THE PREVALENCE OF ACTUAL MEDICATION ERROR 2019-2022 IN THE ONLINE MEDICATION ERROR REPORTING SYSTEM (MERS) AND ITS ASSOCIATED FACTORS IN KELANTAN

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by

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LIST OF ABBREVIATIONS

AdjOR	Adjusted Odds Ratio
DALYs	Disability-Adjusted Life Years
CI	Confidence Interval
HCPs	Healthcare Providers
HREC	Human Research Ethics Committee
ID	Identification Number
JePEM	Jawatankuasa Etika Penyelidikan Manusia
KPIs	Key Performance Indicators
LASA	Look-Alike Sound-Alike
ME/ MEs	Medication Error/ Medication Errors
MERS	Medication Error Reporting System
MOH	Ministry of Health
MPSG	Malaysian Patient Safety Goal
MREC	Medical Research and Ethics Committee
MYR	Malaysian Ringgit
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
NMRR	National Medical Research Registry
OR	Odds Ratio
ROC	Receiver Operating Characteristic
SPSS	Statistical Package for the Social Science
USD	United States Dollar
USM	Universiti Sains Malaysia
WHO	World Health Organisation

LIST OF SYMBOLS

%	Percent
<	Less than
α	Alpha
β	Regression coefficient
n	Frequency

ABSTRAK

KELAZIMAN KESILAPAN UBATAN (MEs) SEBENAR 2019 - 2022 MELALUI SISTEM PELAPORAN KESILAPAN UBATAN ATAS TALIAN (MERS) DAN FAKTOR BERKAITAN DENGANNYA DI KELANTAN

Latar belakang: Sistem Pelaporan Kesilapan Ubatan (MERS) atas talian ialah sistem pelaporan berkaitan kesilapan ubatan (MEs) secara sukarela di kemudahan penjagaan kesihatan awam dan swasta. Diperkenalkan pada tahun 2013, sistem MERS atas talian termasuk pelaporan kejadian MEs nyaris dan MEs sebenar. Kelaziman MEs yang dilaporkan semakin meningkat dan banyak faktor dikaitkan dengan MEs, namun sedikit yang diketahui tentang kelaziman MEs sebenar dan faktor-faktor yang berkaitan dengannya di Kelantan.

Objektif: Objektif kajian ini adalah untuk menentukan kelaziman dan faktor berkaitan dengan MEs sebenar di Kelantan dari 2019 hingga 2022.

Metodologi: Semakan rekod data sekunder secara retrospektif telah dijalankan ke atas jumlah laporan MEs dari 2019 - 2022 di Kelantan yang diperoleh daripada pangkalan data atas talian MERS, Malaysia. Data dianalisis menggunakan Regresi Logistik Mudah dan Regresi Logistik Berganda untuk laporan MEs yang telah disahkan.

Dapatan kajian: Sebanyak 15937 laporan ME daripada pangkalan data telah dianalisa. Kelaziman MEs sebenar pada 2019 - 2022 di Kelantan ialah 1.6%, yang berjulat antara 1.1% hingga 2.8% setiap tahun dari 2019 hingga 2022. Enam pemboleh ubah tidak bersandar dikaitkan dengan ketara pada MEs sebenar termasuklah kakitangan tidak berpengalaman (AdjOR 1.84; 95% CI: 1.36 hingga

2.48), bunyi sebutan ubatan serupa (AdjOR 1.71; 95% CI: 1.12 hingga 2.62), pembungkusan ubatan serupa (AdjOR 3.65; 95 % CI: 2.03 hingga 6.57), pengaturan stok/ masalah penyimpanan (AdjOR 6.72; 95% CI: 3.87 hingga 11.68), kegagalan mematuhi prosedur kerja (AdjOR 10.59; 95% CI: 7.60 hingga 14.75), dan pelabelan/ arahan yang salah pada sampul surat atau botol/ bekas (AdjOR 4.17; 95% CI: 1.89 hingga 9.23).

Kesimpulan: Walaupun dengan peningkatan laporan MEs dan MEs nyaris setiap tahun, tren kelaziman MEs sebenar didapati semakin menurun di Kelantan. Kajian diperlukan untuk menentukan samada situasi ini berlaku akibat kurangnya pelaporan MEs sebenar. Justeru, program kesedaran dan latihan diperlukan untuk meningkatkan pelaporan kesilapan ubatan dengan mengukuhkan program keselamatan ubatan dan memupuk budaya keselamatan dalam proses ubatan untuk pencegahan kes MEs.

KATA KUNCI: Kesilapan ubatan sebenar, pangkalan data sistem MERS, prevalens, faktor berkaitan

ABSTRACT

THE PREVALENCE OF ACTUAL MEDICATION ERROR 2019-2022 IN THE ONLINE MEDICATION ERROR REPORTING SYSTEM (MERS) AND ITS ASSOCIATED FACTORS IN KELANTAN

Background: The online Medication Error Reporting System (MERS) is a voluntary reporting system of medication error (ME) in public and private healthcare facilities. Introduced in 2013, the online MERS includes the reporting of near miss and actual MEs. The prevalence of reported MEs was increasing and many factors were associated with MEs, however little is known about the prevalence of actual MEs and its associated factors in Kelantan.

Objective: The study objectives were to determine the prevalence and factors associated with actual MEs in Kelantan from 2019 to 2022.

Methodology: A retrospective secondary data record review was conducted on ME reports from 2019 to 2022 in Kelantan obtained from the online MERS database. Data was analysed using simple and multiple logistic regression for endorsed MEs report.

Results: A total of 15937 ME reports from the database were analysed. The prevalence of actual MEs in 2019 to 2022 in Kelantan was 1.6%, which ranged from 1.1% to 2.8% yearly from 2019 to 2022. Six independent variables were significantly associated with actual MEs which include inexperienced personnel (AdjOR 1.84; 95% CI: 1.36 to 2.48), sound-alike medication (AdjOR 1.71; 95% CI: 1.12 to 2.62), look-alike packaging (AdjOR 3.65; 95% CI: 2.03 to 6.57), stock arrangements/ storage problems (AdjOR 6.72; 95% CI: 3.87 to 11.68), failure to adhere to work

procedure (AdjOR 10.59; 95% CI: 7.60 to 14.75), and wrong labeling/ instruction on dispensing envelope or bottle/ container (AdjOR 4.17; 95% CI: 1.89 to 9.23).

Conclusion: Even with the increasing number of MEs and near misses reported every year, the prevalence of actual MEs is reducing in Kelantan, further research is warranted to investigate such occurrence as it may imply under reporting. Increasing near misses may also eventually lead to actual MEs. Awareness program and trainings are required to increase reporting of errors by strengthening the medication safety programme and cultivate safety cultures in medication management for prevention of MEs.

KEYWORDS: Actual MEs, online MERS, prevalence, factors associated

CHAPTER 1

INTRODUCTION

1.1 Study background and Significance

Patient safety and medical errors are a critical concern for public health and are responsible for a significant number of global deaths (Makary and Daniel, 2016). When the requirements for medical services become more stringent, it is crucial to address and mitigate medical errors in order to enhance safety and quality of care that been given. Among various medical errors, medication errors (MEs) are prevalent (Morelock and Kirk, 2019; Jachan *et al.*, 2021) and they undermine the effectiveness of healthcare systems by contributing to increased hospitalizations and medical costs in both developed and developing nations (Ahmed *et al.*, 2015).

In March 2017, World Health Organization (WHO) introduced "Medication without Harm" initiative as part of its third Global Patient Safety Initiative. Half of all avoidable harm is caused by medication-related harm. The primary objective of this initiative is to reduce severe and preventable harm caused by medications by 50% worldwide within the next five years (WHO, 2017). This initiative follows the first two challenges: 'Clean Care is Safer Care' and 'Safe Surgery Saves Lives', both introduced by WHO in 2009 (Sheikh *et al.*, 2017). The risk of MEs and medication-related harm has dramatically increased due to the COVID-19 epidemic. Considering this circumstance, 'Medication Safety' has been chosen as the theme for World Patient Safety Day 2022, accompanied by the slogan 'Medication Without Harm' with a call to action to “Know, Check and Ask” (WHO, 2023).

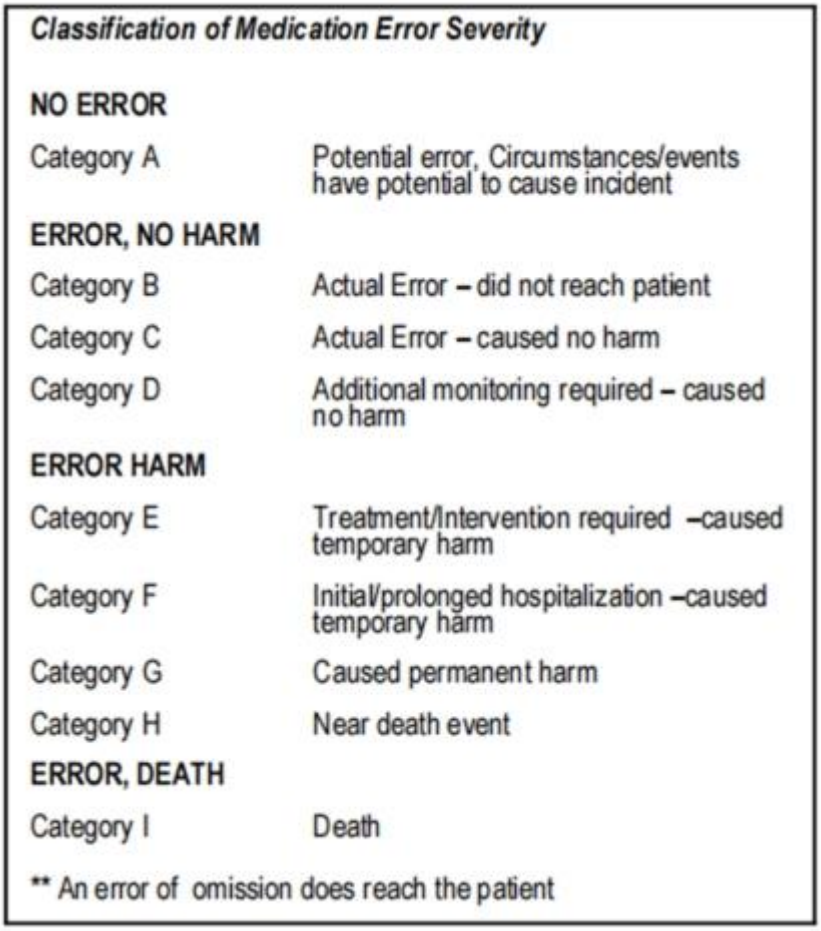
1.2 Definition and Classification of Medication Errors

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) provides a definition of MEs as "preventable events that can lead to inappropriate medication use or patient harm while the medication is under the control of healthcare professionals, patients, or consumers. These events can be associated with various aspects of healthcare practice, including prescribing, order communication, labeling, packaging, dispensing, administration, monitoring, and education" (NCCMERP, 2022). The definitions and classification of MEs provided are crucial in establishing a common understanding and framework for identifying, reporting, and preventing MEs (Lisby *et al.*, 2010). By defining MEs and categorizing them based on their occurrence, potential harm, and outcomes, healthcare systems can work towards implementing effective strategies to reduce medication errors, prioritize medication safety, improve patient safety and continuously evaluate and refine their practices to minimize the occurrence and impact of MEs. Malaysia also using similar definition of MEs as being outlined by NCCMERP (MOH, 2019).

Medication errors can be categorized into two types: actual MEs and near miss MEs. Actual MEs refer to errors that have occurred and reached the patient or have been detected by the patient. On the other hand, near miss MEs are errors that have the potential to cause harm (adverse event) but were intercepted in the process or corrected by healthcare personnel before reaching the patient due to chance or detection (MOH, 2019).

The outcomes of medication errors are classified by the NCCMERP based on algorithm (NCCMERP, 2001) into nine categories, ranging from circumstances that may lead to an error (Category A) to errors that result in patient death (Category I),

as depicted in Figure 1.1 and Figure 1.2 (NCCMERP, 2022). According to the NCCMERP classification, near miss MEs fall under Category A and B, while actual MEs encompass Category C to I in terms of outcome and severity (MOH, 2019; Mutair *et al.*, 2021) .



Classification of Medication Error Severity

NO ERROR	
Category A	Potential error, Circumstances/events have potential to cause incident
ERROR, NO HARM	
Category B	Actual Error – did not reach patient
Category C	Actual Error – caused no harm
Category D	Additional monitoring required – caused no harm
ERROR HARM	
Category E	Treatment/Intervention required –caused temporary harm
Category F	Initial/prolonged hospitalization –caused temporary harm
Category G	Caused permanent harm
Category H	Near death event
ERROR, DEATH	
Category I	Death

** An error of omission does reach the patient

Figure 1.1 Classification of the severity of medication error (NCCMERP, 2001; MOH, 2019)

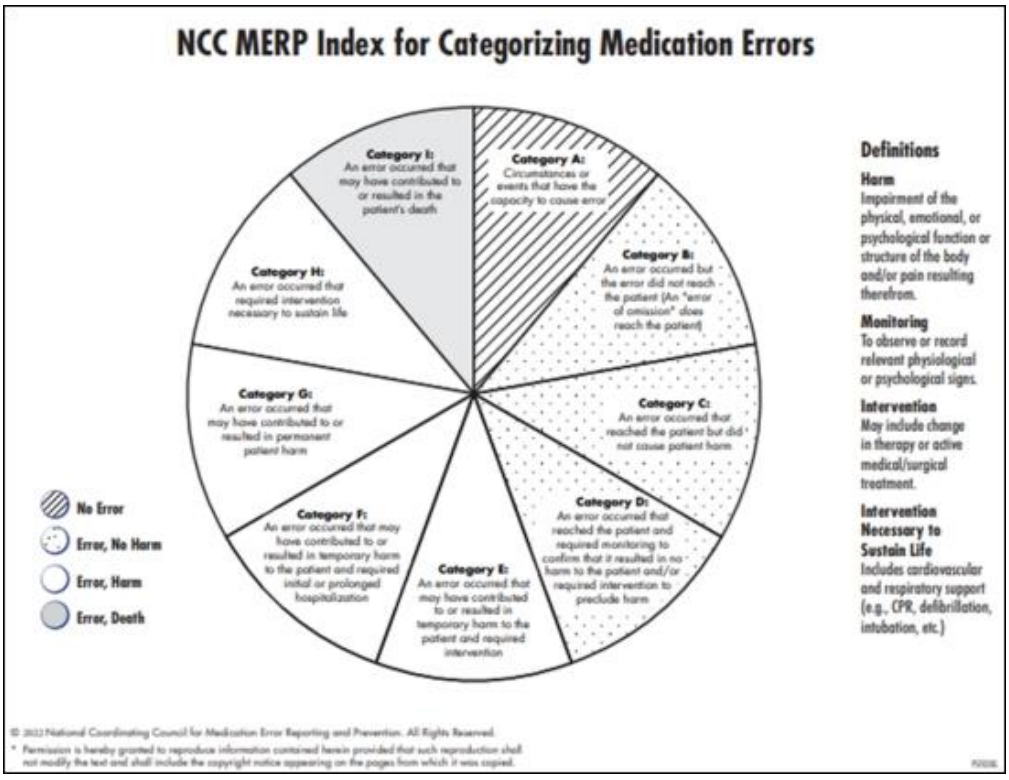


Figure 1.2 Categorizing Medication Errors by NCCMERP Index (NCCMERP, 2022)

1.3 Reporting of Medication Error

A number of substantial interventions have been put into place to decrease the occurrence of MEs. These interventions primarily focus on system-based approaches, such as the establishment of error reporting systems (Kolovos et al., 2008; Neuspiel et al., 2011; Riga et al., 2014), the utilization of technology (Dollarhide et al., 2007; Haller et al., 2007), enhancements in the medication use process (Hauser et al., 2010), and the implementation of safety feedback systems (Benn et al., 2009). These system-based approaches emphasise the requirement for establishing a supportive environment of learning from errors and promotes patient safety. Error reporting systems play a critical role in providing data that can be analysed and transformed into useful information, assisting in risk identification, promoting learning, and developing better recommendations (WHO, 2005, 2014). Reporting errors through local or national reporting systems is one of the tools used

to detect current patient safety issues (WHO, 2014). National reporting systems play a key role in achieving these objectives as they enable the sharing of lessons learned with a broad audience (WHO, 2005). The primary goals are to enhance patient safety through learning, sharing, and exchanging information from past healthcare failures (Larizgoitia *et al.*, 2013). The emphasis on error reporting systems as a crucial tool for detecting patient safety issues and facilitating learning is significant. By encouraging healthcare providers (HCPs) to report errors through local or national systems, valuable data can be collected and analysed to identify trends, root causes, and potential solutions. This data-driven approach enables healthcare organizations to develop targeted plan of action for reducing MEs and improving quality of patient care. The strategic goals of NCCMERP also emphasize the significance of effective and efficient reporting systems and medication safety practices in order to reduce the frequency and severity of MEs. This includes encouraging healthcare organizations to develop and utilize medication error reporting systems and enhance evaluation of error reports to generate recommendations for error reduction and prevention (NCCMERP, 2022). By fostering a culture of reporting, learning, and collaboration, healthcare systems can continually improve medication safety and improve the care provided to patients.

1.4 Medication Reporting System

The establishment of these national reporting systems reflects the recognition of the importance of collecting data on medication errors and fostering a culture of transparency and learning within healthcare systems. These systems serve as centralized databases for reporting incidents, enabling HCPs to share their experiences and contribute to the identification and prevention of medication errors

(Santell *et al.*, 2003; WHO, 2014). By consolidating data from various sources, these systems can detect patterns, highlight common vulnerabilities, and facilitate the development of targeted interventions to enhance medication safety. Many nations and institutions have developed their own mechanisms and systems for reporting errors (Cheng et al., 2011; Cheung et al., 2011; Holmström et al., 2012). These systems can be categorized based on factors such as the type of organization, the management approach (mandatory or voluntary), the scope of coverage, and the types of incidents being reported. Globally, several countries have implemented national reporting systems for MEs. For instance, the United States has the Institute of Safe Medication Practice (ISMP), Canada has the Canadian Medication Incident Reporting and Prevention System (CMIRPS), the United Kingdom has the National Reporting and Learning System (NRLS), and the Netherlands has the Central Medication Incidents Registration (CMR). Similar systems are also in place in Ireland, Australia, France, Spain, Denmark, Norway, Sweden, and Japan (Holmström et al., 2012).

It is important to ensure that these systems are effectively utilized, and reporting is encouraged among healthcare professionals. This requires on-going efforts to promote awareness about the importance of reporting, to address any barriers or concerns regarding reporting, and to ensure that reporting processes are user-friendly and efficient. Additionally, collaboration and information sharing between different reporting systems at the national and international levels can further enhance the collective knowledge and contribute to global efforts in reducing medication errors.

1.5 Medication Reporting System in Malaysia

In Malaysia, the collection of data on MEs report began in 1990 as part of quality assurance initiatives in government hospital pharmacies, specifically targeting errors in prescribing and dispensing processes (MOH, 2009). In August 2009, the MOH introduced Medication Error Reporting System (MERS), a nationwide paper-based reporting system for MEs reporting (MOH, 2009). Reporting MEs through the paper-based reporting system is one of the approaches to safeguard medication safety, aligning with the Malaysian Patient Safety Goals (MPSGs) (MOH, 2013, 2021).

Medication Error Reporting System (MERS) is a voluntary reporting system accessible to HCPs, both in public and private healthcare sectors (MOH, 2009; MOH, 2019). Its purpose is to gather information about MEs, maintain a comprehensive database, analyse and interpret reports, provide corrective actions, and continue monitoring the situation. The system covers all MEs, including near miss MEs and actual MEs, involving any medicine used in public and private healthcare facilities. Some cases, such as administrative errors or pharmacist interventions for treatment optimization, are not reported through MERS but are directed to other appropriate channels for monitoring and follow-up (MOH, 2019).

The reporting process in MERS involves filling out a form with various sections to capture event details, including error description, personnel involved, and the type of medicine associated with the MEs. Guidelines for reporting MEs have been established to provide reference and guidance to those reporting incidents (MOH, 2009, 2017; MOH, 2019). After been upgraded and tested in 2012 to an online system, online MERS was launched in 2013, enhancing the effectiveness and convenience of the reporting process with the manual guidelines for online system

(MOH, 2017; MOH, 2019). The online system allows reporters to have safety feedback systems. Expanding the functionality of the online system could facilitate ider dissemination of feedback to a broader audience, strengthening its role as a medication safety learning platform.

A robust feedback mechanism from the error reporting system is crucial in promoting and maintaining interest among HCPs to report MEs (MOH, 2019). Reporting MEs is considered a shared responsibility, as active management and an effective reporting system contribute to error detection and encourage better medication safety practices. The implementation of MERS since 2009 has advanced medication safety initiatives, aligning with the Malaysian Patient Safety Goals (MOH, 2013, 2021). Previous data reported a steady increase in nationwide medication error reports to the Ministry of Health over the years from 2009 to 2012 (Samsiah *et al.*, 2016b) and also from 2017 to 2020 based on pharmaceutical services programme surveillance annual report 2020 (MOH, 2020b). However, the ME incidents were presumed underreported as study on HCPs practices in reporting MEs found out that the HCPs report the MEs voluntarily if they are aware and familiar with the process of ME reporting system (Samsiah *et al.*, 2016a).

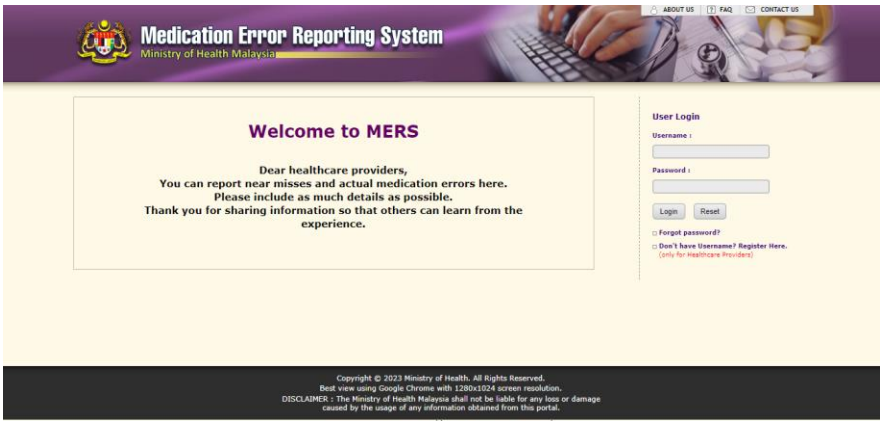


Figure 1.3 Online National Medication Error Reporting System (MERS) Layout (https://mers.pharmacy.gov.my/)

1.6 Problem statement

As for now, data on MEs in Southeast Asia is limited (Salmasi *et al.*, 2015). In Malaysia, there have been few studies conducted on ME in both inpatient settings (Chua *et al.*, 2009; Chua *et al.*, 2010) and outpatient pharmacies (Abdullah *et al.*, 2004). The reported rates of medication errors in these studies varied significantly, ranging from 11.7% to 97.7%, with a focus on different aspects of the medication process. For example, a local study conducted in a geriatric outpatient pharmacy at a teaching hospital in Malaysia revealed an average of 20 medication errors occurring daily (Abdullah *et al.*, 2004). Furthermore, there is only one retrospective descriptive study available in Malaysia that specifically examines characteristic of MEs reported to the national MERS over a four-year period from 2009 to 2012 (Samsiah *et al.*, 2016b). This study provides valuable insights into the nature and prevalence of MEs within the country at that point of time. The scarcity of data on MEs in Southeast Asia, including Malaysia, highlights the need for more comprehensive research and surveillance in this area. Further studies are necessary to gather evidence-based and up-to-date information on the occurrence, types, causes, and consequences of MEs in various healthcare settings. Such research can help identify areas for improvement, guide the development of targeted interventions, and ultimately enhance medication safety in the region.

1.7 Rationale of the study

Medication errors, particularly actual MEs, have significant implications for patient safety and are emerging as major threats. When actual MEs result in harm, they can significantly impact patient outcomes, leading to hospital admissions and incurring healthcare costs. According to a report by the NCCMERP, MEs rank as the

sixth leading cause of mortality in the United States, with 5-10% of reported MEs classified as harmful. MEs have been estimated to cause at least one death per day and harm 1.3 million people annually with USD 42 billion in medication harm-related costs is incurred each year (WHO, 2017). Evidence in Australia showed that medication harm-related admissions account for 3% to 8% of all admissions (Roughhead L *et al.*, 2013). A local study conducted in a teaching hospital's geriatric outpatient pharmacy in Malaysia revealed that around 20 cases of MEs occurred daily with a projected cost of MYR 111,924 (USD 26,150) per year for the consequences cost of MEs, including the financial cost of wasted drugs and the humanitarian impact (Abdullah *et al.*, 2004). These figures highlight the substantial financial burden and negative consequences associated with medication errors in different healthcare systems. Additionally, actual MEs can cause patient morbidity and even mortality, while also damaging the reputation of healthcare facilities and increasing healthcare costs.

It is crucial to evaluate actual MEs in order to improve patient safety and identify error-prone areas for targeted prevention strategies. Understanding the factors associated with actual MEs is beneficial for identifying areas of improvement and planning effective prevention strategies. However, in Malaysia, only one retrospective descriptive study has examined the characteristics of MEs reported by HCPs from 2009 to 2012 based on paper-based reports (Samsiah *et al.*, 2016b). Therefore, this study aims to analyse data on actual MEs over all MEs reported by HCPs through an online MERS database in Malaysia from 2019 to 2022. The study aims to determine the prevalence of actual MEs in the database and determine the factors associated with these errors. By prioritizing prevention over cure, the findings of this study can inform policymakers in managing medication errors, reducing their

occurrence, and ensuring the delivery of high-quality healthcare to patients. This research is crucial for improving patient safety and enhancing the overall healthcare system.

1.8 Research question, Objectives and Hypotheses

1.8.1 Research question

To study the prevalence of actual MEs and its associated factors in Kelantan based on reports submitted via online MERS from 2019 to 2022.

1.8.2 Objectives

1.8.2(a) General objective

To study the prevalence and factors associated with actual MEs in Kelantan based on reports submitted via online MERS from 2019 to 2022.

1.8.2(b) Specific objectives

1. To determine the prevalence of actual MEs in Kelantan, submitted via online MERS from 2019 to 2022
2. To determine the factors associated with actual MEs in Kelantan, submitted via online MERS from 2019 to 2022

1.8.3 Hypotheses

1.8.3(a) Null hypothesis

There is no association between factor associated with actual MEs with actual MEs occurrence reported in Kelantan, submitted via online MERS from 2019 to 2022.

1.8.3(b) Alternative hypothesis

There is association between factor associated with actual MEs with actual MEs occurrence reported in Kelantan, submitted via online MERS from 2019 to 2022.

CHAPTER 2

LITERATURE REVIEW

2.1 Global Strategy on Patient Safety

Since the influential 1999 Institute of Medicine report titled "To Err is Human" (Kohn *et al.*, 2000), patient safety has been acknowledged as a critical public health concern, acquire attention from the HCPs, institutions, agencies and public. The WHO recognizes the significance of patient safety and has made it a priority through its Patient Safety Programme. One of the key objectives of this program is to promote global learning by encouraging better reporting of patient safety incidents (Larizgoitia *et al.*, 2013). Several notable advancements have been made in this field, including the development of the WHO's Draft Guidelines for Adverse Event Reporting and Learning Systems (WHO, 2005), the establishment of the Conceptual Framework for the International Classification for Patient Safety (WHO, 2010) and the publication on the role of pharmacovigilance in reporting and learning systems for medication errors: centres (WHO, 2014). These initiatives aim to improve and uplift patient safety by facilitating the reporting and learning from adverse events on a global scale.

World Health Organisation launched "Medication without Harm" initiative on March 2017 during the Global Ministerial Summit on Patient Safety. This initiative marks the third Global Patient Safety Initiative by WHO and sets a target of reducing severe and avoidable harm caused by medication in all countries by 50% within the next five years (WHO, 2017). This initiative follows two previous WHO initiatives of "Clean Care is Safer Care" and "Safe Surgery Saves Lives," both launched in 2009. It aligns with the patient safety philosophy established by WHO, which recognizes that errors are bound to happen due to deficiencies in healthcare systems. Therefore, the main goal of this initiative is to decrease the occurrence and consequences of

medication errors by improving medication systems and practices. Insights from high-risk industries and collaboration with healthcare safety experts have shown that medication errors are primarily a result of flawed systems and processes, rather than negligence. By addressing deficiencies in service delivery and developing more efficient healthcare systems, the objective of this initiative is to enhance patient safety and minimize harm caused by unsafe practices and errors in medication (Larizgoitia *et al.*, 2013; WHO, 2016, 2017).

The Global Patient Safety Challenge on Medication Safety provides a comprehensive framework and clear objectives to improve medication safety worldwide (WHO, 2017). The objective of the Global Patient Safety Action Plan 2021 - 2030 is towards elimination of avoidable harm in health care with the vision of "a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere" (WHO, 2021). By addressing various aspects, such as surveillance, practices, systems, stakeholder engagement, and patient empowerment, the challenge aims to create a safer and more effective medication environment for all. The challenge aims to assess the extent and nature of preventable harm and strengthen monitoring systems to for medication-related harm surveillance. It also seeks to create an action framework that can be customized to enhance practices related to medication processes, benefiting patients, healthcare professionals, and stakeholders. In addition, the challenge aims to support the establishment of better systems for medication safety, ultimately reducing MEs. Furthermore, it emphasizes the engagement of key stakeholders to raise awareness about medication safety and actively promoting the initiatives to improve it. Lastly, it aims to empower participation of patients, their families, and caregivers in treatment or care decisions for medication safety.

2.2 Malaysia Patient Safety Goal: Medication Safety

The patient safety movement reached a significant milestone following the publication of the Institute of Medicine's report titled "To Err is Human" (Kohn *et al.*, 2000). Since then, ensuring patient safety has become a top priority in healthcare. In Malaysia, for instance, the Ministry of Health (MOH) established the Patient Safety Council of Malaysia in January 2003 with the aim of providing safe healthcare services to the population (MOH, 2013; Ismail and Khalid, 2022)

To further enhance patient safety, MOH introduced the Malaysia Patient Safety Goals in June 2013, which outlined 13 critical areas in patient safety, accompanied by specific goals and targets. Subsequently, numerous programs and initiatives have been implemented at both national and state levels to raise awareness among HCPs about the importance of patient safety (MOH, 2013).

There has been a rise in patient safety incidents, including MEs, transfusion errors, and patient falls since 2014 (MOH, 2021). A local study revealed that around 20 cases of MEs occurred daily in a teaching hospital's geriatric outpatient pharmacy in Malaysia (Abdullah *et al.*, 2004). This upward trend in medical mishaps is worrisome as it suggests that healthcare facilities may not be providing a safe environment for patients and imposing financial burdens on both patients and the ministry. In 2021, the introduction of the Malaysian Patient Safety Goal (MPSG) 2.0 marked the integration of the WHO Global Patient Safety Challenges, which encompassed areas such as hand hygiene compliance, surgical safety, and the prevention of MEs (MOH, 2021). This integration followed the launch of the Global Patient Safety Action Plan 2021-2030 by Dr. Tedros Adhanom Ghebreyesus (WHO, 2021). The MPSG 2.0 combines both global and national objectives, allowing Malaysia to benchmark itself against other countries while addressing critical patient

safety issues specific to Malaysia. The MPSG 2.0 includes a total of seven goals and nine Key Performance Indicators (KPIs) for hospitals, and four goals and four KPIs for clinics. One of the key goals included is "Medication safety: Medication without harm" (MOH, 2021).

2.3 Role of Healthcare Providers in Reporting Medication errors

Encouraging HCPs to report MEs is crucial for patient safety improvement. It is essential to create an environment that promotes open communication, non-punitive reporting systems, and supportive management behaviour. By addressing these barriers and fostering a safety culture of reporting and learning from errors, healthcare organizations can gain valuable insights into systemic issues, implement preventive measures, and ultimately enhance patient safety outcomes. Recurrent near misses ME can have negative consequences, demanding accurate detection and better medication safety management. Healthcare providers must detect errors that occur regularly and learn how to report patient safety incidents (Oyebode, 2013). MEs are formally under reported (Chiang et al., 2010) which can be attributed to various factors, such as individual fear of criticism and punishment, concerns about legal consequences, organizational barriers like a blame culture, user-unfriendly reporting systems, and discouraging management behaviour. Previous studies found that the low reporting of MEs can be linked to individual concerns about facing criticism (Yung *et al.,* 2016) and punishment (Gök & Sarı, 2017). The legal implications associated with reporting errors (Lee, 2017) also contribute to underreporting. Furthermore, organizational factors such as blame culture within the workplace, an unfriendly reporting system, and management practices that discourage feedback (Vrbnjak *et al.,* 2016) act as barriers to reporting MEs. In other study, despite MEs occurring in 63.6% of

participants, only 28.3% of those errors were reported (Kim *et al.*, 2011). Local study also found out that the HCPs voluntarily report the MEs if they are familiar with the MERS (Samsiah *et al.*, 2016a). In a different study, the majority of the reports were done by pharmacists, suggesting a probable under-reporting that could impact the accurate incident rate (Thomas *et al.*, 2021). Previous study also highlighted the issue of reporting barriers in MEs, including the lack of a safety culture, poor teamwork, fear of reporting incidents, and unfamiliarity with the reporting procedures (Faisal and Handayani, 2021).

2.4 Prevalence of actual medication error

Globally, in South Korea, MEs incident is the second most common incidents after falls, constituted approximately 27.8% to 36.6% of all reported patient safety incidents between 2016 and 2019 (Ministry of Health & Welfare, K. I. f. H. A., 2020). A study on voluntary MEs reporting by nurses in Korea found that 80% of the reported errors were near miss MEs, while 20% were actual MEs (Yoon and Sohng, 2021). Similar ratios were reported in England and Wales between 2007 and 2016 (Härkänen *et al.*, 2019). However, previous data from a Finnish university hospital's website showed that 70% of the medication errors were actual MEs and 30% were near miss MEs (Härkänen *et al.*, 2015). A study conducted on MEs in children admitted to hospitals and reported to the Danish Patient Safety Database (DPSD) over a period of 5 years (2010-2014) showed that the majority of MEs resulted in no harm (74.9%), while a smaller percentage caused mild (11.7%), moderate (10.5%), or severe harm (1.3%). However, none of the reported errors were fatal. (Rishoej *et al.*, 2017). In Egypt, a study revealed that Category A potential errors accounted for 25% of all reports, while 11% of the reported medication errors were prevented (Category

B). Medication errors that did not result in harm (Categories C and D) constituted 24% and 27% of the reports, respectively while medication errors that led to patient harm (Categories E-I) comprised 13% of the reports, collectively Category C to I representing 64% of all actual MEs (Shehata *et al.*, 2016)

In Malaysia, based on retrospective national ME reports study, the percentage of ME reports reviewed ranged from 15.1% to 33.3% between 2009 and 2012 from a total 14973 ME reports and was increasing by year. Of these reports, 86.3% were classified as near miss MEs, while 13.7% were classified as actual MEs (Samsiah *et al.*, 2016b). While in an emergency setting study conducted in Malaysia, the prevalence of medication errors was found to be 30.5% (Shitu *et al.*, 2020).

2.5 Implications of actual medication error

MEs pose a significant risk to patient safety and are a global concern. They are recognized as a major threat to patient well-being, leading to increased morbidity and mortality (Salmasi *et al.*, 2015; Samsiah *et al.*, 2016b; WHO, 2017). Unsafe medication practices and MEs contribute significantly to preventable harm within healthcare systems worldwide, impacting patient outcomes and potentially resulting in hospitalization and increased healthcare costs (Samsiah *et al.*, 2016b; WHO, 2016, 2017). The economic burden of MEs is estimated to be around USD 42 billion annually (WHO, 2017), making it a substantial financial concern. MEs account for a considerable proportion of preventable medication-related harm, and in the United States, they are identified as the eighth leading cause of death, surpassing car accidents, breast cancer, and AIDS, with over 98,000 deaths reported annually (Kohn *et al.*, 2000). Medication-related admissions also contribute to a notable portion of overall hospital admissions, ranging from 3% to 8% (Roughhead L *et al.*, 2013).

The impact of MEs is more pronounced in low-income countries, where patients experience twofold the number of disability-adjusted life years (DALYs) lost compared to high-income countries due to medication-related harm (WHO, 2017). MEs occur when weaknesses in human factors and medication systems. These include fatigue, poor work and environmental conditions, or insufficient staffs, affect the stages of the medication process, including prescribing, transcribing, dispensing, administration, and monitoring. These errors can result in medication-related harm, severe harm, disability, or death (WHO, 2017) . However, study on the prevalence of MEs is challenging due to the multiple definitions and classification systems in use as being raised in Middle East countries. The choice of denominator and variations in healthcare system organization and the availability and utilization of event reporting mechanisms further complicate the assessment of MEs rates (Alsulami *et al.*, 2013). Addressing MEs requires comprehensive efforts to enhance medication systems, improve human factors, and implement effective event reporting and learning mechanisms. Collaborative initiatives and standardized approaches to reporting and classifying MEs can facilitate better understanding, prevention, and mitigation of medication-related harm globally (WHO, 2017).

2.6 Factors associated with actual medication error

To prevent future MEs and promote medication safety, it is crucial to analyse data from ME reporting systems and identify the factors that contribute to their occurrence (Airaksinen *et al.*, 2007). Several factors have been identified as influencing the likelihood of MEs, including patient-to-staff ratio, heavy workload, and fatigue resulting from increased workload (Zarea *et al.*, 2018; Yoon and Sohng, 2021). Another study highlighted factors such as personal negligence, workload, and

the presence of new healthcare workers as potential influences on the risk of MEs (Tang *et al.*, 2007). A systematic review of MEs in Southeast Asian countries revealed that factors such as inadequate staffing leading to heavy workload for nurses, distractions among doctors and nurses, and misinterpretation of prescriptions or medication charts were identified as factors contributing to medication errors (Salmasi *et al.*, 2015). Another systematic review conducted in Middle East also emphasized the utilization of synthesis based on Reason's model, which identified the prevailing factors as active failures, primarily slips (10 studies), lapses (9 studies), and mistakes (12 studies). Error-provoking conditions, specifically lack of knowledge (13 studies) and inadequate staffing levels (13 studies), were highlighted, along with latent conditions, predominantly heavy workload (9 studies) (Thomas *et al.*, 2019). In the context of paediatric hospitals, a study found that inadequate knowledge or a lack of practical experience, failure to adhere to regulations or procedures, and frequent work interruptions contributed to MEs (Manias *et al.*, 2019). Furthermore, a review indicated that environmental factors like high workload and busy work environments had a more significant impact on MEs compared to personal factors such as attitude and clinical experience (Parry *et al.*, 2015).

In one study that analysed 38063 ME reports, various contributing factors were identified, with the most common being distractions, followed by increased workload, inexperienced staff, and insufficient staff (Santell *et al.*, 2003). Study in Malaysia revealed that peak hours, inexperienced personnel, failure to adhere to work procedures, and look-alike and sound-alike (LASA) medications were cited as primary contributing factors to MEs (Samsiah *et al.*, 2016b). Similarly, other study found that the most frequently selected causes of MEs included lack of experience and knowledge, environmental factors such as distractions and heavy workload,

inadequate drug information sources, and incomplete prescribing orders (Shehata *et al.*, 2016).

WHO in Technical Series on Safer Primary Care on medication errors summarized the factors that associated with MEs, which include factors related with HCPs and patients, work environment, medicines, tasks, computerized information systems and primary-secondary care interface (WHO, 2016). Understanding these contributing factors is essential for developing targeted interventions and strategies to reduce the occurrence of MEs. By addressing issues such as staffing levels, workload management, adherence to procedures, and providing adequate training and support, healthcare organizations can create a safer environment and minimize the risk of MEs.

2.7 Conceptual framework

The factors associated with actual medication error can be conceptualized by using the Figure 2.1 as below. Five domains of factors associated with medication error, which include staff factor, medication related factor, work and environment factor, task and technology factor and others factor. All of these factors were associated with the medication processes that lead to medication error. However, in this study, others factor was excluded.

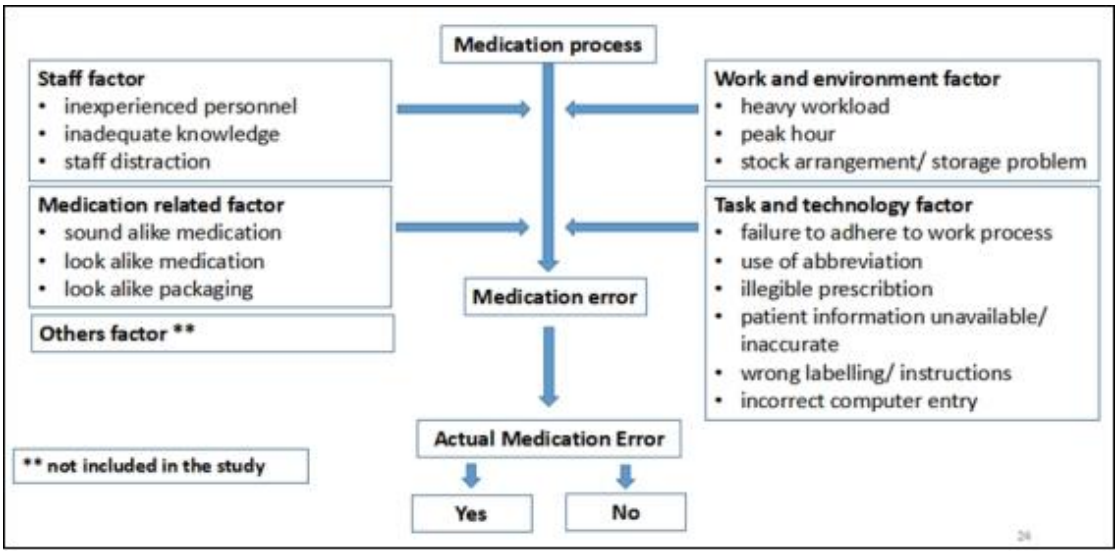


Figure 2.1 Conceptual framework for factors associated with actual medication error occurrence.

CHAPTER 3

METHODOLOGY

3.1 Study design

This is a retrospective secondary record review study based on data of ME reports submitted via online MERS from January 2019 to December 2022 (https://mers.pharmacy.gov.my/).

3.2 Study area, time and duration

3.2.1 Study area

The study area was in Kelantan, the north-eastern state of Peninsular Malaysia which consisted of ten districts by district office of Ministry of Health (Kota Bharu, Pasir Mas, Tumpat, Bachok, Pasir Puteh, Jeli, Tanah Merah, Machang, Kuala Krai and Gua Musang) (as shown in Figure 3.1).

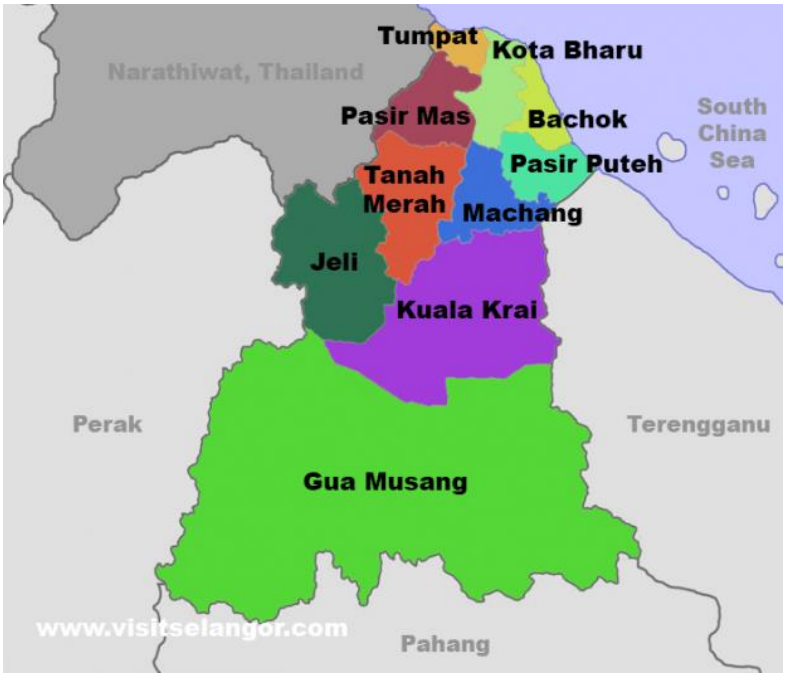


Figure 3.1 District map of the study area under Kelantan State Health of Department (https://www.visitselangor.com/information/malaysia-maps/map-of-kelantan-state/, accessed on 16/05/2023).

3.2.2 Study time and duration

This study was conducted in 12 months duration, from October 2022 until October 2023 and data collection period were after MREC and JEPeM ethical approval, which were from March 2023 to May 2023 using retrospective secondary data of ME reports from 2019 to 2022 from online MERS database.

3.3 Study population

All Kelantan ME reports submitted via online MERS and being endorsed as ME and fulfilled the study criteria from January 2019 to December 2022.

3.4 Reference population

All ME incidents that occurred in healthcare facilities in Kelantan from January 2019 to December 2022.

3.5 Source population

All ME incidents that occurred in healthcare facilities in Kelantan and reported through online MERS from January 2019 to December 2022.

3.6 Sampling frame

All ME incidents that occurred in healthcare facilities in Kelantan and reported through online MERS, and being endorsed in online MERS from January 2019 to December 2022.