DESIGN AND EVALUATION OF MEDICATION ERROR REPORTING USING APPLICATION (MERA) AMONG HEALTHCARE PROFESSIONALS IN PERAK: A MIXED-METHOD APPROACH

DORIS A/P GEORGE VISUVASAM

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by

DORIS A/P GEORGE VISUVASAM

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LIST OF ABBREVIATIONS

AIMS	Australian Incident Management System
ASHP	American Society of Health-System Pharmacists
App	Application
CI	Confidence interval
CMIRPS	Canadian Medication Incident Reporting and Prevention System
DATIX	Integrated risk management information system
HaiPro	Medication Error Reporting, Reporting System for Safety Incidents in Health Care Organizations
HCP	Healthcare professional
IOM	Institute of Medicine
IQR	Interquartile Range
ME	Medication Error
MERA	Medication Error Reporting Application
MERS	Medication Error Reporting System
MOH	Ministry of Health
NPRS	National Patient Safety Incidents Reporting System
NRLS	National Reporting and Learning System
NR	Not Reported
NYOPTS	New York Patient Occurrence Reporting and Tracking System
SD	Standard deviation
SUS	System Usability Scale
UK	United Kingdom
QR	Quick response

LIST OF APPENDICES

REKABENTUK DAN PENILAIAN PELAPORAN KESALAHAN PENGUBATAN MELALUI APLIKASI TELEFON (MERA) BAGI GOLONGAN PROFESSIONAL KESIHATAN DI PERAK: PENDEKATAN KAEDAH GABUNGAN

ABSTRAK

Kesalahan pengubatan memberikan impak ketara dari segi kewangan, klinikal dan emosi kepada pesakit. Pelaporan kesalahan perubatan merupakan komponen asas bagi pembelajaran dan penambaikan untuk mengelakkan kesilapan pengubatan berlaku di masa hadapan. Di Malaysia, kadar ketidak-laporan adalah tinggi dan cenderung dilaporkan oleh pegawai farmasi di hospital. Tujuan kajian ini adalah untuk merekabentuk dan menguji aplikasi talipon dan sebagai sistem pelaporan komplemen kepada sistem sedia ada. Kajian ini dijalankan dalam tiga fasa. Fasa pertama dijalankan untuk mengenalpasti kebolehterimaan dan feasibiliti penggunaan aplikasi talipon untuk melapor kesalahan melalui kajian soal selidik eletronik dikalangan doktor dan pegawai farmasi di Perak. Fasa kedua adalah rekabentuk aplikasi and ujian aplikasi menggunakan kaedah gabungan. Ujian '*usability*' dijalankan melalui tiga kaedah: perlaksanaan tugasan, soal selidik dan diskusi kumpulan berfokus *(FGD*). Fasa terakhir adalah ujian efikasi aplikasi yang dijalankan di satu hospital kerajaan di Perak menggunakan rekabentuk kajian *pre - post*. Di fasa pertama, didapati 84% (283/334) doktor dan pegawai farmasi di Perak menggunakan aplikasi kesihatan untuk tugas harian dan 79% (264/334) mempunyai kadar sambungan internet yang cepat, baik atau serdahana Majoriti, 87% (289/334) melaporkan akan menggunakan aplikasi pelaporan kesalahan pengubatan sekiranya sedia ada. Di fasa dua, tiga ujian "*usability*' melibatkan 45 penguji telah dijalankan,

Sebanyak 135 laporan lengkap telah berjaya dihantar dengan peratus laporan yang betul adalah 79%. Jumlah markah median "*System Usability Scale*" meningkat secara signifikan daripada 67% di sesi pertama ke 88% di sesi ketiga, $p < 0.001$. Walaubagaimanpun, median masa laporan melalui aplikasi adalah seragam dengan masa pelaporan selama 6.0 minit. Pada fasa tiga, selepas pelancaran aplikasi, terdapat peningkatan significant dari segi peratusan laporan pada hari kejadian (48% berbanding 0.3%, $p<0.001$), laporan kesalahan yang sampai pesakit (8.0% vs 1.2%, $p<0.001$) dan pelapor dari kakitangan bukan farmasi (4.2% berbanding 0.6%, $p<0.001$). Laporan mingguan sebelum dan selepas aplikasi tidak meningkat secara signifikan. Oleh yang demikian, aplikasi baru yang telah diuji untuk pelaporan kesalahan pengubatan, boleh diterima, mesra pengguna, meninkatak laporan pada hari kejadian, laporan kesalah sampai pesakit dan boleh melibatkan pelapor selain kakitangan bukan farmasi di Perak.

DESIGN AND EVALUATION OF MEDICATION ERROR REPORTING USING APPLICATION (MERA) AMONG HEALTHCARE PROFESSIONALS IN PERAK: A MIXED-METHOD APPROACH

ABSTRACT

Medication error (ME) causes substantial monetary, clinical and emotional impact on patients. Reporting ME is the corner stone that promotes learning and safety improvements to prevent future MEs. However, in Malaysia underreporting of ME is high and skewed by pharmacists as reporters at hospitals settings. The aim of this research is to design and test a mobile phone application to complement existing reporting system. This research was conducted in three phases. First phase was conducted to determine acceptability and feasibility of mobile application to report ME using electronic questionnaire among doctors and pharmacists in Perak. Second phase of the study, was to design and test the developed application using mixed method analysis. Usability testing was used incorporating three methods: task performances, questionnaire and focus group discussions (FGD). Final phase was efficacy testing of application (MERA) was conducted in a single tertiary public-funded hospital using pre-post design to compare weekly report, reporting time, types of reports and reporters. In phase one, 84%, (283/334) of doctors and pharmacist in Perak used medical application for work and 79% (26/334) have fast to average internet connections at work. Majority, 87% (289/334), would report ME using an application if one was made available. In phase two, three usability testings involving 45 testers. Total 135 reports successfully reported with 79% of reports were correct. Median total SUS scored significantly increased in first session 67% to 88%, $p<0.001$ in third session. However, median time to submit

report was constant within the sessions with median reporting time of 6.0 minutes. In phase three, after introduction of the application; there was significant changes in reports reported within error occurrence day (48% vs 0.3%, $p<0.001$), errors that reached patients (8.0% vs 1.2%, $p<0.001$), and non-pharmacy staff reporters (4.2% vs 0.6%, $p<0.001$). Weekly reports before and after introduction was not significantly different. Therefore, this novel application to report ME is accepted, user friendly, increased reports within error occurrence day, increased reports that reached patients and was able to engage non-pharmacy staff in reporting in Perak.

CHAPTER 1: INTRODUCTION

1.1 MEDICATION ERROR DEFINITIONS

Medications or drugs are given to patients in healthcare settings to alleviate symptoms, correct imbalances, treat, prevent and occasionally diagnose diseases. (Shoemaker *et al*., 2008) Medication error (ME) is an error that has occurred or prevented error or error that may occur in the future which may or may not cause harm to patients due to non-performance in the treatment process. (Aronson, 2009). Medication errors are classified further based on (i) medication error performance, (i) point of medication use process that medication errors occurred, and (iii) outcome or harm caused by the ME. (Grober *et al*., 2005)

Medication error are classified as commission and omission errors based on medication errors performance. (Perren *et al.*, 2009) Commission errors are errors that occur due to cause of flawed medication processes performance. Example of commission errors are wrong dose prescribed, administering wrong medication, or dispensing medications to the wrong patients. Omission errors are errors that occur due to failure to perform a medication use stages such as not prescribing a need medication or missing out needed instructions and not administrating a medication as per scheduled time.

Treatment process or medication use process are categorised as point of prescribing medication or point of transcribing prescriptions or orders, (Velo *et al.* 2009) point of dispensing medications ordered (Aldhwaihi *et al.*, 2016) and point of administration of medications ordered or prescribed (Keers *et al.*, 2013). If a medication error occurred at the point of prescribing, the error is classified as

prescribing error and so forth. More than one medication use processes can be involved in one medication error. If more than one medication use processes were involved in the medication error; the initial medication process that the medication error was initiated is considered as the point of medication error and therefore classified accordingly.

Medication errors are also categorised based of the outcome of error (European Medicines Agency, 2015). Actual medication errors are errors that reached patients either causing harm or no harm. Near misses are medication errors that did not reach patient. These are errors that were intercepted before reaching patients during screening of prescriptions, double checking of medication prepared or other safety measures in place at the organisations. Potential medication errorss are when no errors occur but are risky situations or conditions that is potential to cause errors in the future if no remedial action is taken. Medication errors medication errors that caused harm are commonly classified based on the National Coordinating Council for Medication Error Reporting and Prevention (National Coordinating Council for Medication Error Reporting and Prevention, 2001). Harm are classified as patients experiencing no harm and harm. In the category of harm to patients are, harm: no harm, requiring monitoring and or intervention(s) to rule out harm. In the category of harm to patients, harm is classified as non-permanent harm, initial or prolonged hospitalisation, permanent harm, require intervention necessary to sustain life and lastly error that resulted in the patient's death.

1.2 FREQUENCY OF MEDICATION ERRORS

1.2.1 MEDICATION ERRORS AT PRESCRIBING PROCESS

Medication error in the prescribing process, among adult patients at hospital in-patient settings was reported as 6 – 15 errors for every 100 medications prescribed. (Thirumagal *et al.*, 2017), (Ashcroft *et al.*, 2015), (Seden *et al.*, 2013), (Franklin *et al.*, 2011)

Prescribing in specific disciplines such oncology setting, prescribing error rate was 15.1 errors for every 100 prescriptions ordered or 1.6 errors for every 100 prescriptions ordered. (Ferracini *et al.*, 2018) In a renal center, prescribing error rate was found to be 75 errors for every 100 prescriptions prescribed. (Babatunde *et al.*, 2016)

In a Malaysian paediatric in-patient setting 9.2 errors for every 100 medications prescribed was reported. (Khoo *et al.*, 2017). In this paper the prescribing error rate was higher in the general wards with rate of 10.6 errors per 100 medication ordered compared to intensive care units, with rates 8.3 and 7.3 errors per 100 medication ordered in paediatric and neonatal intensive care unit respectively. In Hong Kong an error rate among hospitalised paediatric patients were 3 errors for every patient admitted to the intensive care. On average patients had 6.8 errors per patient. (Ewig *et al.*, 2017)

1.2.2 MEDICATION ERROR AT ADMINISTRATION PROCESS

In 2 systematic reviews, medication administration median error rate was reported as 10 errors (Berdot *et al.*, 2013) and 8 errors (Keers *et al.*, 2013) for every

100 opportunities of error. This rate was not including errors of administrating drug at the appointed time plus minus 60 minutes. If such errors was included, median error rate was 25 errors (Berdot *et al.*, 2013) and 20 errors (Keers *et al.*, 2013) for every 100 opportunities of error. Total doses administered and adding in doses that were omitted is how the opportunities of error are derived.

In a study published after the 2 systematic reviews above, in Vietnam reported higher administration error rate of 0.4 for every 100 doses ordered (including doses omitted). Prospective direct observation method was used to collect data of errors in 2 public funded hospitals in this study. (Nguyen *et al.*, 2015)

1.2.3 MEDICATION ERROR AT DISPENSING PROCESS

The occurrence of dispensing errors is obtained through observation as in administration errors. In such study involving 50 community pharmacies in US revealed 1.57 dispensing errors for every 100 prescriptions received. (Flynn *et al.*, 2012) In a well-controlled clinical trial, ARISTOTLE, dispensing error rate was 1.04 for every 100 study participants in the apixaban group and 0.8 for every 100 study participants in the warfarin group. (Alexander *et al.*, 2013) It was also reported that the incorrect pill boxes were supplied to 7% of the apixaban study patients and 1.2% of the warfarin study patients at the point of the research.

A prospective study was conducted for 10 months to evaluated dispensing error and it was found that there were 4.8 dispensing errors for every 100 in-patient prescriptions ordered. (Sekhar *et al.*, 2011) In this study the errors were reported by nurses from a large academic hospital of which wrong medication dispensed

errors were the highest. In southern Thailand, a study was conducted during the implementation of modified unit dose delivery system to daily dose delivery system. In the daily dose delivery system medication were prepared for 24 hours however were packed together in one package to reduce the workload of pharmacy, Dispensing error rate was compared and reported as 5.2 errors for every 100 doses and 7 errors for every 100 doses in the unit dose delivery method and daily dose delivery method respectively. (Leelasiriwilas *et al*., 2005) Additional to these data, in a systematic review, the dispensing error rate in hospital settings ranged from as low as 0.015% to as high as 33.5%. This vast difference was reported due to dispensing system used, research methods employed and classification of errors. (Aldhwaihi *et al.*, 2016) This review also included studies employing retrospective review of reporting data of dispensing error which is an inaccurate method to obtain rate of errors.

1.2.4 MEDICATION ERRORS AT TRANSITION OF CARE

A recent systematic review of medication error among patients transitioning from hospital discharge to community setting was conducted. (Alqenae *et al*., 2019) In this review of 14 studies, medication error rate among adult and elderly patients was 33% (IQR 19-52).

In another review, among patients discharged from the hospitals, the rate of medication error was 2 to 8.7 of every 10 patients discharged. This review involved more than 6000 patients across various international hospitals from 15 articles reviewed. Medication error per patients was 1.2 to 5.3 number of medication errors increased with number of medication that the patients was prescribed

with.(Michaelsen *et al.*, 2015) Medication omitted from the discharge medication list topped the list of type of medication errors.

In Australian settings, it was estimated that at hospital discharge medication error occurred as high as 2 errors per patient in the medication documentation in the discharge summaries. (Roughead, *et al.*, 2016)

1.3 IMPACT OF MEDICATION ERRORS TO PATIENTS

Medication errors can cause minor harm or even serious harm such as death to patients. Medication errors can also cause economic impact to healthcare providers as well as to patients. Despite these burdens, patients and care-givers can succumb to emotional stress due to preventable medication errors when seeking medical treatment in health care facilities.

1.3.1 CLINICAL IMPACTS OF MEDICATION ERRORS

A prospective study among 200 adult patients with solitary kidney transplant thatwere followed up for a mean 2.5 ± SD 0.7 years was conducted to determine clinical implication of medication errors medication errors to patients in South Carolina, US. (Taber *et al.*, 2014) A total of 233 medication error was documented by either physicians, pharmacists or nurses. Among these patients, 68% had at least one patient related medication errors medication errors with 68% were due to patient factors, 17% were due to pharmacy factor and the rest were due to prescribing process in this study. Patients with medication error were classified further as having clinically significant medication error. Patients with clinically

significant medication errors medication error had a higher post-transplant readmission 1.0 (0.0–5.0) compared the patients that had no-clinically significant medication error 0.0 (0.0–2.0), *P*=0.06. Acute rejection at the end of follow-up period was significantly higher among patients that had clinically significant medication error 26 verses 9, *P* =0.01 compared to the patients that had non - clinically significant medication error.

In a retrospective study conducted in University of Chicago Medicine, USA by reviewing ME reporting forms to identify patient that experienced medication error. (McCarthy *et al.*, 2017) Matching control group were patients that did not experience medication error throughout stay or admitted due to medication error during the study period (April 2014 and May 2015) or had no reports of medication error. A total 242 medication error patient with medication error reports and 3, 279 control patients without medication error reports were included in this study. Hospital stay was significantly longer among the patients identified with medication errors compared to patients with no medication errors with median hospital stay of 7 days (IQR 5 – 12) and 5 days (IQR 4 - 7), *P*=0.002 respectively.

Similarly, patient that had medication errors and patient that had no medication errors significant differed in mean hospital stay in a study conducted by Choi *et al*., 2016. Patients with medication errors had doubled hospital stay with mean days of 13.1 ± standard deviation (SD) of 14.7 compared to patients with no medication errors who had mean hospital days of 5.0 days with SD of 6.3, p = 0.003. This study was conducted among hospitalised patients at two hospitals (community and academic hospitals) located in USA from the year 2005 to. (Choi *et al.*, 2016) Data on medication error were extracted from the hospitals' voluntary reporting systems which were reported either by physicians, pharmacists or nurses.

Medications of geriatric patients, aged more than 65 years, that was discharged from a hospital was assessed by a geriatric nurse within 72 hours post discharge (Coleman *et al.*, 2005). Geriatric nurses documented discrepancies in patent's discharge and compared with patient's gold medication list. Unintended discrepancies were classified as medication error. Among patients that experienced ME post discharge, 14.3% had readmission at 30 days which was significantly higher compared to only 6.1% among those who did not experience medication error post discharge ($p = 0.04$).

A recent study was published which was conducted among 24 hospitals in Southern and Central region of USA to determine impact of medication error on patients admitted from 2009 to 2012. In this study, 20 random patients' charts were collected each month from each of the 24 hospitals during the study period as stated above and finally 21, 007 patient admission was included in the study. Patients that experienced no harm had the least mean length of hospital stay of 3.6 (SD = 2.7) compared to patients that experienced temporary harm [mean length of hospital stay, 5.5 days (SD 4.2)] and patients that experienced harm [mean length of hospital stay, 8.0 days (SD 6.8)], $p < 0.001$. Odds of readmission rate at 30 days among patients that experienced temporary harm was significantly greater than patients that experienced no harm with an odd ratio (OR) of 1.2 (95% CI 1.05 to 1.37), $p = 0.006$.

Similarly, odd of readmission at 30 days among patients that experienced harm was greater than patients that experienced no harm, OR of 2.88 (95% CI 2.56 to 3.24), $p < 0.001$. Mortality rate among patients that experienced no harm was 0.9%, patients that experienced temporary harm was 1.8% and patients that experienced harm was 3.2%. (Adler *et al.*, 2018)

1.3.2 ECONOMIC IMPACTS OF MEDICATION ERRORS

The retrospective study by Choi *et al.* (2016), of 57, 554 patients admitted to two New Jersey hospitals for a two-year period revealed additional cost due to medication error were USD 8,898 and estimated a mean difference in cost for patients with medication error of USD 8,439.

A study was conducted in an Iranian university affiliated hospital with 20 bedded medical wards among 100 patients, to determine medication error occurrence among hospitalised patients as detected by clinical pharmacist. (Boostani *et al.*, 2019) It was found that patients would have to pay additional USD 7.46 per patient of total medication cost if medication error was not timely intervened by clinical pharmacists.

A retrospective review of in-patient charts from 24 hospitals in USA from 2009 to 2012 was conducted to identify patients that experienced harm. Patients that experienced temporary harm had an additional mean cost of US 2, 187 compared to patients experienced no harm from medication errors. While patients that experienced harm had an additional mean cost of US 4, 617 compared to patients that experienced harm and no harm. (Adler *et al.*, 2018)

In another study conducted in across USA, clinical pharmacists collected data of medication error for a period of 14 days. (Samp *et al.*, 2014). The clinical practice varied and a total of 779 medication error was documented by the 62 participating clinical pharmacists in the study. The cost of a medication error was estimated was USD 89.35.

In another study, the Nationwide Emergency Department Sample was used

to estimate the cost of a medication error in the emergency department at a university affiliated hospital in Kentucky. This study reported an additional USD 268.00 of total cost of emergency department and in-patient services were due to medication error. This study involved 59, 633 patients presented with medication error and 150 000 patients without medication error as control group. (Bowman, 2010)

1.3.3 EMOTIONAL IMPACTS OF MEDICATION ERRORS

It was reported that medication error cause emotional stress to healthcare professionals that are involved in medication error. Doctors, nurses and pharmacists involved in ME may require some sort of support by management to deal with the stress and cope with their daily activities. (Tipton *et al*., 2003). Many at times. this support is not available to healthcare professionals. Patients that experience medication error and has been informed of the error would experience anger, frustration, dissatisfaction, and may instill lack of confidence towards their healthcare providers.

1.4 MEDICATION ERROR REPORTING SYSTEM

1.4.1 HISTORY OF MEDICATION REPORTING SYSTEM

In the past two decades, research have been focused on gathering information on errors in health care facilities with the intention to improve healthcare processes and minimize errors. Incident Reporting System is a structured report of unexpected and preventable events that could cause harm or injury to patients.(El-Dawlatly, 2010) Incident reporting is a general term used for all patient

safety event reporting such medication error, patient fall, blood transfusion error, equipment failure, etc.

Medication error reporting system is essential in providing insight of possible medication error and medication error that occurs in a healthcare setting. Medication error reporting system consist of (i) mode of medication error reporting. (ii) analysis of medication error medication error reports that are reported via the medication error reporting system and (iii) feedbacks or learning aspects of reporting system.

The Institute of Medicine (IOM) recommends that a nationwide reporting should be mandatory for healthcare incidence that resulted in death or serious harm. IOM also recommends voluntary reporting of healthcare incidence. Due to this, healthcare incident reporting system boomed worldwide. Medication error reporting system was first developed in USA in 1975 and named MERP (Medication Error Reporting Program). Subsequently, many countries have developed medication error reporting system either national or local institutional reporting system. Medication error reporting system is developed either as stand-alone systems or incorporated in the incident reporting system.

National healthcare reporting that are well established are National Reporting and Learning System (NRLS) in United Kingdom (UK), Canadian Medication Incident Reporting and Prevention System (CMIRPS) in Canada, Australian Incident Management System in Australia, Integrated risk management information system (DATIX), Scotland, Taiwan Patient-Safety Reporting in Taiwan, and National Patient Safety Incidents Reporting System (NPRS) in China.

In certain countries incident specific reporting such medication error

reporting has been established such as MEDMARX in United Stated of America, Central Medication Incident Registration (CMIR) in The Netherlands and Medication Error Reporting, Reporting System for Safety Incidents in Health Care Organizations (HaiPro) in Finland, National Adverse Event Reporting and Learning System in Japan, MERS in Malaysia. Summary of the medication error system in the country is listed in *Table 1.1* (Cheng *et al.*, 2011), (Holmström *et al.*, 2012), (Taneda, 2019).

Table 1.1 History of National Medication Reporting System in the World

Country	Name of Reporting System	Establishment	Event Reporting	Features
United State of America	MERP	1975	Medication error	V, N, NP
	MedMARx	1998	Medication error and adverse drug reaction	V. N, C
Australia	AIMS	1998	Patient safety incidence	Partial M, C
Canada	CMIRPS	2002	Medication error	V
United Kingdom	NRLS	2003	Patient safety incidence	M. NHS centers,
Taiwan	TRP	2003	Patient safety incidence	V, Province
Japan	-	2004	Patient safety incidence	M&V, N
The Netherlands	CMR	2006	Medication Error	V
Finland	HaiPro	2007	Patient safety incidence	V, N
Malaysia	MERS	2009	Medication Error	V, N, NP

V- voluntary, M-mandatory, N-national, NP-non-profit, C-commercial

1.4.2 MEDICATION REPORTING SYSTEM IN MALAYSIA

Medication error reporting in Malaysia is done via the Medication Error Reporting Form (BPF/104/ME/02) shown in *Appendix* A and was revised in 2019 as shown in *Appendix* B. This medication error reporting method was first established in 2009 by the Pharmaceutical Services Division with the guidance and cooperation of the Medication Safety Technical Advisory Committee. This reporting method is called the Medication Error Reporting System (MERS). This effort was thought to develop a nun-punitive culture and promote voluntary medication error reporting.

Currently, medication error reports are either filled in manually or done through a web- based form. The web-based form was fully operational in year 2012. Manually filled reports are keyed into the Medication Error Reporting System (MERS) by an appointed pharmacist in the hospital. All reports are verified by a verifier either at the hospital or state level. Complete and verified reports are then further approved and endorsed by MERS administrators. If a reporter chooses to report directly through the web-based form, the reporter is required to register as a user which includes providing information of place of practice, profession and an active email address. Medication error that can be reported include potential error, near miss and actual error. This system is a stand-alone system and only reports error related to medications. Adverse drug reaction incidences are reported to Malaysian Adverse Drug Reactions Advisory Committee using as different form. Adverse drug reporting is also coordinated by pharmacists in public-funded health care facilities. Other non- medication related incidences such blood transfusion incidences, patient falls, nosocomial

infection etc. are reported using the Incident Reporting form. Incident reporting are handled by designated nurses in the public funded healthcare facilities.

1.4.3 ISSUE OF UNDERREPORTING OF MEDICATION ERRORS

Several studies have identified that not all actual medication errors encountered are reported using the reporting system at the institutions. Methods used to identify underreporting were comparing reported incidence of medication errors with medication errors detection through reviewing patients' chart reviews or direct observation. Reviewing patients' charts are usually conducted retrospectively while direct observation is conducted prospectively.

1.4.4 FREQUENCY OF UNDERREPORTING OF MEDICATION ERRORS

In a recent study, incident reports from two major hospitals in Sydney were compared with reporting and with errors detected through reviewing medical charts and observation. Both hospitals' reporting system were electronic and reports can be made anonymously. Chart reviews were done by pharmacists through clinical audits to detect prescribing errors. Trained research nurses observed preparation and administration of medication by nurses to detect administration error. In this study, 12, 567 prescribing error were encountered and of which 539 were clinically important errors. However, only 15 prescribing errors were reported during the same period indicating underreporting of only 1.2 errors reported for every 1000 errors encountered. Administration errors encountered during observation were 10, 955 of which 209 were clinically important errors. None of the administration error were

reported. (Westbrook *et al.*, 2015)

In a large NHS hospital trust in England; patients' case notes were reviewed by five trained nurses and then subsequently three doctors reviewed all detected incidences to classify type and outcome of incidences. At the same time, incidences detected were compared with incident reports to determine percentages of the detected incidences that were actually reported. The study was conducted for 5 months period in 2004. A total of 1006 complete patients' case

reports were randomly reviewed. Among these patients; a total 24 unique medication related errors were detected: 19 through case notes review and 7 through error reporting. It can be concluded that less than 50% of medication error are reported although incidence of medication errors were as high as 2.4 per 100 admissions. (Sari *et al.*, 2007)

In another study conducted in a 12 bedded ICU in United Kingdom (UK), NHS Trust hospital, medication error detected by the unit pharmacist were recorded and severity were categorized for a period of four months in 2004. During the same period, only two medication errors (1 administration error and 1 prescribing error) were reported using the hospital reporting system. It was reported that about 50 non-reported medication errors of low to very low severity were recorded by the unit pharmacist. Therefore, this indicates that about only 4 of 100 medication errors detected in this ICU were reported. (Sanghera, *et al*., 2007)

A study was conducted in a psychiatric department from a large multi-discipline, academic hospitals to evaluate prevalence of medication error by reviewing charts. Total bed included in the study was 88. A total of 40 charts each year in 2005 and 2007 were randomly chosen. medication error detected through this

method was compared with medication error reports submitted during the same year. For every 1 error reported, 21 errors were detected through audit in 2005 and 24 errors in 2007. This translates to rate of reporting as only 4% of all error occurrences in these hospitals. (Jayaram *et al.*, 2011) Hence underreporting of medication error is high in this department accounting to 96%.

A prospective review of medication charts and direct observation of medication administration was conducted in five pediatric hospitals in UK. (Ghaleb *et al.*, 2010) Four teaching hospitals and one non-teaching hospital were purposively selected to represent the pediatric hospitals in UK and resulted in 11 wards included in the study. Data was collected by pharmacist during weekdays for two weeks. Rate of prescribing errors was 13.2 per 100 medications ordered. Rate of administration error observed was 19.1 per dose administered

(opportunities for error). During these periods ME reported were analyzed and it was found that only one out of 391 the prescribing errors detected were reported, hence underreporting was 99.7%. And none of the administration errors were reporting resulting in underreporting of 100%.

In a tertiary Malaysian public hospital, a study was conducted to determine prevalence was medication errors at discharge. The study was prompt as there was no data of medication error at discharge in Malaysian setting. The study protocol was approved as a quality improvement research. Discharge prescription at discharge from Monday to Thursday (4 days in a month) was collected and reviewed for 6 months. It was discovered proportion of patients receiving discharge prescriptions with at least one or more errors was 32%. (George *et al.*, 2019). Overall medications with any error was 7.9 per 100 medications prescribed. A total of 522 errors were detected among 987 discharge patients. All errors were detected by ward pharmacists

and each error was discussed with the attending physicians. During this study, none of the errors were reported to the ME reporting system either by the ward pharmacist or by the attending physicians recording underreporting as 100%.

1.4.5 BARRIERS TO REPORTING OF MEDICATION ERRORS

Reasons for underreporting of medication error has been studied using either quantitative or qualitative methods. Quantitative methods used either surveys or questionnaires method and qualitative method used either interviews or focus group discussions. A systematic review of literatures dated from 1980 to March 2014 was conducted and total of 110 literatures were included in the review (Archer *et al.*, 2017). The literature included studies from more than 20 countries involving more than 29 726 participants. Reasons for underreporting and number of times it was cited are listed in *Table 1.2.*

Table 1.2: Barriers to Reporting Medication Errors and Number of Times Cited in Literatures

Reasons	Number of Times Cited
Reporting system (including knowledge and skills)	194
Fear of the consequence of reporting	161
Characteristics of event	92
Characteristics if healthcare personnel	89
Working environment	80
Management factors	76
Team factors	33
Professional ethics	23

In this paper, the most common reason for not reporting a patient safety event was the reporting process and system for reporting. Reporting process that is lengthy and complex are frequently cited barriers for reporting. Besides laborious reporting process with busy and hectic working environments further prevents reporting medication error. (Samsiah *et al.*, 2016), (Kang *et al.*, 2017), (Alqubaisi *et al.*, 2016), (Sarvadikar *et al*., 2010)

Reporting system that lacks anonymity and or confidentiality is not preferred for reporting. Participants also felt that reporting process is not done because information required in the reporting process is not available. A focus reporting is preferred and would encourage reporting. Barriers on knowledge and skill such as lacking awareness of reporting system and training of reporting system also contributes to barriers pertaining to reporting process and system. Working environment that has limited access to reporting forms also contributes to barriers in reporting.

The other most commonly cited factors for not reporting an incident is fear and anxiety of the consequences of reporting. The most common anxiety associated with reporting are (i) ramification of reporting, (ii) issues related to litigation, (iii) blame, issue, (iv) discernment, (v) impact of interpersonal relationship among other healthcare professionals and lastly (vi) impact on damaging effect on profession. (Alqubaisi *et al.*, 2016), (Hartnell *et al.*, 2012) Other fears cited are requirement to be present in meeting or discussion pertaining to report.

Factors that discourage reporting can be classified as modifier factors and less-modifier factors. (Uribe *et al.*, 2002) Characteristics of patient safety event that discourages reporting are event that occurs frequently, no harm or less harm and unpreventable events. (Sarvadikar *et al.*2010). Detailed breakdown of barriers for underreporting are listed as modifier factor less modifier factors in the *Table 1.3* based on several literatures (Stewart *et al.*, 2018), (Archer *et al.*, 2017),

Table 1.3: Barriers to Reporting Medication Errors as Cited in Literatures

Barriers	Breakdown of Barriers
Modifiable Factors	
Reporting process and system (including knowledge and skills)	Takes time to report Complex Data not available for reporting Not anonymous Not confidential Not focus reporting Lack information on terms in reporting Lack knowledge on what to report Lack of training and exposure on reporting Lack awareness of reporting Inability to recognize error
Working environment	High workload Lack of access to reporting form
Management factors	Lack of feedback on reporting Non positive reporting culture Lack of improvement and learning components Poor management of reported data Poor response to reports.
Team factors	Negative impact on relationships with colleagues and superiors. Seniors not supporting reporting Uncomfortable reporting colleagues
Less Modifiable	
Characteristics of event	Frequent event No harm or minimal harm Unpreventable
Characteristics of healthcare personnel	Negative attitude or value on patient safety reporting Perception that reporting cause no improvement Forgot to report Exposure to events Length of time in service Previous reporting emotions and experiences
Professional ethics	Lack personal responsibility to report Concealment of error

Recently, a study was conducted in Malaysia among doctors, pharmacists, pharmacist assistants, nurses and medical officers to determine barriers in reporting medication error. The study was conducted in government health clinic settings. The study design was qualitative in nature. (Samsiah, *et al*., 2016) Six main themes were identified as barriers to reports in descending orders are: type of medication error, reporting system, management factors, healthcare factors, reporter's burden and benefit of reporting. Medication errors that are frequent and causes no harm to patients are likely not reported. Reporting system that is not confidential is stated as barrier to reporting. Access to reporting form are also seen as a barrier by participants. Other contributing barriers for non-reporting are lack of training on reporting, scanty feedback on reports, positive changes after reporting were not noticed after reporting, uncertain role of reporting and busy and high workload working environment. In another study conducted in Malaysia among doctors and pharmacists in public funded health care clinics in Kedah, blame culture at workplace was the most common reason for not reporting medication error. (Teoh, *et al*., 2015)

Table 1.4: Barriers to Reporting Medication Errors in Malaysia

Barriers	Breakdown of Barriers
Fear of the consequence of reporting	Fear pf superior's reaction Fear of repression from patients Fear of colleague's reaction Fear of getting low mark in annual performance appraisal Fear of being labelled as incompetent Fear others will know of error done
Reporting process and system (including knowledge and skills)	Various reporting mode available Complex reporting form Lacks confidentiality Lacks targeted reports Lack of knowledge on reporting system
Characteristics of event	Minor or no harm events Frequent errors Repetitive errors Insignificant errors
Characteristics of healthcare personnel	Lacks sense of responsibility
Working environment	Not a routine practice Overlapping reporting High workload Huge paper work Lack of staff
Management factors	Lacks education and training No push factors No dedicated staff for reporting related matters Lacks feedback
Team factors	Need to maintain professional relation Fear of breakdown professional relationship
Professional ethics	Role of reporting

1.5 PROBLEM STATEMENT

Medication error reporting system, such as any other incident reporting system, is the cradle of information for the purpose of learning and improvement in securing patient safety. However, medication errors are grossly underreported (Sadeghipour *et al.*, 2018), (South *et al.*, 2015), (Christiaans-Dingelhoff *et al.*, 2011) worldwide. In Malaysia, review of medication error reported to the national database from the year 2009 to 2012 yielded a total of 17,357 reports (Samsiah *et al.*, 2016). The findings of this review, was large percentage of reported medication errors were from the hospital settings and percentage of reports from the government hospitals were 82%. however, not all government hospital reported medication errors yearly as reported by this review. Reports from the government clinics were 16% and the remaining reports were from the private settings or teaching hospitals (2%). In this review also reported that large percentages of medication error reporters were pharmacists (98%).

Healthcare personnel related issues which contributed to underreporting are fear of litigation or impending actions, and fear of damaging professional image and relationships (Vrbnjak *et al.*, 2016), (Williams *et al*., 2015). Reporting system that are tedious and time-consuming methods are also reported as contributors to underreporting in those studies. Lack of timely feed backs and improvement action taken discourages reporting as stated in many qualitative studies (Lee *et al.*, 2018), (Hartnell *et al.*, 2012), (Kingston *et al.*, 2004). Medication error reports are also skewed in its reporting by either pharmacists or nurses (Mitchell *et al.*, 2016). In Malaysia, medication errors are predominantly reported by pharmacists, and majority of which are error corrected before reaching during prescription screening by