to generalize the initial qualitative study findings, a cross-sectional survey has been carried out with a sample of nurses attached to the same hospital (n = 310). Using new validated self-administered questionnaire. **Result:** Four major themes were emerged from the transcripts. Almost all the interviewed nurses were aware of the existence of MER system, MER process and the importance of MER. However, although the majority of interviewed nurses did not submit any ME report, they showed a positive attitude towards MER. The main barriers for MER were the impact of time and workload, the shame feeling, fear of being investigated and the impact of MER practices on job record, negative reaction from person in-charge, the confidentiality of the reporting form, and absence of effective feedback. The obtainable response rate was equal to 90.3%. The mean for their total knowledge score was 5.6 (SD= 1.4). Almost all participants considered MER is important (99.3%) but 30 % of those who committed ME last year did not report their errors. Almost all the respondents agreed that MER is part of their professional duties (92.1%). The main reasons for underreporting were fear of liability or lawsuit issues (63.6%), fear of being labelled as an incompetent nurse (52.1%), and lack of effective feedback from the nursing manager (33.6%). The main facilitators toward MER were compulsory MER (90.7%), conducting training program specifically for MER (84.3%), analysis/feedback criteria (80%), encouragement from nurse leaders (75.7%), and using anonymous reporting form (73.2%). **Conclusion:** This study revealed that although the nurses had reasonably acceptable knowledge and positive attitudes toward MER, there was low involvement of nurses toward MER. Their decisions to report MEs were highly affected by barriers. In order to improve the participation of nurses toward MER, the related authorities should work on strategies which can help to improve the involvement of nurses such as creating a MER environment free from blaming, reporting anonymously, and conducting a training program.

خلاصة البحث

معدل توتيق الاخطاء الطبية منخفض في كل دول العالم, هده المشكلة تضعف انظمة توتيق الاخطاء الطبيه .هده الدراسة تهدف الي استكشاف المدي المعرفي للممرضات حول نظام التوتيقي للاخطاء الطبية وتحديد موقفهم اتجاه توتيق الاخطاء. بالاضافة الي استكشاف الاسباب التي قد تمنعهم من توتيق اخطاءهم . واستكشاف العوامل التي قد تحفزهم علي توتيق تلك الاخطاء. لاجابة اسئلة البحت تم استخدام طرقتين طريقة نوعية وطريقة كمية. في الطريقة النوعية , تم اجراء ثلاثة وعشرون مقابله مع الممرضات. باستخدام دليل اسئلة معدة مسبقا لتغطية الجوانب المتعلقة بموضوع الدراسة. بعد 20 مقابله تم الوصول لدرجة التشبع للمموضوعات حيت تم تاكيدها بعد اجراء 3 مقابالات اضافية . الملفات الصوتية للمقابلات تم تحويلها الي نصوص مكتوبة لتحليلها .اربعة موضوعات رئيسية تم استخلاصها من للمقابلات . اغلب الاعضاء الدين تم مقابلتهم اظهروا بانهم لديهم قدر كافي من المعرفة حول وجود نظام ,و كيفة توتيق اخطائهم, وفهم اهمية التوتيق. وبالرغم من ان اغلبيتهم كشفوا بانهم لم يقوموا بعمل توتيق لاي خطأ طبي من قبل الا انهم ابرزوا موقف ايجابي. العوائق الرئيسية ضد هي تاتير الوقت وعبء العمل, الشعور بالخجل, الخوف من التحقيق والخوف من تاتر السجل الوظيفي.ولتعميم النتائج الاولية, تم توزيع استبيان علي عينة من الممرضات اللاتي يشتغلن بنفس المستشفى المذكور (310). معدل الاستجابة كان (90.3 %). متوسط درجات المعرفة كان 5.6. اغلب المشاركين يعتبرون توتيق الاخطاء امر هام جدا (99.3 %). ولكن (30 %) من المشاركين الدين اعترفوا بارتكابهم اخطاء طبيه خلال السنة الماضية اظهروا انهم لم يقوموا بتوتيقها. اغلب المشاركين موافقين علي ان عمليه توتيق الاخطاء الطبية هو جزء اساسي من واجباتهم المهنية (92.1 %). الاسباب الرئيسية وراء عدم توتيق الاخطاء الطبية رسميا هي الخوف من المسائل القانونية (63.6 %). الخوف من اعتبار مرتكب الخطأ علي انه غير كفؤ (52.1 %). اهم المحفزات تسهيل وزيادة عمليات توتيق الااخطاء الطبيه هي جعل التوتيق اجباري (90.7 %). اجراء برنامج تدريبي يخص التوتيق الرسمي للاخطاء الطبية (84.3 %). بالرغم ان المشاركات لديهم قدر معرفي مقبول وموقف ايجابي نحو توتيق الاخطاء الا انه تم ملاحظة ان مساهمتم منخفضة. كما ان قرارهم يتاتر بعوائق معينة.ولزيادة مساهمتهم علي صانعي القرار ان يشتغلو علي خطط لتسهيل التوتيق في بيئة خالية من لوم مرتكب الخطأ, توتيق بدون دكر هوية الشخص مرتكب الخطأ او الشخص الدي قام بتوتيق الخطأ, اقامة برنامج تدريبي بخصوص التوتيق الرسمي للاخطاء الطبية.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice).

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DECLARATION

I hereby declare that this thesis is the result of my own investigations. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

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In the Name of Allah, the Most Gracious, the Most Merciful. All praise is due to Allah alone, I praise him, seek his aid and seek his forgiveness. I testify that there is no God except Allah. And that Mohammed (peace be upon him) is his slave and messenger. I thank Allah Almighty for giving me the inspiration, patience, time, and strength to finish this work. With Allah's will and mercy, I have been able to achieve all of this.

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LIST OF ABBREVIATION

A&E	Accident and Emergency Unit
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
CCU	Critical Cardiac Unit
CNE	Continuous Nurse Education
HTAA	Hospital Tengku Ampuan Afzan
ICU	Intensive Care Unit
IIUM	International Islamic University Malaysia
IOM	Institute Of Medicine
IREC	International Islamic University Research Ethical Committee
MAE	Medication Administration Error
ME	Medication Error
MER	Medication Error Reporting
NICU	Neonatal Intensive Care Unit
NMRR	National Medical Research Register
QUAL	Qualitative
QUAN	Quantitative
SOP	Standard of operation
SSIG	Semi-Structured Interview Guide
WHO	World Health Organization

CHAPTER ONE
MEDICATION ERROR REPORTING

1.1 RESEARCH BACKGROUND

Saving life is the principle objective of any health care system. At the same time, ensuring patient safety is an important issue to prevent any patient harm. The patient safety is considered as one of the main concept in the field of health care system as well as a key factor in maintaining the quality of health care services. Adverse events and medical errors are the main issues affecting patients' safety. These are the most important problems of all health care systems (Bifftu, Dachew, Tiruneh, & Beshah, 2016). Medication errors are the most common type of medical mistakes (Abdel-Latif, 2016).

The terminology of Medication Error (ME) can be confusing due to overlapping definitions (Wittich, Burkle, & Lanier, 2014). It has been defined as an actual or a potential serious lapse in the standard of care provided to a patient or harm caused to a patient through the performance of a health service or a healthcare professional (Khoo et al., 2012). Furthermore, ME has been defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer"(Lau, 2008).

The World Health Organization (WHO) has estimated that millions of people suffer injuries directly attributed to medical care, many of them are preventable (Khoo et al., 2012). The estimated rate of hospital MEs in France was high and involved 1.9 patient per day (Fontan, Maneglier, Nguyen, Brion, & Loirat, 2003). In the United States, data from 1993 indicated that 7391 patients died from ME (Stetina, Groves, &

Pafford, 2005), patients' length of hospitalization associated with MEs increased by 4.6 days, with a resulting cost increase of $4685 per patient (Lau, 2008). As for Malaysia, about 2572 cases of MEs were reported in 2009 (Johari, Shamsuddin, Idris, & Hussin, 2013). However, there is a lack of information about the ME rate in Kuantan city.

MEs can occur at any point during the medication process such as ordering, transcribing, dispensing, administrating, and monitoring (Alsulami, Conroy, & Choonara, 2013; Ronda G. Hughes & Blegen., 2008). The most prevalent MEs are the errors which include administration at inappropriate times, errors in the prescription of medicines, over prescribing, failure to follow the proper prescription, error in drug concentration, and giving medicine to the wrong patient due to improper identification of patients (Koohestani, Hamid Reza, & Baghcheghi, 2009). In the UK, the National Patient Safety Agency (NPSA) revealed that the percentage of MEs according to each stage of the medication treatment process was 16% in the prescribing one, 18% in the dispensing, and 50% in the administration stage of drugs (National Patient Safety Agency, 2009).

Internationally, many systems have been established to document MEs. However, most of them were voluntary reporting systems such as Food and Drug Administration (FDA- MedWatch,), Medication Error Reporting Program, and MEDMARX (Wittich et al., 2014). The Safe Medical Devices Act of 1990 is an example of a mandatory reporting system. In Malaysia, MER system is a voluntary system under the control of Malaysian Ministry of Health (National Patient Safety Agency, 2009). Table (1.1) summarizes the differences between compulsory and voluntary reporting systems.

Table 1.1 Characteristics of mandatory and voluntary medical errors reporting systems as proposed by the IOM (Redhead, 2005).

	Mandatory reporting systems	**Voluntary reporting systems**
Purpose	Accountability	Safety improvements; detection and analysis of systemic problems before serious injury or death occurs
System administration	State government	Private organization
Obligation to report errors	Establishes legal obligation to report; relies on penalties and sanctions to encourage compliance	Relies on trust in the reporting system and a commitment to its purpose
Type of data reported	Medical errors that result in serious injury or death	Medical errors that result in no harm (close calls) or minimal harm
Public disclosure of data	Validated information available to the public	Strictly confidential; only de-identified data publicly available
Use of reported data	Verification of data to ensure consistency with reporting definitions and attribution to error; analysis of data and identification of ways to avoid a reoccurrence of the error; oversight and evaluation of corrective actions taken	Analysis and interpretation of errors; identification of system vulnerabilities; development of preventive strategies

The mandatory reporting system is used to gather standardized data on adverse events that result in death or serious harm (American Society of Health-System Pharmacists, 2000). The voluntary reporting systems is considered as a complementary system helped to collect data on errors that result in little or no harm (Redhead, 2005). The non-punitive and confidential voluntary reporting systems provide more useful data about MEs and their contributing factors than compulsory MER systems (O'Leary, 2000). As the voluntary programs give the frontline health care practitioners the opportunity to report the whole story without fear of revenge. The depth of information contained in

these stories is a key to understand the errors. While, practitioners who are obligated to report errors in the mandatory programs are less likely to submit in depth information because their principle motivation is self-protection and adherence to the law, not to help others avoid the same error. Voluntary programs also encourage practitioners to report hazardous conditions and errors that did not cause harm but have the possibility to do harm (O'Leary, 2000). The voluntary reporting system such as FDA-MedWatch has the ability to influence the pharmaceutical industry, device manufacturers, and regulatory bodies to change healthcare standards and medical product design if they are directly related to the MEs. While little action is taken by the mandatory reporting program when significant numbers of harmful errors have been reported (O'Leary, 2000).

MEs are committed by many healthcare practitioners such as physicians, pharmacists and nurses. However, nurses are usually placed on the frontline when MEs occur (Mrayyan, Shishani, & AL-Faouri, 2007) because they are the last persons in the sequence of medication process (prescribing, dispensing, preparing, administering) (Lane, Stanton, & Harrison, 2006). They are responsible for the preparation, administration, and assessment of patients' therapeutic responses to the administered drugs (Koohestani et al., 2009). All these activities requires particular level of knowledge and attitude to properly execute these services (Bayazidi, Zarezadeh, Zamanzadeh, & Parvan, 2012).

In comparison to other health care practitioners, the responsibility of most occurred MEs has been attributed to the nurses (Mayo & Duncan, 2004) due to the fact that they are the largest therapeutic team (Hashish & El-Bialy, 2013), and most of them need to comply with the correct drug orders. In addition, 40% of nurses spend their time in hospitals taking care of patients (Ehsani et al., 2013; Miladinia et al., 2016). Managing patients' medications is a high-risk nursing activity (Hashish & El-Bialy, 2013). It has been estimated that about 78% of nurses have committed MEs (Miller, Haddad, &

Phillips, 2016). Keohane et al conducted a study aimed to quantify the workflow of nurses in the medication administration process. They found that different percentage of nurses' time is spent on different tasks about 27% on drug-related activities, 7.4% to obtain and verify medication orders, 6.7% to deliver medications, 3.9% to retrieve information, another 3.9% is to manage physicians' orders, and lastly, 2.8% is spent on medication documentions (Keohane et al., 2008).

The harmful effects of MEs on patients are not the only problem that results from MEs, there are several other negative consequences such as unsuccessful and imperfect treatment, legal problems, increase of term and cost of hospitalization, damage to the professional reputation of nurses, and mistrust of patients and the society in the healthcare system (Mayo & Duncan, 2004; Miladinia et al., 2016).When a mistake occurs, disclosing and quickly reporting it to the appropriate authority is the right action (Johnstone & Kanitsaki, 2006). Whether the nurse is the source of error, a contributor, or a witness; organizations depend on nurses as front-line staff to recognize and report MEs (Mayo & Duncan, 2004; Miladinia et al., 2016).

Medication error reporting (MER) reduces the negative effects and efficiently helps to avoid future errors that can cause harm to patients. Consequently, personal suffering and financial costs will be diminished (Bayazidi et al., 2012; Yung, Yu, Chu, Hou, & Tang, 2016; Zivin & Pfaff, 2004). However, only a small percentage of MEs are actually reported. The MEs are underreported in all countries, particularly in developing countries (Alsulami et al., 2013; Yung et al., 2016).

The MER systems are helpful in identifying the MEs root causes and patterns. Moreover, they provide valuable information for quality improvement efforts (Pierson et al., 2007). However, these systems cannot capture all errors because they rely on spontaneous reporting. This challenge is known as'underreporting problem'.

Furthermore, numerous other issues arose from the submitted reports, such as their subjective nature, the lack of consistency and validation of incident data classification. All of the above mentioned concerns constrain MER from being used as a reliable epidemiological tool to measure the frequency of events and whether interventions are effective in improving patients' safety (Evans et al., 2006).

In order to improve the effectiveness of the MER system in documenting all MEs and improving the quality of ME reports, the assessment of nurses' knowledge towards the issue, and evaluation of their attitudes, as well as an exploration of barriers and facilitators towards MER are important.

1.2 PROBLEM STATEMENT

Medication errors are serious problem which lead to high morbidity and increased cost of health care service. The medication error reporting is an effective way to collect database regarding drug related problems in the health care facilities. This information can be used to improve the patient safety and the quality of health care services. The ideal situation, when the medication error occur the health care provider should report this error. The collected reports will exposed to root cause analysis which help to identify the contributing factors for the medication errors and hence prevention strategies can be developed accordingly. Sending feedback to the health care practitioners is the final step. The feedback will help health care practitioners to be more alert regarding MEs contributing factors and help them to avoid repeating the same error in future. However, there is a gap between the number of MEs which actually occurred and the number of reported MEs. This gap is known as underreporting. The underreporting of MEs is a major challenge which faced all MER systems. This issue leads to limit the efficiency of MER systems in collecting data about the MEs. Collecting data about the MEs is the

first step in MER process followed by the analysis and finally come out with the final report which should be referred to the health care professionals as a feedback for their reporting practices. The responsibility of MER relies on the healthcare professionals and patients to the variety healthcare organizations such as local MER system, FDA and IOM. Literature indicated that nurses can play a significant role in MER as they are in daily direct contact with the patients. It was documented that the possible causes of the underreporting problem are poor knowledge of nurses about the MER, their negative attitudes toward the MER, or organizational and individual barriers. Similar to other countries, collecting data about MEs in Malaysia depends on the spontaneous reporting system. This system has been established since 2009. The Malaysian MER system like other MER systems faced the underreporting issue by healthcare providers. There is a limited information about the reasons for the underreporting in Malaysia among healthcare providers in general and among nurses in particular. To understand why the MER among nurses is low. It is essential to assess and evaluate the nurses knowledge and attitude toward the MER, to determine the factors which could perceived as a barriers toward the MER, and to investigate the factors which could improve the nurses involvement to increase the number and quality of ME reports

This is a mixed methodological study which intended to attain deeper insight into the knowledge, attitudes held by Malaysian nurse practitioners towards MEs concept and MER process, as well as to investigate the barriers preventing them from reporting their MEs.

1.3 RESEARCH QUESTIONS

1. What is the current MER status among nurses?
2. What do nurses know about the ME and MER system?
3. What are the nurses' attitudes toward MER?
4. What are the barriers which could hinder nurses from reporting their MEs?
5. What are the factors which could facilitate the MER among nurses?

1.4 RATIONALE OF THE STUDY

MEs is a significant problem resulting in excessive patient morbidity and cost. Errors can be minimized as well as the safety of patients can be improved by utilizing MER, which help to design a more strong healthcare system. A valuable data base can be collected about MEs through MER systems. Analysing these data are helpful to understand MEs and their contributing factors. If the MEs contributing factors can be identified then the prevention strategies can be developed. These strategies will help to minimize MEs occurrence and ultimately will lead to improve the patient safety. Nursing administrators should fully understand the objectives, importance, and meaning of the nursing-related drug adverse event classification standard and their reporting processes.

Study on the knowledge and attitudes of the nurses towards MER in developed countries has already been carried out and documented, whereas, limited studies on this subject has been reported in developing countries such as Malaysia. To the best of our knowledge, this study is the first of its kind in Malaysia using mixed methodological study design. Assessing the knowledge, and attitudes of nursing practitioners relating to spontaneous reporting of MEs is very important.

Studying the MER issue among nurses will be worthwhile to diagnose underreporting problems by measuring the depth of their knowledge, attitudes, and