Medication Errors and Role of Clinical Pharmacist in Identification, Assessment and Prevention: Need of the Time

Prashar Abhimanyu^{*1}, Agrawal Vijit²

1. Department of Pharmacy Practice, JSS College of Pharmacy and Department of Clinical Pharmacy, JSS Hospital, JSS University, Mysore.

2. Department of Pharmacy Practice, MM College of Pharmacy and Department of Clinical Pharmacy, MM Medical College & Hospital, MM University, Mullana.

Corresponding Author's*: abhi.parashar29@gmail.com

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Abstract:

Medication errors (ME's) are one of the contributing factors for patient's morbidity and mortality. Medication errors can occur at any stage of prescribing, transcribing, dispensing and administration of medications. Identification and resolution of the ME's will improve the patient safety and therapeutic outcome. Before identification, Assessment and Evaluation of ME's it is essential to understand the types of errors and contributing factors to ME's as it provides opportunities for error prevention at the earliest point of the medication process and improves the patient care, prevents potential adverse events and will decrease the healthcare cost burden on the patient. Drug therapy aims at achieving a defined therapeutic outcomes which is key element in improving patient quality of life and minimising the risks of the drugs prescribed There are inherent risks with drugs which is also known as Drug Misadventuring that includes both Adverse Drug Reactions as well as the Medication Errors. Frequent occurrence ME's has become a global issue as it is a major threat to attain the Therapeutic goals by compromising patient's confidence in the Health care system and increase healthcare cost so it is the need of the time to focus on such an embrasure of the Healthcare scenario and design preventive strategies for it.

Key words: Medication Errors, Identification of Errors, Prevention of Errors.

Introduction:

The concept of Medication Error's (ME's) is not new but its importance still exists in the healthcare system globally so it's really the need of the time to start concentrating on this under addressed issue. ME's are like an "Iceberg" *as what we see is often a fractional part of what it is.*

Drug therapy is a complex process and one can face challenges at various levels which involve prescribers, pharmacists, nurses and the patients. The Drug therapy aims at achieving a defined therapeutic outcomes which is key element in improving patient quality of life and minimising the risks of the drugs prescribed There are inherent risks with both prescription and non prescription drugs which is also known as *Drug Misadventuring* that includes Adverse Drug Reactions (ADR's) as well as the Medication Errors ¹. Frequent occurrence ME's has become a global issue as it is a major threat to attain the therapeutic goals by compromising patient's confidence in the healthcare system and increase healthcare cost as well as patient's quality of life so it is the need of the time to focus on such an embrasure of the healthcare scenario and design preventive strategies for it.

Medication Errors and Occurrence

The National Coordinating Council for Medication Error (NCCMER) defines a medication error as being *'any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer*²." These events may be related to professional practice, health care products, procedures and systems including: prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education monitoring; and use.

The Institute of Medicine (IOM) report published in 2000, *To Err Is Human: Building a Safer Health System* identified medication errors as the most common type of error in health care and attributed several thousand deaths to medication-related events.³

In United States 2% of Patient admitted to hospital experience Medication Errors.⁴ A study in United Kingdom hospital identified 1.5% prescribing errors of 36200 medication orders, and most of them (54%) were associated with the choice of dose; 0.4% errors were potentially serious. A 12 months cross sectional study conducted in 173 hospitals in England and Wales in year 2006, by the National Patient Safety Agency, collected 40000 Medication Errors among them 15% resulted in slight harm and 5% moderate to severe harm.⁵

Nearly a decade ago, researchers estimated that the annual cost of drug-related illness and death in the ambulatory care setting in the United States was approximately \$76.6 billion. Using the same approach, this cost was estimated to be \$177.4 billion in 2000. Therefore, it is important that all ME's resulting or potentially resulting in serious injury or death are evaluated to assess whether improvement in the healthcare delivery system can be made to minimize the likelihood of similar events occurring in the future ⁶.

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India provides numerous attractive opportunities in the field of healthcare because of its large population. The World Health Organization's 2000 global healthcare profile ranked India's healthcare system 112 out of 190 countries despite of its 1.2 Billion populations ⁷. The reason behind it is that Indian population is divided into two groups based on economy, the first group that consists of upper class and middle class and resides in the urban areas which have access to quality healthcare system and the other group consists of people who are living below the poverty line in rural areas and do not have access to a proper healthcare facility and system. Besides lack of overall healthcare infrastructure another major cause of concern according to WHO on India's healthcare industry is its lack of a medically insured population and high out-of-pocket expenditure ⁸. Other then these two well documented causes the other major problems that is arising in the Indian healthcare system is also Medication Misadventuring (ADR's and ME's).

A prospective study conducted for duration of 1 year in Uttrakhand, an Indian state observed that in a sample of 1586 patients the ME rate was 25.7%. Most of the errors were related to treatment procedures. Other causes of ME's were related to clerical procedures and the reason attributed to it was long working hours and night shifts. Outcomes of majority of errors were not significant whereas few errors resulted in mild morbidity. The Incidence of errors resulted in moderate and severe morbidity was found to be 10.49% and 6.28% respectively. The major causes that contributed for ME's were due to content errors, errors in administration followed by faulty procedures and clerical errors ⁹.

Looking into all the global as well as Indian statistics from past decade it's really crucial that one should come out with critical designing and strategic implementation of methods to prevent ME's in Indian Healthcare Scenario. The ME's studies should be conducted nationwide in all Primary, Secondary and Tertiary healthcare systems and the Policy makers must take bold decisions in the implementation of the ME's prevention studies to overcome this Iceberg of healthcare system.

Medication Errors: Types and Levels

Before identification, assessment and evaluation of ME's it is very important to understand the types of errors and contributing factors to ME's as it provides opportunities for error prevention at the earliest point of the medication process and also improves the patient care, prevents potential adverse events, improve health related quality of life and will decrease the overall healthcare cost burden on the patient. USP-ISMP (US Pharmacopoeia - Institute of Safe Medication Practice), started Medication Error Reporting (MER) program as they recognised that there were many causes for medication errors and no organization was equipped to address this threat to patient safety. Therefore, the USP spearheaded an effort to convene a group of concerned national organizations that had the authority, mechanisms, and resources to confront the complexities of medication errors and seek solutions for those issues that adversely affected patient safety ².

The best way to understand the types and occurrence of medication errors and designing the preventive strategy is to consider their classification, which can be contextual, modal or psychological. Contextual classification deals with the specific time, place, medicines and people involved. Modal classification examines the ways in which errors occur. Psychological classification is to be preferred, as it explains events rather than merely describing them. Its disadvantage is that it concentrates on human rather than systems sources of errors ¹⁰.

The Medication process undergoes five stages, which initiates from ordering/prescribing, followed by transcribing and verifying, dispensing and delivering, administering and finally monitoring and reporting ¹¹. The ME can occur at any Level among the above mentioned stages.

The levels of ME's can be classified as: Prescribing Errors, Administering Errors, and Dispensing as described in Fig (A).





American Society of Health-System Pharmacists (ASHP) defines a Prescribing Error as Incorrect drug selection which sub-categories it based on indications, contraindications, known allergies, existing drug therapy, and other factors like dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors that reach the patient ¹.

prescribing errors can be classified into different types as like drug use without indication, incorrect drug selection, provided alternate dosage form, improper dose, wrong duration, wrong frequency, no instruction for use of drug, unauthorized drug, illegible prescription, drug duplication, monitoring error, treatment started late, allergy. Administration errors include dose omission, wrong administration, wrong time, compliance error. Dispensing errors include wrong drug, wrong strength, and wrong formulation ¹. Levels, types and personnel involved in the ME's discussed in Fig (B).



Fig (B): Levels, types and personnel involved in Medication Errors

What causes Medication Errors?

The problem of Medication Errors is multidisciplinary and multi-factorial which includes the healthcare professionals as well as the patients. It involves both experienced and inexperienced physicians, nurses, pharmacists, supportive personnel as well as students. ME's can occur because of lack of knowledge, substandard performance and mental lapses or defects in the system ¹². Most common causes of medication errors include prescribing errors, drug-drug interactions, dose miscalculations, incorrect drug administration and lack of patient education. Other factors that can contribute are job-related stress; improper training or education; sound-alike brands and look alike packaging of medications ¹². The common causes of ME's are described in Figure (C).

According to some studies the major barriers involved in an error free drug therapy at the levels of prescribing as well as administration are- 1) Inappropriate prescribing 2) Inappropriate regimen (Inappropriate drug, dosage form, dose, route, dosage interval, or duration). 3) Unnecessary regimen. 4) Drug not available when needed because of economical barriers, biopharmaceutical barriers, sociological barriers and inappropriate delivery.

Causes of ME's involved at the level of dispensing can be because of 1) Incorrect or inappropriate labelled prescription 2) Incorrect patient information or advice 3) Inappropriate behaviour by the patient 4) Compliance with inappropriate regimen 5) Noncompliance with appropriate regimen 6) Patient idiosyncrasy 7) Idiosyncratic response to the drug 8) Mistake or accidental ingestion of drugs





How to identify Medication Errors?

For Identification of ME's many strategies are available that can be used but the best strategy is designing a suitable data collection and assessment form which should be designed in order to collect and document the data. Designed data collection form should contain the all relevant information's regarding the demographics of patients, date of admission as well as discharge, and length of hospital stay. The medical history must include reasons for admission, past medication history, social as well as family history, allergy history and co-morbid conditions and diagnosis.

The patient's medication details like medication name, dose, route and frequency, formulation, start date and stop date, reason for use, duration of use, total number of medications received both prior and after hospital admission/visit and details of medications prescribed on discharge.

The assessment form must contains details like date of ME's identified, total number of MEs, description of error, product information, levels of ME and types of ME. The error outcome section must include NCCMERP categorization, human factors and contributing factors of ME. All patients being admitted to wards should be reviewed on daily basis. Medical records of enrolled patients must be reviewed to detect medication errors, if any. All in-patients should be followed from the day of admission until the day of discharge. Any change in the patient's management including change in medication orders should be noted and updated on daily basis. There should be a proper *computerization of data collection and assessment form* as all the data should be recorded properly and to be entered in software database for the easy and suitable retrieval and analysis of data

Medication Errors Outcomes:

Many ME's are probably undetected that occurs mostly because of the outcome(s) of ME's will not be clinically significant and will not adversely affect the patient but some ME's results in serious morbidity and mortality. Thus ME's must not be taken lightly and effective system should be established to safeguard and prevents the occurrence of them.²

NCCMERP recommends that medication error information be collected and reported as soon as possible, while the information is still fresh. In selecting the patient outcome category, select the highest level severity that applies during the course of the event. For example, if a patient suffers a severe anaphylactic reaction (Category H) and requires treatment (Category F) but eventually recovers completely, the event should be coded as Category H. Only one category which best fits patient's profile should be selected for outcome assessment. **No Error** *Category A:* Circumstances or events that have the capacity to cause error.

Error, No Harm [Note: Harm is defined as temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from requiring intervention.] *Category B:* An error occurred but the error did not reach the patient (An "error of omission" does reach the patient.) *Category C:* An error occurred that reached the patient, but did not cause patient harm 1. Medication reaches the patient and is administered ². Medication reaches the patient but not administered *Category D:* An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm **Error, Harm** *Category E:* An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention *Category F:* An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization *Category G:* An error occurred that may have contributed to or resulted in permanent patient harm *Category H:* An error occurred that required intervention necessary to sustain life **Error, Death** *Category I:* An error occurred that may have contributed to or resulted in the patient harm *Category H:* An error occurred that may have contributed to or resulted in permanent patient harm *Category I:* An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention necessary to sustain life **Error, Death** *Category I:* An error occurred that may have contributed to or resulted in the patient's death².

Role of Clinical Pharmacist in Prevention of ME's:

Pharmacists are the experts to provide pharmaceutical care through their knowledge and skills in pharmacotherapeutics and clinical practice. In a hospital a clinical pharmacists have a liaison between the patients as well as with the healthcare professionals. The pharmacist plays an important role in accessibility of medicines to the healthcare professionals and their move will provide learning to persons other than pharmacists ¹⁴.

The WHO reports states "Effective medicine can be practiced only where there is efficient drug management". Only when the pharmacist has been accepted as a vital member of the healthcare team can the necessary supporting services be organized with the professionalism that they demand" ¹⁵. Monitoring error, compliance error, drug duplication, incorrect drug selection, drug use without indication, improper dose, wrong duration and wrong administration are the common causes of ME's found in tertiary healthcare setting. Following are some of the strategies to prevent ME's.

Pharmacist is a healthcare professional who is trained to provide counselling sessions to patients with minor illnesses and often to those who are suffering from chronic conditions as well as the patients on established maintenance therapy; they provide liaison between the duties of prescribing and selling medicines and in so doing they dispose of any perceived or potential conflict of interest between these two functions.

1. Monitoring errors: It was noticed that many errors had occurred due to insufficient monitoring by clinicians, ward clinical pharmacists and nurses. It is important that medical records should be documented systematically with all relevant patients' details on daily basis. This will facilitate communication amongst all HCP's and uniform coordination in better patient care.

2. Compliance Error: There is a strong need to control the prescribing according to availability in local settings. Many compliance error were due to, prescribing of expensive brands and due to poor understanding of patients regarding importance of medications so these problems can be overcome if drugs (brands) are prescribed considering easy access to patients, availability of other economic brands, affordability of patients and by providing medication counseling to patients to improve their understanding respectively. Clinical pharmacists should contribute more actively to counsel the patients where it is needed. Nurses may also follow the patients to ensure medication adherence. Prescribing in generic name is also useful to avoid omission errors due to unavailability of prescribed drug (brand) as in the absence of prescribed brand hospital pharmacist may dispense the alternative brand if generic name is known.

3. Drug duplication: Prescribing by generic name in the treatment chart and prescriptions to avoid confusions. If prescribing is by any chance in brand names then generic name of the drug should be written next to the brand name in the treatment chart. Ward clinical pharmacists should review treatment chart more thoroughly on daily basis in the wards where drug duplication/class duplication is found more frequently.

4. Incorrect drug selection/Improper dose: It was noticed that reason for the incorrect drug selection was regular practice of clinicians which was not rational in many instances. Also, many patients were prescribed with drugs to which they were contraindicated. Proper coordination of clinicians and clinical pharmacists are needed. Clinicians must retrieve detailed medical profile of the patients before they make decision on prescribing and clinical pharmacists must assist clinicians for suggesting correct doses of the drug so that incorrect drug selection and improper doses can be avoided.

5. Wrong Frequency: Many drugs were prescribed with inappropriate administration frequency. The clinical pharmacists must review treatment chart soon after prescribing. Even nurses can review drug frequency in treatment chart before they administer it so that drug use with wrong frequency can be prevented. Nurses may be provided with standard text books and references in the wards to refer if needed. Clinician may consult clinical pharmacists before prescribing as needed and

interventions made by pharmacists to correct the drug regimen should be accepted if it was justified properly.

6. Drug use without indication: Prescribing of antibiotics, PPIs, multi vitamins, pain killers are very common without any valid indication so same should be restricted by Pharmacy and Therapeutics committee. Clinicians should be advised by PTC to use these drugs only if there is a valid indication. Inventory of these drugs also should be limited in the hospital pharmacy. Drug utilization evaluation may be done for such drugs and results can be presented to hospital authorities with the intention of rational drug use.

The role of pharmacist in health care is only towards manufacturing and distribution of drugs but the role of Pharmacist is more than meets the eye but there are numerous Hurdles because of which, pharmacists have not been able to pursue their international mandate in our country which includes: Lack of understanding of the role of pharmacist in healthcare; Lack of identification of "Health-care-team" as a policy concept and centre-stage role only to medical professionals in the maintenance of health; More stress on curative measures rather than preventive measures for health related issues; Lack of national objectives of professional education being reflected in policy implementation.

There has been increasing discussion in pharmacy circles on the question of pharmacist prescribing. Pharmacist may engage in repeat prescribing for stabilized patients with chronic conditions; prescribing from a limited formulary agreed upon collaboratively by physician and pharmacist; Prescribe discharge medication; Adjust quality and frequency as per jointly developed protocols; Order laboratory tests and modify drug therapy accordingly; and Implement agreed patient specific clinical management plan. Pharmacoeconomics of Interventions

For a ME"s to be prevented it must be an identifiable one. Those that are unpredictable i.e., like idiosyncratic response to drugs, ADRs, may not be preventable while other drug related morbidities are preventable For a ME"S to be prevented the ME"s must are recognizable and the likelihood of an undesirable clinical outcome must be foreseeable.

Application of Technology in Reduction of Medication errors^{18, 19}: With the advancement of time, new technologies are also taking over in healthcare system which are emerging and offering scenarios to ensure efficient and accurate healthcare which results in improved patient safety and health related quality of life.

Computer prescription order entry (CPOE) systems: CPOE is one of computer technologies that accepts the physicians order for diagnostic and treatment services electronically instead a written prescription. The computer can assess the orders against standards for dosing, patient allergies or interactions with other medications and warn the prescriber about potential problems. CPOE has been widely recommended as a way to improve Patient safety and to reduce the medication error rates.

Bar code identification: This is one of the measures introduced for reducing medication errors. This system provides a wristband to all patients that include a unique identity bar code. This bar code is also placed on all medications to be administered. The similar bar code also identifies the person who administers the drugs. A bar code drug administration system would be linked to clinical information and the medication profile, so that when the dose is to be given, an automatic check could be ME"S to assure the fact that the drug was prescribed for the patient, the dose, time and the route of administration was correct, and that the patient does not have allergy to the medication being given.

Automated Medication Dispensing: Automated medication dispensing systems are now widely used as a less labour-intensive method for dispensing. Automated pharmacy dispensing systems are more efficient at performing pharmacist's tasks that require tedious, repetitive motions, high concentration and reliable record keeping, which can all lead to medication dispensing errors. When utilized appropriately, automated medication dispensing systems help to reduce medication errors and improve patient safety. Food and drug administration (FDA) has recently strongly endorsed this mechanism for reducing Medication errors.

Conclusion:

MEs in hospitalized patients can be prevented if patient's medical history is taken properly and patients are properly followed. A Clinical Pharmacist can play an important role by conducting awareness and education programs for nursing staff and other health care professionals regarding detection and reporting of ME's can minimize the frequency of the same. A Clinical Pharmacist can also conduct Drug Utilization Evaluation studies in order to prevent the irrational prescribing of drugs. Appropriate team work from all HCPs can certainly reduce occurrence of MEs in hospitalized patients.

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