ORIGINAL ARTICLE

Assessment of Medication Safety Incidents Associated with High-alert Medication Use in Intensive Care Setting: A Clinical Pharmacist Approach

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Abstract

Background: High-alert medications (HAMs) potentiate heightened risk of causing patient harm ranging from 0.24 to 89.6 errors per 100 prescriptions. High-alert medications are crucially utilized in the intensive care settings (ICUs) due to their excellent potential in delivering therapeutic efficacy, yet these medications could cause severe harm if used inappropriately. Despite the cautious use of these medications, medication safety issues persist, which compromises patient safety.

Methods: A prospective interventional study was conducted in ICUs for a period of 6 months. The HAMs were adopted from the Institute for Safe Medication Practices (ISMP) list of HAMs that were used. A suitably designed medication error assessment form was used to capture the necessary data, including demographics, medications, medication error, and the contributing factors. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) index was used to categorize the medication errors (MEs). The error rate was calculated using error rate formula. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented in frequencies and percentages.

Results: A total of 165 patients were enrolled during the study period, with 98 (59.4%) being male and 67 (40.6%) female. The majority [54 (32.73%)] of the study participants belonged to the 61–70 age range. A total of 204 MEs were reported, of which [92 (41.5%)] errors were prescribing errors, followed by documentation errors [69 (33.82%)] and administration errors [43 (21.08%)]. The baseline medication error rate was noted to be 160.12/1,000 patient days. Potassium chloride, tramadol, propranolol, aspirin, insulin, and metoprolol were identified as the most common HAMs to cause errors. According to NCC MERP classification, 41.18% were categorized as category B, followed by category C (35.78%). An overall of 666 contributing factors (CFs) were identified for 204 errors. Stress (24.32%) was the most common factor that contributed to the MEs, followed by workload (21.47%).

Conclusion: While great strides have been adopted in error prevention, yet the goal of making HAM errors "never" event has not been achieved. Thus, an active surveillance by a clinical pharmacist could support the healthcare team in promoting patient care.

Keywords: Contributing factors, High-alert medications, Medication error, Patient safety.

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Highlights

Clinical pharmacists play a vital role in assessing and preventing medication safety incidents involving high-alert medications (HAMs) in intensive care settings. The study highlights:

- The types of medication safety incidents that occur in ICUs.
- The most common HAMs involved in medication errors.
- The contributing factors to medication errors in ICUs.
- The strategies that clinical pharmacists can use to prevent medication errors.

Introduction

Globally, up to four out of every ten patients are harmed while receiving health treatment in primary healthcare settings, with up to 80% of the harm deemed to be preventable.[1] The modern patient safety movement began with the publication of the Institute of Medicine (IOM) report "To Err Is Human" in 1999, which projected that medication errors (MEs) caused up to 98,000 patient deaths per year. This high number of deaths exceeded the amount ascribed, making it the third greatest cause of death at the time and, hence, refocusing the healthcare community on the need for patient safety.[2,3]

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Though all the medications pose a level of risk if used improperly, a limited subset of them carries a higher risk of causing serious patient injury. These medications are referred to as HAMs. High-alert medications are medicines with a low therapeutic

index (a low ratio of the maximally tolerated dose of medication to the minimal curative or effective dose), for which the Institute for Safe Medication Practice (ISMP) and the American Society of Health-System Pharmacists (ASHP) have developed a list that can be incorporated into the respective hospital formularies and will aid in aiming to enhance patient safety while using these high-risk medicines to reduce the risk of errors. Although mistakes may or may not be more frequent with these medications, the consequences could be catastrophic for patients.[4–7]

According to a 1998 Institute for Safe Drug Practices (ISMP) report on MEs, of all major MEs, heparin and insulin administration errors accounted for 8.9% and 11%, respectively.[8] Additionally, the summary data from the 2002 MedMarx[SM] report on medication events revealed that the top-seven drugs associated with harmful events are HAMs, including insulin, morphine, heparin, intravenous concentrated potassium chloride, warfarin, hydromorphone, and fentanyl.[9] The ISMP report of 2018 highlighted high-risk medications (HRMs) to potentiate the risk of causing patient harm, ranging from 0.24 to 89.6 errors per 100 prescriptions.[10]

High-alert medications are crucially utilized in intensive care units (ICUs) due to their excellent potential for delivering therapeutic efficacy.[11] Polypharmacy prevails among critically ill patients due to their multiple ailments and complex nature.[12,13] This increases the chance of them experiencing iatrogenic harm. Reports suggest that MEs account for 78% of severe outcomes, and patients admitted to intensive care, on average, experience around 1.7 errors per day per patient.[14] In addition, giving a single dose to a critically ill patient can entail 80–200 steps, inclusive of various processes starting from prescribing, indenting, dispensing, procuring, administering, recording, monitoring, and documenting, which itself creates a big-enough window for MEs to occur in the first place.[15]

Despite the cautious use of the medications, medication safety issues persist, thus compromising patient safety. Furthermore, regardless of the establishment of reporting programs in developing countries, the trend of underreporting persists.[16] This could be due to complex issues such as a lack of time, fear of medical–legal implications, public and peer embarrassment, sanctions, loss of credibility, retraining, and a lack of awareness about the significance of reporting.

Hence, further assessment of MEs in the healthcare system is necessary in light of the current global situation and Indian medical practices. This study aims to assess the rate, pattern, outcomes, and underlying contributing factors of medication incidents associated with HAMs in the ICUs of a tertiary care teaching hospital.

Methods

This study employed a six-month prospective interventional study design to evaluate the medication safety issues associated with the use of HAMs in the intensive care setting between January 2022 and July 2022. This study was approved by the Institutional Ethics Committee of JSS Medical College, Mysuru, Karnataka, India. The study was conducted at an acute care, tertiary care teaching hospital located in the southern part of India with a capacity of 1,800 beds. The ICU is a 100-bedded setting comprising various critical care units (intensive care units, medical intensive care units, and cardiac critical care units).

A consecutive method of selecting study participants was used, where all the patients aged ≥18 years who were admitted to the ICUs during the study period and prescribed with at least one HAM were included in the study, with the exception of discharge against medical advice (DAMA) cases and the patients whose length of ICU stay was ≤24 hours.

The data were collected on a suitably designed ME assessment form by the research pharmacist by reviewing all the patient treatment charts and medical records, interviewing patients, and interacting with healthcare professionals while ensuring anonymity. Data collection for the study was performed through a combination of electronic medical records and direct observation of medication administration. The baseline information was collected for each patient within 48 hours of ICU admission with the help of an interdisciplinary team consisting of pharmacists, nurses, and physicians who were trained on the appropriate use of HAMs and conducted regular rounds in the ICU to identify and address any unsafe medication practices. The collected data were reviewed by the medication error review committee. The information collected included basic demographic data, a detailed description of the error identified, HAM details implicating the error (name, strength, frequency, date of prescription, number of doses received, and opportunities for medication errors), the details of the personnel involved in the error, the cause of the error, measures taken to resolve the error, and the outcome of the error. The identified errors were reviewed and acknowledged by the investigator before being documented electronically.

All MEs were further assessed for levels, type, cause, and outcomes. The errors identified were categorized into prescribing errors, administration errors, dispensing errors, and documentation errors as per NCCMERP classification. These MEs were divided into subgroups based on their nature of occurrence. The ISMP list of HAMs was adopted to identify the HAMs.[10] Following the identification of MEs, an attempt was made to determine the underlying cause of the errors. The HCPs involved in the error were interviewed, and the factors contributing to the error were determined subjectively. These causes, however, are based on the investigator's perceptions. The drugs involved in MEs were categorized based on the anatomical therapeutic chemical (ATC) Classification system, and the severity of errors (outcome of errors) was determined using the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) harm index.[16]

The error rate was calculated by dividing the error rate/1,000 patient days using the formula:

No. of errors/Total patient days*1,000

The collected data were entered in Microsoft Office Excel 2016. Statistical analysis was performed using SPSS software V.18 for Windows. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented in frequencies and percentages.

Results

A total of 165 patients were enrolled during the study period, with 98 (59.4%) being male and 67 (40.6%) female. The majority [54 (32.73%)] of the study participants belonged to the 61–70 age range. Most of the study participants [74 (44.85%)], presented with 2–4 comorbidities, with type 2 diabetes mellitus being the most common at 56%, followed by hypertension. The majority [88 (53.33%)] of the patients' hospital stays were about 6–10 days, followed by 2–5 days [45 (27.27%)] and [32 (19.4%)] patients who stayed beyond 10 days in the hospital. Overall, 1,953 drugs were prescribed, giving an average of 11.84 ± 4.21 drugs per patient day.

Table 1: Demographic details of the study population

Characteristics	*Number of patients (%)*
Gender	
Male	98 (59.4)
Female	67 (40.6)
Age (in years) (mean ± SD) [63 ± 15.4]	
21–30	5 (3.03)
31–40	11 (6.67)
41–50	18 (10.91)
51–60	14 (8.48)
61–70	54 (32.73)
71–80	41 (24.85)
≥80	22 (13.33)
Number of comorbidities	
No comorbidities	11 (6.67)
1	19 (11.51)
2–4	74 (44.85)
>5	61 (36.97)
Length of hospital stay in days (mean ± SD) [7.72 ± 3.81]	
2–5	45 (27.27)
6–10	88 (53.33)
≥11	32 (19.34)
Polypharmacy (mean ± SD) [11.84 ± 4.21]	
No polypharmacy (1–5 drugs)	12 (7.27)
Moderate polypharmacy (6–10 drugs)	47 (28.48)
Major polypharmacy (11–15 drugs)	72 (43.64)
Excessive polypharmacy (≥16 drugs)	34 (20.61)
Units	
ICCU	56 (33.94)
MICU	49 (29.7)
CCU	24 (14.54)
SICU	36 (21.82)
Total	165 (100)

During their hospitalization, 43.64% of the participants received major polypharmacy, i.e., 11–15 drugs. The distribution of patients based on demographics is presented in Table 1.

Types of Medication Errors

A total of 204 errors were reported. The error rate was found to be 160.12/1,000 patient days. The highest number of errors were prescribing errors [92 (45.1%)], followed by documentation errors [69 (33.82%)] and administration errors [43 (21.08%)]. These MEs were further divided into subgroups based on their nature of occurrence. Among the prescription errors, incomplete prescriptions were the most common error, observed in [54 (26.47%)] prescriptions, followed by transcription errors [31 (15.2%)]. The wrong route of medication was observed in [4 (1.96%)] prescriptions, and [3 (1.47%)] prescriptions were illegible.

Among the 43 administration errors, medications administered at the wrong frequency and time were the most common error [28 (13.73%)]. This was followed by [12 (5.88%)] omission errors and [3 (1.47%)] wrong doses of medications administered.

Among the 69 documentation errors, late documentation in the treatment chart contributed to the highest number [30 (14.71%)], followed by [22 (10.78%)] failure to date, sign, and time a medical entry in the treatment chart and [17 (8.33%)] prefilling of the treatment charts. The classification of the types of errors is presented in Table 2.

Table 2: Distribution of categories of medication errors

ME level	*Type of error*	*Number of errors n (%)*
Prescribing errors	Illegible prescription	3 (1.47%)
	Transcribing error	31 (15.2%)
	Wrong route	4 (1.96%)
	Incomplete prescription	54 (26.47%)
	Total	92 (45.1%)
Administration errors	Wrong dose	3 (1.47%)
	Wrong frequency and time	28 (13.73%)
	Omission error	12 (5.88%)
	Total	43 (21.08%)
Documentation errors	Failure to date sign and time a medical entry	22 (10.78%)
	Late documentation in treatment chart	30 (14.71%)
	Pre-filling of the treatment chart	17 (8.33%)
	Total	69 (33.82%)
	Grand total	204 (100%)

Healthcare Professionals Involved in Medication Error

Nursing staff were responsible for the most MEs reported, with 112 (54.9%) errors. PG doctors followed closely behind, with 46 (22.55%) errors. Doctors and interns were responsible for the remaining errors, with 15 errors (7.35%) and 31 errors (15.2%), respectively.

Drugs and Drug Classes Involved in Medication Errors

Of the 204 MEs reported associated with HAMs, the majority of medications involved belonged to the alimentary tract and metabolism (n = 75). Of these medications, potassium chloride was involved in 26 (12.94%) of MEs, followed by insulin [19 (9.45%)], sodium chloride [11 (5.47%)], glimepiride [10 (4.97%)], and magnesium sulfate [9 (4.48%)]. Medications under the cardiovascular system accounted for 58 (28.85%) of the errors. This was followed by medications under the nervous system [33 (16.42%)], blood and blood-forming organs [30 (14.92%)], and IV fluids [5 (2.49%)] were the least HAMs used in error. The details of these drugs and their classes are presented in Table 3.

Distribution of Outcome Categories of Medication Errors

The outcomes of MEs reported were categorized according to the NCC MERP harm index. The majority of the errors (41.18%) were categorized as category B, followed by category C (35.78%), category A (20.1%), and category D (2.94%). The distribution of errors by category is shown in Figure 1.

Factors Contributing to Medication Errors

In addition to the types and subtypes of error, an attempt to determine the underlying cause of error was made and a total of 666 contributing factors were identified for 204 MEs reported. Among these, the majority (63.51%) of the factors were contributed

Table 3: High alert medications involved in medication error

ATC classification		*Subclassification*	*Name of the medication*	*ATC code*	*No. of MEs*	*Percentage n (%)*
Alimentary tract and metabolism	Blood glucose lowering agents	Peptide/protein hormones	Insulin	A10AD01	19	9.45
		Sulfonylureas	Glimepiride	A10BB01	10	4.97
	Mineral supplements	Strong electrolytes	Potassium chloride	A12BA01	26	12.94
			Sodium chloride	A12CA01	11	5.47
		Sulfates	Magnesium sulfates	A12CC02	9	4.48
Blood and blood forming organs	Antithrombotic agents	Heparin group	Heparin	B01AB01	4	1.99
			Enoxaparin	B01AB05	3	1.49
		Platelet aggregating inhibitors	Acetylsalicylic acid	B01AC06	21	10.45
		Vitamin K antagonists	Acenocoumarol	B01AA07	2	1.00
Cardiovascular system	Antiarrhythmics	Class III	Amiodarone	C05BA03	4	1.99
	Antihypertensives	Beta blocking agents	Metoprolol	C07AB02	19	9.45
			Propranolol	C07AA05	23	11.44
	Cardiac therapy	Cardiac glycosides	Digoxin	C01AA05	5	2.49
	Catecholamines	Adrenergic agonists	Norepinephrine	C01CA03	7	3.48
IV fluid	IV fluid	Glucose elevating agent	Dextrose	V06DC01	5	2.49
Nervous system	Analgesics	Opioids	Tramadol	N02AX02	25	12.44
	Anxiolytics	Benzodiazepines	Lorazepam	N05BA06	8	3.98
Grand total					201	100

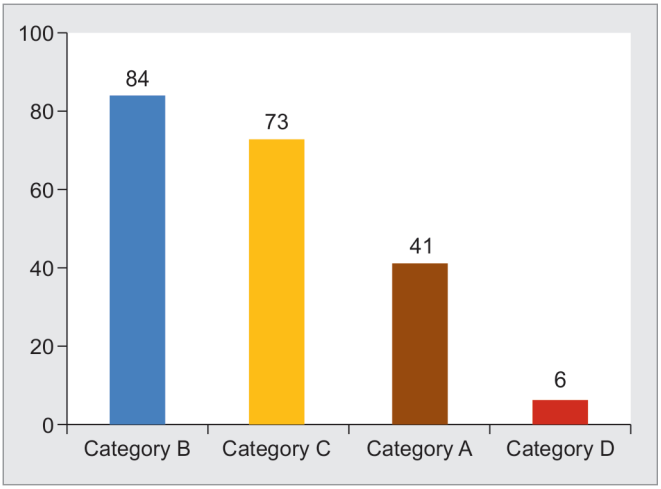

Fig. 1: Distribution of outcome categories of medication errors

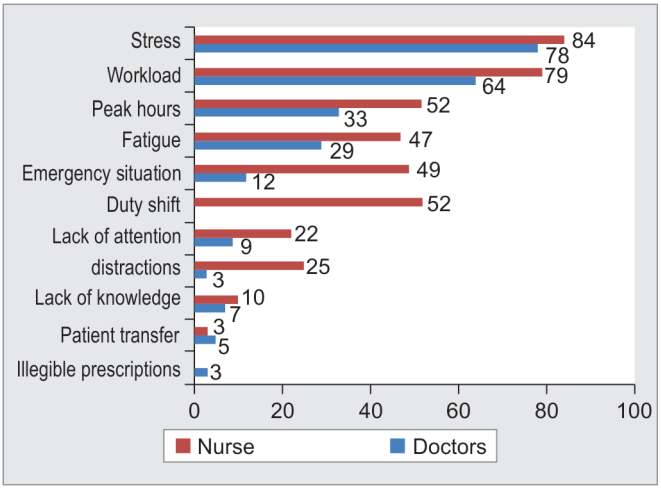

Fig. 2: Factors contributing to medication errors

by the nursing staff, i.e., documentation and administration errors, followed by 36.49% of factors were contributed by the doctors, i.e., prescribing errors.

The leading cause of MEs was identified as work-related stress, which accounted for 24.32% of the CFs, followed by workload (21.47%). The remaining factors responsible for the errors were peak hours (12.76%), fatigue (11.41%), emergency situation (9.16%), duty shift (7.81%), lack of attention (4.65%), distractions (4.21%), lack of knowledge (2.55%), patient transfer (1.21%), and only 0.45% of the illegible prescriptions contributed to the reported MEs. The distribution of contributing factors is shown in Figure 2.

Discussion

According to published reports, the rate of MEs reported in ICUs varies significantly, with rates as low as 9.8% of prescriptions to as high as 52% of prescriptions.[17] Though medication error-reporting systems are established in various countries across the globe, the trend of underreporting continues. Patients in ICUs are especially vulnerable to medical errors since they are extremely ailing and require constant monitoring.[18] Since HAMs are crucially utilized in ICUs due to their excellent potential in terms of therapeutic efficacy, they are also capable of inflicting severe harm when used inappropriately.

Though MEs are widely studied globally, to our knowledge, this study is the first to assess the rate, pattern, contributing factors, and outcomes of MEs involving HAMs in the intensive care setting of a tertiary care teaching hospital in southern India.

In this study, the error rate per 1,000 patients was found to be 160.4/1,000 patient days. However, MacFie et al. reported a significant variance in the incidence, ranging from 5.1 to 967 errors per 1,000 patient days, in an integrative analysis of 40 papers about

MEs in the ICU.[19] Another study by Laher et al. on MEs in the ICU setting in South Africa revealed an error rate of 621.1/1,000 patient days.[20] Kane-Gill and Weber conducted a review of 20 studies on the prevalence of error rates in the ICUs and reported an error rate of 1.2–947 errors per 1,000 patient days.[21] The authors in this study attributed this large variance in the error rate to various factors like the geographical location, type of hospital, and type of setting, and above all, this study only involved the errors associated with a subclass of medications, namely HAMs, which explains the contrast in the result.

Prescribing errors were the most common type of error seen in our study, which is consistent with the findings of Silva MD et al.[22] Of the prescribing errors reported, incomplete prescriptions, followed by transcription errors, were the most common. In our setting, junior doctors (PGs) write medications into treatment order sheets/charts. Their inexperience and lack of expertise have increased the likelihood of errors. They must be properly trained about the patient's treatment plan and should not just retype from previous orders. Incomplete prescriptions result in inaccurate transcription. Prescriptions written in an ideal, comprehensive format in legible handwriting might easily prevent this. The use of Computerized Physician Order Entry (CPOE) could help reduce prescribing errors and improve compliance with complete prescriptions.

Consistent with the previous study conducted by Zirpe et al., our study revealed a preponderance of documentation errors over administration errors.[23] Late documentation in the treatment chart and failure to date, sign, and time the medical entry by nursing staff accounted for the majority of documentation errors, whereas administration of the medication at the wrong frequency and time, followed by omission errors, accounted for the majority of administration errors. The possible explanation for this could be associated with various factors like workload, nurse–patient ratio, stress, and frequent changing of nurses in the wards. Also, it can be challenging for novice nurses to quickly adjust to the medication procedure, particularly in an intensive care setting. Effective communication between healthcare professionals would prevent these administrative errors. Introducing methods of enhancing patient safety by training new staff on HAMs and adopting barcode systems and timeline tracing of medication administration could greatly prevent administration errors. Involving clinical pharmacists in the cross-verification and active surveillance of medication chart review could play a significant role in reducing the errors.

The ISMP list was adopted to identify the HAMs and it was noted that the most common HAMs implicated in error were potassium chloride [26 (12.94%)], followed by tramadol [25 (12.4%)], propranolol [23 (11.44%)], acetyl salicylic acid [21 (10.45%)], insulin [19 (9.45%)], and metoprolol [19 (9.45%)]. These results were consistent with the findings of the study conducted by Alves S et al.[24] and Zirpe KG et al.[23] This is most probably due to the fact that they are the most commonly prescribed medications in critical care units. Also, the patients admitted to ICUs undergo invasive and painful procedures for which the analgesics and anesthetics are usually prescribed for the patients' ease. Patients in ICUs commonly experience electrolyte misbalance for which the utilization of electrolytes is more common in these settings. Similarly, the patients in ICUs usually present with comorbidities like diabetes mellitus and hypertension for which insulin and antihypertensives are more commonly used, justifies the utilization of these HAMs in ICU settings.

The majority of the errors were categorized as category B. The NCCMERP harm score index was used to determine the outcome of the error in our study, with the majority of the errors falling into category B (41.18%), followed by category C (35.78%), category A (20.1%), and category D (2.94%). A research in West Ethiopia, on the other hand, found that most of the errors were belonging to category C (63.1%), followed by category B (20.6%). There have been no fatalities as a result of medication error. The vast majority of errors fall into category B, which means that the error occurred but did not reach the patient. As a result, 61% of errors are prevented, whereas only 39% are actual errors. This is attributed to the clinical pharmacist's active surveillance during each step of medication process that aids in enhancing patient safety and reducing errors.[25]

Each ward in our study had consistently insufficient numbers of nurses and doctors, which raised the workload, created a tense work atmosphere, and increased the possibility of MEs.

The contributing factors were determined toward the medication error by subjectively interviewing the involved HCP in the error and it was noted that the most common factor that contributed to the MEs was found to be work-related stress, which accounted for 24.32% of the CFs, followed by workload (21.47%). These findings were consistent with the study conducted by Chalasani and Ramesh.[15] The possible explanation for this could be that since the ICUs are very sensitive domains and comprise vulnerable patients, extra care and caution are required for patient care in these units. Furthermore, there were consistently insufficient numbers of nurses, which raised the workload, created a tense work atmosphere, and increased the possibility of MEs. On top of this, the literature suggests that the nationally recommended nurse-to-patient ratio in ICU settings is 1:2. However, our setting had a lower ratio, which in turn resulted in increased workload and burnout syndrome. This explains the errors.

However, these parameters need to be worked on rather than ignored or denied. Incorporating various strategic methods and educating all the healthcare professionals about the importance of MEs and their reporting would result in a reduced incidence of MEs.

Conclusion

High-alert medications are crucially utilized in ICUs. While great strides have been adopted in error prevention, yet the goal of making HAM errors "never" event has not been achieved. Clinical pharmacists play a major role in supporting healthcare professionals by developing guidelines, implementing, and monitoring safer use of high-risk medicines, and improving patient safety. Thus, an active surveillance by clinical pharmacists could support the healthcare team in promoting patient care.

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