

MINI REVIEW ON: A STUDY OF ADRS IN GERIATRIC OR PEDIATRIC PATIENTS IN A TERTIARY CARE HOSPITAL

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Article Info:

Received: 30 March 2026,

Revised: 20 April 2026,

Accepted: 10 May 2026

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Citation:

Adarsh Verma^{1*}, Dr. Manish Kumar Patel², Akshat Patel¹, Akash Kushwaha. (2026). Mini Review On: A Study Of Adrs In Geriatric Or Pediatric Patients In A Tertiary Care Hospital. International Journal of Clinical and Pharmaceutical Innovations, 1(2), 72-78.

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ABSTRACT

In clinical practice, adverse drug reactions, or ADRs, pose a significant obstacle, particularly for vulnerable populations like children and the elderly. These groups are highly susceptible due to physiological differences, polypharmacy, and altered pharmacokinetics and pharmacodynamics. In tertiary care hospitals, the purpose of this review is to investigate the incidence, patterns, risk factors, and outcomes of ADRs in geriatric and pediatric patients. Multiple studies' findings indicate that ADRs significantly increase hospital admissions and morbidity. In geriatric patients, polypharmacy, comorbidities, and age-related physiological changes increase ADR risk, whereas in pediatric patients, immature organ systems and dosing errors are key contributors. Various assessment tools such as the Naranjo Scale and Hartwig Severity Scale are widely used to evaluate ADRs. Pharmacovigilance programs play a crucial role in monitoring and preventing ADRs. The review highlights the need for improved ADR reporting systems, rational prescribing, and patient-specific therapeutic approaches to minimize adverse outcomes.

KEYWORDS: ADR Pharmacovigilance, Geriatric, Pediatric, Polypharmacy, Tertiary Care Hospital.

INTRODUCTION

Adverse drug reactions (ADRs) constitute a significant challenge to patient safety and healthcare delivery systems worldwide. In a nutshell, They are any harmful, unintended, or undesirable effects of a medication that occur at doses typically prescribed for human prophylaxis, diagnosis, or treatment. Edwards and Aronson's conceptual framework for ADR classification divides reactions into predictable (Type A) and unpredictable (Type B) events, as well as chronic (Type C) and delayed (Type D) reactions. This classification not only aids in understanding the mechanistic basis of ADRs but also facilitates clinical decision-making, risk stratification, and preventive strategies in routine medical

practice.

Epidemiological Burden of ADRs

ADRs are a significant burden on healthcare systems and are acknowledged as a global leading cause of morbidity and mortality. Epidemiological investigations have consistently demonstrated that ADRs account for approximately 5–10% of hospital admissions and are responsible for a considerable proportion of in-hospital complications. Furthermore, a Significant number of patients experience at least one ADR during their hospital stay, which often leads to prolonged hospitalization, increased healthcare expenditure, and, in severe cases, fatal outcomes. The fact that adverse drug

reactions (ADRs) are frequently underreported has been emphasized by landmark studies, limiting the effectiveness of pharmacovigilance systems and obscuring their actual incidence. This underreporting is

particularly pronounced in developing countries, where structured reporting mechanisms and awareness among healthcare professionals remain suboptimal.

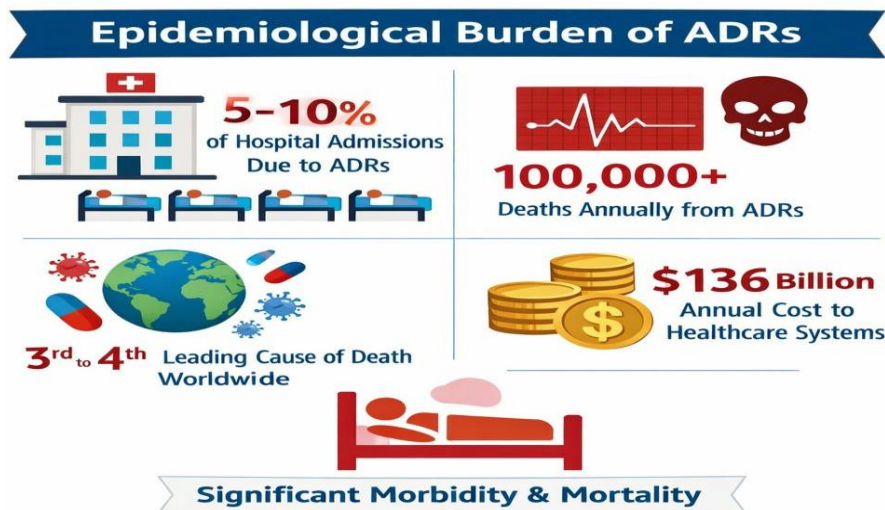


Figure- 1

ADRs in the context of tertiary care hospital

Tertiary care hospitals represent a critical setting for the evaluation and management of ADRs due to their role in treating complex and critically ill patients. High rates of comorbid conditions, extensive use of cutting-edge pharmacotherapeutic interventions, and high patient turnover are all characteristics of these facilities. As a consequence of this, patients who are admitted to tertiary care facilities are frequently exposed to multiple

medications at the same time, which raises the potential for adverse drug reactions and interactions. A significant factor in the occurrence of adverse drug reactions (ADRs) has been identified as the phenomenon of polypharmacy, which is especially prevalent in such settings. Moreover, the presence of severe underlying diseases often necessitates aggressive treatment regimens, further compounding the risk of adverse drug events.

Risk Factors for ADRs

Table: Risk Factors

Factor	Geriatric	Pediatric
Polypharmacy	High	Low
Organ immaturity	No	Yes
Comorbidities	High	Moderate Dosing errors, Moderate, High

ADR Reporting System

Flow Diagram-
Patient → ADR occurs → Doctor detects → Report to Pharmacovigilance Center

Role of Healthcare Professionals

Doctors → Prescribing

Pharmacists → Monitoring & counseling Nurses → Detection & reporting

Vulnerability of Geriatric Population

Due primarily to the high prevalence of comorbidities and age-related physiological changes, the geriatric population is one of the most vulnerable to ADRs. Changes in body composition, such as an increased fat-to-lean body mass ratio, and alterations in pharmacokinetic processes, such as decreased renal clearance and diminished hepatic metabolism, are all linked to aging. The likelihood of drug accumulation and

toxicity is raised by these modifications, which can have a significant impact on drug distribution and elimination. Additionally, polypharmacy, a Well-established risk factor for ADRs occurs when elderly patients are prescribed multiple medications to manage chronic conditions. Inappropriate prescribing practices, including the use of potentially inappropriate medications, further exacerbate the risk in this population.

Consequently, careful monitoring and individualized therapeutic approaches are essential for minimizing ADRs in geriatric patients.

Risk Factors and Contributing Determinants

The occurrence of ADRs is influenced by a complex interplay of patient-related, drug- related, and healthcare system-related factors. Polypharmacy, comorbidities, and physiological decline are the determinants of ADR risk

in elderly patients. In contrast, pediatric ADRs are often associated with dosing inaccuracies, off-label drug use, and developmental pharmacokinetic variability. The prevalence of adverse drug reactions (ADRs) in both populations is further exacerbated by additional factors such as genetic predisposition, drug interactions, and inappropriate prescribing practices. The identification and mitigation of these risk factors are critical for reducing the burden of ADRs and improving patient outcomes.

Susceptibility of Pediatric Population

Due to the unique characteristics of their developing physiological systems, pediatric patients are another group at high risk for ADRs. Age-related changes in organ function and enzyme activity are largely responsible for the significant variation in drug absorption, distribution, metabolism, and excretion that children exhibit in comparison to adults. The immaturity of hepatic and renal systems in neonates and infants can lead to altered drug clearance and increased susceptibility to toxicity. Additionally, the use of off-label and unlicensed medications frequently becomes necessary due to a lack of adequate clinical trials in pediatric populations, raising the risk of adverse outcomes. A common cause of ADRs in children is dosage errors, particularly those involving weight-based calculations. These factors underscore the importance of age-appropriate dosing guidelines and vigilant monitoring in pediatric pharmacotherapy.

Problems with ADR Reporting

Underreporting remains a significant obstacle in pharmacovigilance, despite the recognition of the significance of ADR monitoring. Factors contributing to underreporting include lack of awareness among healthcare professionals, uncertainty in identifying ADRs, fear of legal consequences, and absence of incentives for reporting. In addition, time constraints and workload pressures in clinical settings often limit the ability of healthcare providers to document and report ADRs effectively. Education programs, simplified reporting procedures, and the integration of electronic health records with pharmacovigilance systems are all needed to address these issues.

Rationale and Objectives of the Review

Given the substantial burden of ADRs and the increased vulnerability of geriatric and pediatric populations, there is a pressing need for comprehensive studies that evaluate the patterns, risk factors, and outcomes of ADRs in these groups. Tertiary care hospitals provide an ideal environment for such investigations due to their diverse patient population and extensive use of pharmacotherapy. The present review aims to synthesize available evidence on ADRs in geriatric and pediatric patients, with a focus on their epidemiology, causative factors, clinical manifestations, and prevention strategies. By highlighting the key determinants of ADRs and identifying potential areas.

MAIN Body

1. The prevalence and epidemiology of ADRs

Adverse drug reactions (ADRs) represent a substantial proportion of preventable morbidity in hospital settings, particularly within tertiary care institutions. A significant proportion of hospital admissions and in-hospital complications are attributed to ADRs, according to epidemiological studies. The incidence of ADRs varies widely depending on the study design, population characteristics, and healthcare setting; however, it is consistently observed that hospitalized patients are at a higher risk due to increased exposure to multiple pharmacological agents. In geriatric populations, the incidence of ADRs is markedly higher, largely due to age-related physiological changes and the presence of multiple comorbid conditions. On the other hand, despite the fact that pediatric populations may have relatively lower reported incidence rates, this is frequently a result of diagnostic difficulties and underreporting rather than an actual decrease in incidence. The variability in ADR incidence highlights the need for robust pharmacovigilance systems and standardized reporting mechanisms in tertiary care hospitals.

2. Polypharmacy and Its Clinical Implications

Polypharmacy, which is defined as taking five or more medications at once, is common among elderly patients and a major cause of adverse drug reactions (ADRs). The clinical implications of polypharmacy extend beyond the increased risk of ADRs to include drug-drug interactions, medication non-adherence, and functional decline. Chronic conditions like hypertension, diabetes, and heart disease frequently necessitate the use of multiple medications in elderly patients. This makes pharmacokinetic and pharmacodynamic interactions more likely, which can amplify adverse effects. Furthermore, inappropriate prescribing practices, including the use of unnecessary or contraindicated medications, exacerbate the risk. In pediatric populations, although polypharmacy is less common, the use of multiple medications in critically ill children can similarly increase the risk of ADRs. Therefore, regular medication review and rationalization of drug therapy are essential strategies for minimizing polypharmacy-related risks.

3. Considerations Concerning Pharmacokinetics and Pharmacodynamics Modifications

In pharmacokinetic and pharmacodynamic processes have a significant impact on the incidence of ADRs in the pediatric and geriatric populations. In geriatric patients, physiological aging leads to decreased renal function, reduced hepatic metabolism, and changes in body composition, such as increased adipose tissue and decreased lean body mass. These changes can result in prolonged drug half-life, altered drug distribution, and increased susceptibility to toxicity.

Pharmacodynamic changes, including altered receptor sensitivity, further contribute to variability in drug

response. Drug disposition and response in children are significantly monitoring to prevent ADRs. The significance of individualized pharmacotherapy is emphasized by the dynamic nature of physiological changes in both populations.

Patterns and Clinical Manifestations of ADRs

The clinical presentation of ADRs varies widely depending on the patient population and the drugs involved. In geriatric patients, ADRs commonly manifest as gastrointestinal disturbances, central nervous system effects such as dizziness and confusion, and cardiovascular complications including hypotension and arrhythmias. These manifestations can often be mistaken for symptoms of underlying diseases, leading to underdiagnosis and inappropriate management. ADRs frequently manifest as gastrointestinal symptoms like nausea and diarrhea in pediatric patients in addition to cutaneous reactions like rashes and urticaria. Allergic reactions and hypersensitivity responses are also more commonly observed in this population. The identification of ADRs in children is particularly challenging due to limited communication abilities in younger age groups and the nonspecific nature of symptoms. To stop ADRs from progressing to more severe outcomes, prompt diagnosis and treatment are essential.

Classes of drugs frequently linked to ADRs

Certain classes of drugs are more frequently implicated in ADRs across both geriatric and pediatric populations. Antibiotics are among the most commonly reported causes of ADRs, particularly in pediatric patients, where they are associated with allergic reactions and gastrointestinal disturbances. Especially in elderly patients, nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently linked to gastrointestinal bleeding and kidney impairment.

Antihypertensive agents, antidiabetic drugs, and anticoagulants are also commonly implicated in ADRs in geriatric populations due to their widespread use and narrow therapeutic indices.

Inappropriate dosing, drug interactions, and patient-specific characteristics all increase the risk associated with these drug classes. To reduce the risk of adverse drug reactions (ADRs) associated with commonly used drug classes, it is therefore necessary to select medications with care, optimize doses, and monitor patients frequently.

Causality Assessment of ADRs

A crucial aspect of ADR evaluation is the precise assessment of causality, which is necessary to establish the connection between a drug and an adverse event. One of the instruments that is utilized the most frequently for this purpose is the Naranjo Adverse Drug Reaction Probability Scale. It employs a structured questionnaire to assign a probability score, categorizing ADRs as definite, probable, possible, or doubtful. This methodical

approach makes ADR evaluation more objective and makes it easier to compare studies. Causality assessment is particularly important in complex.

Assessment of Severity and Clinical Results

From mild, self-limiting reactions to severe, life-threatening conditions, ADR severity can vary. Typically, the Hartwig Severity Assessment Scale is utilized to classify ADRs according to their impact on the clinical setting. Moderate reactions may necessitate adjustments to therapy or additional treatment, whereas mild reactions typically do not require significant intervention. Hospitalization, permanent disability, or death are possible outcomes of severe ADRs. Due to the presence of multiple risk factors, including comorbidities and polypharmacy, severe ADRs are more prevalent in elderly patients. Even though many ADRs in children are mild, severe reactions like anaphylaxis and Stevens-Johnson syndrome can happen. Prioritizing interventions and improving patient outcomes depend on knowing how severe ADRs are.

Risk Factors Relating to ADRs

A variety of intrinsic and extrinsic factors influence the onset of ADRs. Important risk factors in elderly patients include polypharmacy, multiple comorbidities, impaired organ function, and advanced age. Dosing errors, age-related physiological immaturity, and the use of off-label medications are all risk factors in children. A number of other factors contribute to the occurrence of adverse drug reactions (ADRs), including genetic variation, drug interactions, and influences from the environment. For the purpose of putting preventative measures into action, it is essential to identify these risk factors.

High-risk patients can be identified and pharmacotherapy tailored using risk stratification tools and clinical judgment. Dosage adjustments, therapeutic drug monitoring, and patient education are all preventative measures that can significantly lower the incidence of ADRs.

Pharmacovigilance and ADR Reporting Systems

Pharmacovigilance relies heavily on accurate ADR reporting to identify new safety signals and enhance drug safety. Tertiary care hospitals frequently use spontaneous reporting systems, which rely on healthcare professionals to report suspected ADRs. Pharmacovigilance centers collect and analyze these reports to discover ADR occurrence patterns and trends. Despite the importance of ADR reporting, underreporting remains a major challenge. Low reporting rates are caused by factors like a lack of awareness, a lack of time, and a fear of legal consequences.

Strengthening pharmacovigilance systems through education, training, and the use of electronic reporting platforms can enhance ADR detection and prevention. Improving patient safety necessitates incorporating pharmacovigilance into routine clinical practice.

A multifaceted strategy involving healthcare professionals, patients, and healthcare systems is required for the prevention and management of ADRs. The selection of appropriate drugs and doses, as well as rational prescribing practices, is essential to reducing ADR risk. Geriatric patients benefit especially from regular medication review and deprescription of unnecessary medications. By facilitating early recognition of adverse effects and increasing medication adherence, patient education and counseling play a crucial role in preventing ADRs. In pediatric patients, accurate dosing and careful monitoring are essential to

prevent medication errors. Electronic prescribing and clinical decision support systems both have the potential to further improve medication safety. Early detection and prompt management of ADRs are critical for reducing their severity and preventing complications. The offending drug should be stopped, symptomatic treatment should be started, and supportive care should be provided. Hospitalization and specialized treatment may be necessary in severe cases. Patient outcomes can be significantly improved and the burden on healthcare systems reduced with a proactive approach to ADR prevention and management.

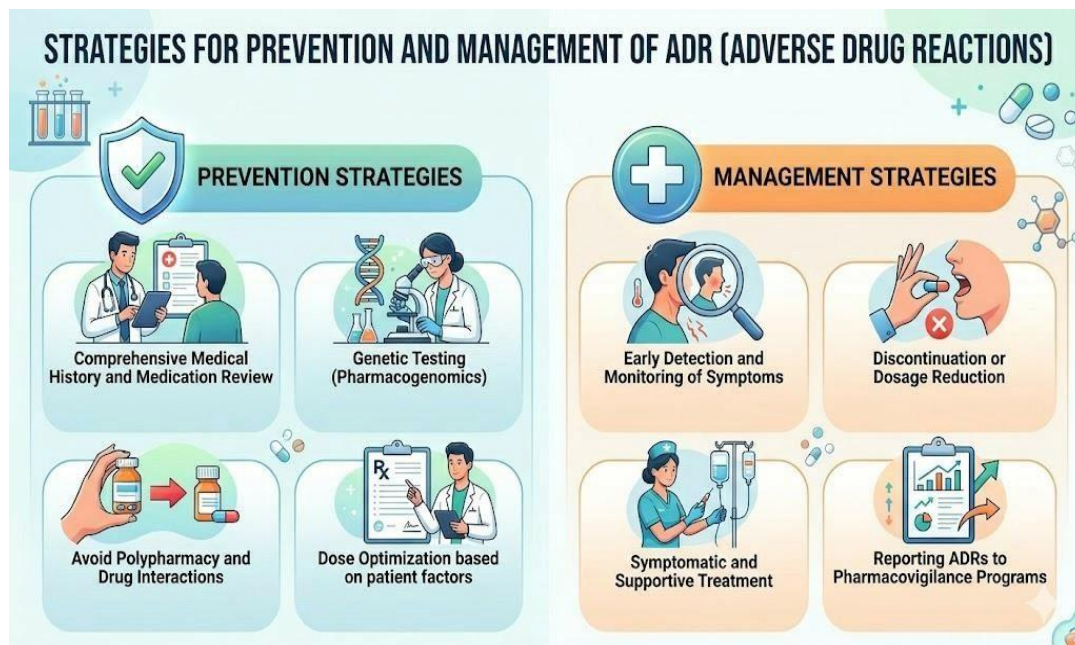


Figure no.- 2

THE DISCUSSION

In clinical practice, adverse drug reactions (ADRs) continue to be a significant obstacle, particularly in tertiary care hospitals where patient conditions and therapeutic regimens are significantly more complex. Due to distinct physiological and pharmacological factors, the geriatric and pediatric populations are particularly susceptible to ADRs, according to this review's synthesis of findings. The high prevalence of comorbidities and the widespread use of multiple medications significantly increase the incidence of adverse drug reactions (ADRs) in elderly patients. Age-related changes in pharmacokinetics and pharmacodynamics further exacerbate this risk, leading to altered drug responses and increased susceptibility to adverse outcomes. Previous research has identified polypharmacy and physiological decline as ADR determinants in elderly populations, and these findings are in line with these observations. In contrast, pediatric patients present a different but equally important set of challenges. ADRs are more likely to occur because of the variability in drug metabolism and excretion caused by the immaturity of organ systems, especially in newborns and infants. Additionally, the frequent use of off-label

and unlicensed medications in pediatric practice contributes to uncertainty in drug safety and efficacy. Dosing errors, often arising from weight-based calculations, are another critical factor that predisposes children to ADRs. The problem is made even more complicated by the difficulty in identifying and reporting ADRs in children, particularly in younger age groups who are unable to effectively communicate symptoms. These factors collectively underscore the need for specialized approaches to pharmacotherapy in pediatric populations.

The role of pharmacovigilance in detecting, assessing, and preventing ADRs cannot be overstated. Underreporting of ADRs persists despite the establishment of national and international pharmacovigilance programs. This review highlights those factors such as lack of awareness, inadequate training, time constraints, and fear of legal low reporting rates among healthcare professionals. Despite its value, relying on spontaneous reporting systems is constrained by these obstacles. Therefore, there is a need to strengthen pharmacovigilance systems through the integration of electronic health records, automated

reporting mechanisms, and continuous education of healthcare providers. Enhancing the culture of safety within healthcare institutions is essential to improve ADR reporting and patient outcomes.

The significance of standardized tools in the evaluation of ADRs is another significant aspect that has been brought to light in this review. Instruments such as the Naranjo Adverse Drug Reaction Probability Scale and the Hartwig Severity Assessment Scale provide a structured approach to evaluating causality and severity, respectively. The reliability and comparability of ADR data across studies are enhanced by using these tools. However, their application in routine clinical practice may be limited by time constraints and lack of familiarity among healthcare professionals. Training programs and the incorporation of these tools into clinical workflows may improve their utilization and contribute to more accurate ADR assessment.

In general, the focus of this review is on the fact that ADRs are a multifactorial issue that necessitates coordinated efforts on the part of healthcare professionals, patients, and healthcare systems. Pharmacotherapy strategies must be tailored to each patient due to the distinct risk profiles of the geriatric and pediatric populations. In order to lessen the burden of ADRs in tertiary care hospitals, it is essential to improve healthcare providers' awareness, promote rational drug use, and strengthen pharmacovigilance systems.

CONCLUSION

Adverse drug reactions, or ADRs, continue to be a major concern for public health, particularly in vulnerable populations like children and the elderly. The findings of this review demonstrate that the incidence and severity of ADRs are influenced by a complex interplay of physiological, pharmacological, and healthcare-related factors. Geriatric patients are at a higher risk of ADRs due to age-related physiological changes, multiple comorbidities, and polypharmacy, whereas pediatric patients are particularly susceptible due to immature organ systems, variability in drug metabolism, and the frequent use of off-label medications.

The study underscores the critical role of pharmacovigilance in monitoring and preventing ADRs. Underreporting remains a significant obstacle despite the availability of structured pharmacovigilance programs, highlighting the need for enhanced awareness, training, and reporting systems. The use of standardized tools for causality and severity assessment can enhance the accuracy and reliability of ADR evaluation, thereby contributing to better clinical decision-making.

A multidisciplinary approach that incorporates rational prescribing, regular medication reviews, patient education, and the utilization of advanced clinical support systems is.

In conclusion, tertiary care hospitals must reduce the number of ADRs by improving pharmacovigilance procedures, promoting patient-centered care, and implementing strategies based on evidence. Future research should focus on developing innovative approaches for ADR detection and prevention, as well as enhancing the integration of pharmacovigilance into routine clinical practice to ensure safer and more effective use of medications.

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