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Mediation Error and Patient Safety in India: Causes, Underreporting, and the Way Forward

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Abstract: ***Medication errors are a major yet underreported threat to patient safety and healthcare quality, particularly in developing countries such as India. A medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of a healthcare professional, patient, or consumer. These errors may occur at any stage of the medication-use process, including prescribing, transcription, dispensing, administration, monitoring, and patient use, and are frequently associated with failures in professional practice, healthcare systems, and communication. Due to a multitude of variables including a large patient load, shortages of staff, a dependence on handwritten prescriptions, a lack of health information technology, polypharmacy, and inadequate training, medication errors are a significant issue in India. According to research, a significant number of adverse drug events can be avoided, and pharmaceutical errors put a substantial clinical and financial burden on the healthcare system. Despite their seriousness, most drug errors remain underreported due to a lack of understanding, a fear of being held accountable, and lack of regulatory frameworks. Strengthening pharmacovigilance infrastructure, promoting a non-punitive reporting culture, and instituting standardized medication-safety procedures are all required to reduce preventable harm while bettering patient outcomes in India.***

Keywords: Medication Errors, Patient Safety, Pharmacovigilance, Adverse Drug Events, Prescribing Errors, Administration Errors, India, Healthcare Quality, Error Reporting

1. Introduction

Medication errors can happen at any stage of the medication management process, including transcribing, administering, prescribing, dispensing, and monitoring. Several factors heighten the risk of medication errors, including individuals with severe health conditions, the elderly, pediatric patients, and those on multiple prescribed medications. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) defines a medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.” Medication errors significantly impact the well being of individuals, organizations, and healthcare systems. Medication errors are classified through several approaches, such as at the stage of the drug-use process sequence, which includes prescribing, transcribing, dispensing, administration, and monitoring[1].

Another approach is the type of error that occurs, which can be related to the medicine, dose, frequency, route of administration, or the patient. Other classifications can be as a result of planning actions (based on knowledge and rules), errors in carrying out adequately planned actions (based on actions known as "slips"), or errors due to memory or thought processes known as deviations. Most of the Medication errors (MEs) are under-reported in almost all nations. It represents one of the most important serious consequents in patient with complex medical conditions. There are no stringent regulatory guidelines for handling medication errors in India. Responsibility lies in all healthcare professionals but not restricted to clinicians. Correspondingly, all developing countries including India, often record ME’s as per British Medical Journal.

There is need of hour to all healthcare professionals in India to report medication errors to National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission, Ghaziabad to promote patient safety in the country. The medication errors committed by the nurses takes the first place because they spent 40% of their work time in administering drugs. In hurry to complete their work, their may be a chance for occurrence of medication errors.[2]

2. Nature

In the Indian healthcare setting, medication errors are preventable failures occurring at any stage of the medication-use process—from prescribing and transcription to dispensing, administration, and monitoring—and are often driven by a combination of human and system-related factors. These errors may arise from knowledge gaps such as overlooking drug allergies or necessary dose adjustments, misapplication of clinical rules, action-based mistakes like selecting look-alike or sound-alike medicines or incorrect volumes, and memory lapses including omitted or repeated doses. Such risks are amplified in India by overcrowded hospitals, high patient-to-provider ratios, staff fatigue, frequent interruptions, handwritten prescriptions, and inconsistent labeling and packaging practices. Medication errors commonly present as inappropriate prescribing, transcription inaccuracies, dispensing of incorrect drugs or strengths, administration errors—particularly among nursing staff, where they account for a substantial proportion of cases—and inadequate monitoring of laboratory parameters

[1] THE STARTLE REALITY OF MEDICATION ERRORS IN INDIA: ROLE OF PHARMACOVIGILANCE

[2] MEDICATION ERRORS: AN ETHICAL ANALYSIS

or therapeutic response[3]. These failures can convert routine treatment into avoidable patient harm, prolonged hospital stays, or even mortality, yet many are preventable through standardized treatment guidelines, pharmacist involvement, double-checking practices, use of health information technology, and a non-punitive reporting culture that recognizes errors as indicators of system weaknesses rather than individual blame.

Definition:

In the Indian healthcare setting, a medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while a medicine is under the control of a healthcare professional, patient, or consumer. This definition aligns with the framework proposed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), which attributes medication errors to failures in professional practice, healthcare products, procedures, and systems, including prescribing, order communication, labeling and packaging, drug nomenclature, compounding, dispensing, distribution, administration, patient education, monitoring, and use (NCC MERP, 2001).[4] Within India, the risk of medication errors is further intensified by high patient volumes, dependence on handwritten prescriptions, variable regulatory enforcement, limited integration of health information technologies, and differences in patient literacy and awareness, which affect understanding and adherence to medication instructions. These challenges contribute to medication errors across hospitals, primary health centres, community pharmacies, and home-care settings, consistent with the World Health Organization's recognition that system-level weaknesses and contextual factors play a critical role in medication-related harm, particularly in low- and middle-income countries (WHO, 2017).[5]

SCOPE:

In the Indian healthcare context, the scope of medication errors is extensive, encompassing any preventable event that may result in inappropriate medication use or patient harm while medicines are under the control of healthcare professionals or patients. These errors can occur at all stages of the medication-use process, including prescribing, transcription, dispensing, administration, monitoring, and patient compliance, across diverse settings such as public and private hospitals, primary health centres, community pharmacies, and home-based care. Contributing factors in India include high patient volumes, limited consultation time, variable levels of staff training, reliance on handwritten prescriptions, multilingual communication barriers, and uneven adoption of electronic health records, all of which increase the risk of errors and compromise medication safety[6].

Medication errors in India commonly arise from inappropriate prescribing practices, illegible prescriptions, dispensing inaccuracies, and administration errors—particularly in resource-constrained environments where nurses and pharmacists manage heavy workloads. Inadequate monitoring of renal and hepatic function, limited access to laboratory services in rural areas, and poor continuity of care further exacerbate the problem.

3. Types of Medication Errors

Medication errors occur across the entire medication-use continuum, with process-stage classification identifying where breakdowns happen—from prescription to patient monitoring.

1) Prescribing Errors[7]

Which account for approximately 54% of all medication errors and represent the most common category, occur when physicians or other authorized prescribers select, calculate, or document an inappropriate therapy for a patient. The prescribing error is a common drug error that can be prevented in hospitals around the world. Additionally, commission errors encompass mistakes like prescribing the wrong drug strength, incorrect drug name, inappropriate dosage form, and potential drug interactions. These errors frequently stem from knowledge deficits, clinical inexperience, fatigue, and system-related weaknesses such as illegible handwriting and reliance on verbal orders. Contributing factors include polypharmacy, inadequate access to complete patient histories, unrecognized allergies, and poor clinical decision support. The consequences of prescribing errors are substantial, accounting for nearly 21% of medication-related harm, and may result in drug toxicity, therapeutic failure, prolonged hospitalization, or death, as illustrated by catastrophic dosing mistakes such as prescribing 80 units of insulin instead of 8 units.

2) Dispensing Errors

Which account for approximately 18–23% of medication errors, occur during the pharmacy stage when prescriptions are prepared, labeled, or supplied to patients. Different hospital units utilize various medication dispensing systems, each with its own set of expectations regarding potential errors.[8] The primary causes include look-alike and sound-alike drug packaging, high prescription volumes, workload pressure, insufficient staffing, absence of independent double-check systems, and pharmacy database errors, such as incorrect patient identification or medication selection. One potential cause of these errors is that some pharmacists may fail to verify patients' identification before dispensing medication. Dispensing errors can delay treatment, propagate errors to the administration stage, or directly cause patient harm if undetected; however, most are highly preventable

[3] A COMPREHENSIVE REVIEW OF MEDICATION ERRORS IN HEALTHCARE: ANALYZING THEIR CAUSES, CATEGORIES, AND PREVENTION METHODS IN INDIA
[4] NATIONAL COORDINATING COUNCIL FOR MEDICATION ERROR REPORTING AND PREVENTION (NCC MERP). (2001). *ABOUT MEDICATION ERRORS*. NCC MERP.
[5] WORLD HEALTH ORGANIZATION. (2017). *MEDICATION WITHOUT HARM: WHO GLOBAL PATIENT SAFETY CHALLENGE*. WORLD HEALTH ORGANIZATION
[6] EVALUATION OF MEDICATION ERRORS IN ONE OF THE LARGEST PUBLIC HOSPITAL: A RETROSPECTIVE STUDY
[7] MEDICATION ERRORS: UNDERSTANDING THE TYPES, CAUSES, AND PREVENTION, AND THE CRITICAL ROLE OF PHARMACISTS
[8] MEDICATION ERRORS: UNDERSTANDING THE TYPES, CAUSES, AND PREVENTION, AND THE CRITICAL ROLE OF PHARMACISTS

through interventions such as barcode-assisted dispensing, standardized labeling, automation, staff training, and the integration of health information technologies.

3) Administration Errors

Which represent the largest proportion of medication errors and occur most frequently in nursing practice, arise during the direct delivery of medications at the patient's bedside. Other errors in drug administration include using improper techniques and administering incorrect or expired medications.[9] Key contributing factors include frequent interruptions—often exceeding 10 per hour, high nurse-to-patient ratios, fatigue, inadequate staffing, poor interprofessional communication, and limited access to guidelines or formal training, with some studies reporting up to 88.4% of nurses untrained in safe medication administration.

4) Monitoring Errors

A monitoring error occurs when prescribed medication is not observed in accordance with established standards of care in routine clinical practice. accounting for approximately 1–12.6% of medication errors, occur when there is a failure to adequately assess and follow up on a patient's response to medications after administration. These errors include the absence of essential renal or hepatic function tests, failure to recognize or act upon drug–drug interactions, overlooking adverse drug reactions (ADRs), and inadequate evaluation of therapeutic efficacy or toxicity.[10] Monitoring failures often delay the detection of patient harm, allowing preventable adverse events to progress and significantly contributing to the estimated 50% of avoidable medication-related harm. Effective prevention strategies include adherence to the "five to ten rights" of medication administration, implementation of independent double-checks, and adoption of health information technologies such as barcode medication administration (BCMA) systems, which have been shown to reduce medication administration errors by approximately 50%.

4. Legislative Measures for Medication Errors

Legislative and regulatory measures focus on mandatory reporting, standardized guidelines, and accountability to reduce medication errors, though the provided content emphasizes ethical/legal obligations for reporting rather than specific laws; these drive systemic improvements like blame-free cultures and tech adoption

Reporting medication errors is both a legal and ethical obligation in healthcare systems, as it is fundamental to protecting patient safety and identifying underlying system failures. Failure to report medication errors conceals latent risks, allows unsafe practices to persist, and undermines organizational learning and accountability. Several countries have institutionalized mandatory reporting to strengthen patient-safety cultures. In the United Kingdom, the National Patient Safety Agency (NPSA) established compulsory reporting requirements, with healthcare trusts facing financial penalties of up to £4,000 for non-compliance, reinforcing organizational responsibility for transparency. Similarly, Denmark's mandatory national reporting system has achieved reporting rates of nearly 50%, in stark contrast to countries such as Australia, where voluntary systems capture as little as 1% of medication errors, highlighting the limitations of non-mandatory approaches.[11] At the international level, structured frameworks support standardized reporting and prevention: the US National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) provides uniform definitions and classification systems to facilitate learning and benchmarking; the Saudi Food and Drug Authority (SFDA) operates a National Pharmacovigilance Center that mandates adverse drug reaction (ADR) surveillance; and the World Health Organization (WHO), through its global patient-safety challenge "Medication Without Harm," urges governments to implement robust reporting and learning systems as a key strategy to reduce medication-related harm and achieve potential savings of up to US$42 billion annually. Together, these legal, ethical, and policy-driven frameworks underscore that medication-error reporting is not punitive but a critical tool for system improvement, risk reduction, and sustainable healthcare quality.

Guidelines and Protocols

International and institutional standards play a central role in preventing medication errors by promoting safe, standardized practices across healthcare systems. The World Health Organization (WHO), through its 2017 patient-safety strategies, emphasizes the development and implementation of evidence-based clinical guidelines, continuous skill-building and training, and standardized medication-use protocols, including adherence to the "five to ten rights" of medication administration—right patient, drug, dose, route, time, assessment, evaluation, and documentation. WHO also mandates medication reconciliation during all transitions of care, such as admission, transfer, and discharge, to prevent omissions, duplications, and dosing errors. At the institutional level, studies demonstrate that the absence of clear guidelines significantly increases the likelihood of medication errors, with an adjusted odds ratio (AOR) of 1.65, underscoring the protective role of standardized protocols. Effective medication-safety programs further require non-punitive reporting systems, supported by standard operating procedures (SOPs), leadership commitment, and, where appropriate, incentives that encourage transparent reporting and learning. National initiatives such as Egypt's Egyptian Neonatal Safety Training Network (ENSTN) and Ireland's National Adverse Events Management System (NAEMS) exemplify best practices by enforcing confidential, structured reporting, particularly in high-risk settings like neonatal intensive care units (NICUs), thereby fostering a culture of safety, accountability, and continuous quality improvement.[12]

[9] MEDICATION ERRORS: UNDERSTANDING THE TYPES, CAUSES, AND PREVENTION, AND THE CRITICAL ROLE OF PHARMACISTS
[10] MEDICATION ERRORS: UNDERSTANDING THE TYPES, CAUSES, AND PREVENTION, AND THE CRITICAL ROLE OF PHARMACISTS
[11] UNRAVELING MEDICATION ERRORS IN INDIAN SCHOLARLY ARTICLES (2010–2023): A COMPREHENSIVE REVIEW
[12] UNRAVELING MEDICATION ERRORS IN INDIAN SCHOLARLY ARTICLES (2010–2023): A COMPREHENSIVE REVIEW

Enforcement and Accountability

Regulatory and organizational approaches increasingly emphasize blame-free yet accountable systems to address medication errors by balancing learning with responsibility. Modern patient-safety frameworks legally protect healthcare professionals who report errors in good faith, fostering non-punitive reporting cultures that encourage transparency and early detection of system flaws. However, when unsafe practices persist or are repeatedly ignored, accountability is enforced through institutional committees, clinical governance mechanisms, and senior leadership oversight. Persistent underreporting, documented at 66.7% in Turkey and with nearly 90% of errors disclosed only through self-reports, often triggers targeted audits, feedback loops, and corrective action plans to strengthen compliance and safety behavior. Alongside cultural reforms, technology- and process-based regulations play a critical preventive role: barcode medication administration linked to electronic medication administration records (BCMA–eMAR) has been shown to reduce administration errors by approximately 50%, computerized physician order entry (CPOE) systems with clinical decision support (CDS) minimize prescribing and transcription errors, and smart infusion pumps help prevent dosing and rate-related mistakes. The widespread adoption of electronic prescribing further eliminates handwriting-related errors and improves communication across care teams.[13] Collectively, these measures shift the focus from individual blame to system-level risk reduction, supported by laws and policies that mandate ongoing training—particularly vital given reports of 88.4% of nurses lacking formal medication-safety training—as well as workload optimization, interruption control, and multidisciplinary oversight by pharmacists and nurses, strategies that together have the potential to prevent up to 75% of medication-related harm.

5. Conclusion

All healthcare professionals share a collective responsibility to identify and address the factors contributing to medication errors, utilizing this understanding to minimize their occurrence. Medication errors arise from a complex interplay of multiple factors, necessitating a multidisciplinary strategy that acknowledges the universal potential for human error within healthcare settings. It is imperative that healthcare workers feel encouraged to report such errors without fear of professional repercussions, fostering a culture of transparency and learning rather than blame. Comprehensive safety protocols should be widely implemented to strengthen patient safety mechanisms.

An effective medication error reporting system should ensure reporter safety, generate actionable recommendations, result in meaningful systemic improvements, involve all relevant stakeholders, and be adequately supported by institutional resources. Research indicates that while potential drug interactions are not directly correlated with hospital stay duration, several factors significantly contribute to medication administration errors—these include inadequate training, lack of clear medication administration guidelines, interruptions during medication delivery, ineffective communication during problem-solving, and failure to adhere to the “ten rights” of medication administration.

To mitigate these errors, healthcare institutions must implement structured and standardized measures, such as continuous education and training programs, independent double-check systems, clear procedural protocols, adherence to the “five rights,” accurate documentation, and open channels of communication. Additionally, patients should be informed about the medications they receive, labeling and packaging should be improved for clarity, and work environments should be optimized to reduce workload and distractions. Building a supportive, blame-free culture and enhancing job security for nurses are also vital to encourage active error reporting. Hospital administrations must take an active role in revising reporting processes, promoting awareness about the importance of medication error reporting, and ensuring consistent system improvements. Ultimately, awareness among healthcare professionals and patients regarding the types, causes, and prevention of medication errors is essential to safeguarding patient safety and elevating the overall quality of healthcare delivery.

[13] UNRAVELING MEDICATION ERRORS IN INDIAN SCHOLARLY ARTICLES (2010–2023): A COMPREHENSIVE REVIEW