**Student's Journal of Health Research Africa**
**e-ISSN: 2709-9997, p-ISSN: 3006-1059**
**Vol.6 No. 6(2025): June 2025 Issue**
**https://doi.org/10.51168/sjhrafrica.v6i6.2005**
**Original Article**

# Incidence and pattern of adverse drug reactions among pediatric inpatients: A prospective observational study.

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## Abstract

### Background:
Adverse drug reactions (ADRs) are a significant cause of morbidity in the pediatric population due to age-specific pharmacodynamic and pharmacokinetic variations. Active surveillance is crucial to understanding the pattern and burden of ADRs in this vulnerable group.

### Objectives:
To determine the incidence, spectrum, causality, and severity of adverse drug reactions in pediatric patients at a tertiary care hospital.

### Methods:
A prospective observational study was conducted over 12 months (March 2024–February 2025) in the Department of Pediatrics, Santhiram Medical College, Nandyal, Andhra Pradesh. A total of 100 inpatients aged <12 years were enrolled and monitored daily for suspected ADRs, which were documented and analyzed. Severity was graded using the Modified Hartwig and Siegel Scale, and causality was assessed by WHO-UMC criteria.

### Results:
Out of 100 children, 26 (26%) experienced at least one ADR, accounting for 35 reactions. Infants aged <1 year showed the highest incidence (30%), with a slight male predominance. Antibiotics (48.6%) were the most frequently implicated drug class, followed by antiepileptics (20%) and NSAIDs (14.3%). Gastrointestinal (31.4%) and dermatological (25.7%) systems were most affected. Most ADRs were mild (65.7%), while 28.6% were moderate and 5.7% severe. According to WHO-UMC criteria, 40% were classified as possible, 37.1% as probable, and 22.9% as certain.

### Conclusion:
A significant proportion of pediatric inpatients experienced ADRs, predominantly associated with antibiotics and antiepileptics. Most were mild to moderate and resolved without sequelae. The study underscores the importance of proactive monitoring and reporting systems to improve pediatric medication safety.

### Recommendations:
Routine pharmacovigilance training and electronic monitoring should be integrated into pediatric care to reduce preventable adverse drug events.

***Keywords:*** *Adverse drug reactions, Pediatrics, Pharmacovigilance, Drug safety, Antibiotics, Causality assessment*
***Submitted: March 20, 2025 Accepted: May 15, 2025, Published: June 30, 2025***
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## Introduction
Adverse drug reactions (ADRs) represent a significant clinical concern in pediatric pharmacotherapy, contributing to notable morbidity and, in some instances, mortality [1]. Children are inherently more vulnerable to ADRs than adults due to their physiological immaturity, age-dependent

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pharmacokinetics, and evolving pharmacodynamic responses [1,2]. The prevalent use of off-label and unlicensed medications in pediatric practice further compounds this risk, often without adequate safety data [2]. Globally, the incidence of ADRs among hospitalized pediatric populations has been reported to range between 2% and 20%, with particularly elevated rates observed in intensive care settings [3]. In resource-constrained settings such as India, underreporting remains a major obstacle in accurately estimating ADR burden, often due to limited awareness, insufficient pharmacovigilance systems, and the inherent diagnostic challenges in non-verbal or preverbal children [4].

Commonly implicated drug classes include antibiotics, antiepileptic drugs, and nonsteroidal anti-inflammatory drugs (NSAIDs), with frequent clinical presentations involving gastrointestinal, dermatological, or neurological manifestations [5]. Although many available studies rely on retrospective or passive surveillance data, which tend to underestimate both frequency and severity, prospective observational studies using active monitoring provide more reliable estimates and actionable insights [3,6]. Standardized assessment frameworks such as the WHO-UMC causality assessment and the Modified Hartwig and Siegel severity scale are increasingly recommended for consistent and objective ADR evaluation [6].

Given this background, the present study was undertaken to evaluate the incidence, nature, severity, and causality of ADRs among pediatric inpatients in a tertiary care setting through a prospective observational design. The findings aim to contribute to the evidence base required for improving pediatric drug safety and enhancing pharmacovigilance efforts in clinical practice.

## Materials and Methods

### Study Design and Setting:

This was a hospital-based prospective observational study conducted in the Department of Pediatrics, Santhiram Medical College, Nandyal, Andhra Pradesh, over 12 months from March 2024 to February 2025.

### Study Population:

Pediatric patients aged between **1 month and 12 years** who were admitted to the pediatric ward during the study period were included. Children were monitored throughout their hospital stay for the development of any suspected adverse drug reactions (ADRs).

### Inclusion Criteria:

Pediatric inpatients aged 1 month to 12 years.
Children who received one or more medications during hospitalization.
Consent obtained from parents or legal guardians.

### Exclusion Criteria:

Patients with known hypersensitivity reactions to drugs before admission.
Children admitted for poisoning or drug overdose.
Patients were discharged within 24 hours of admission.

### Data Collection:

A structured proforma was used to collect demographic details, clinical diagnosis, drug history (dose, route, and duration), and details of suspected ADRs. Active daily surveillance was done through chart reviews, patient monitoring, and discussions with treating clinicians.

### ADR Assessment:

All suspected ADRs were assessed by a team of pediatricians and pharmacologists.
Causality assessment was performed using the WHO-UMC criteria.
Severity of ADRs was graded using the Modified Hartwig and Siegel Scale.
Preventability was evaluated using the Schumock and Thornton criteria (if applicable).

### Sample Size:

The sample size was determined based on the average inpatient admissions to the pediatric ward during the study period and the feasibility of daily monitoring for ADR detection. Thus, 100 consecutive inpatients meeting the inclusion criteria were enrolled, ensuring adequate representation across different age groups.

### Data Analysis:

Data were entered into Microsoft Excel and analyzed using SPSS version 26. Descriptive statistics such as frequencies and percentages were used to summarize the data. Incidence of ADRs was calculated, and cross-tabulations were done by age group, drug class, and severity level.

### Bias:

To minimize selection bias, all consecutive eligible pediatric inpatients were included during the study period. Observer bias was reduced by using a standardized proforma and

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validated scales (WHO-UMC and Modified Hartwig and Siegel) for assessment. Underreporting was limited through active daily surveillance by the research team in collaboration with treating clinicians. However, recall bias after discharge could not be fully eliminated as follow-up was not performed.

## Ethical Considerations:

The study was approved by the Institutional Ethics Committee o**f Santhiram Medical College**, Nandyal. Written informed consent was obtained from the parents or guardians of all participants before inclusion.

## Results

All consecutive pediatric inpatients meeting the inclusion criteria during the study period were enrolled, resulting in a final sample of 100 children. No participants were excluded after enrollment, and all were analyzed until discharge.

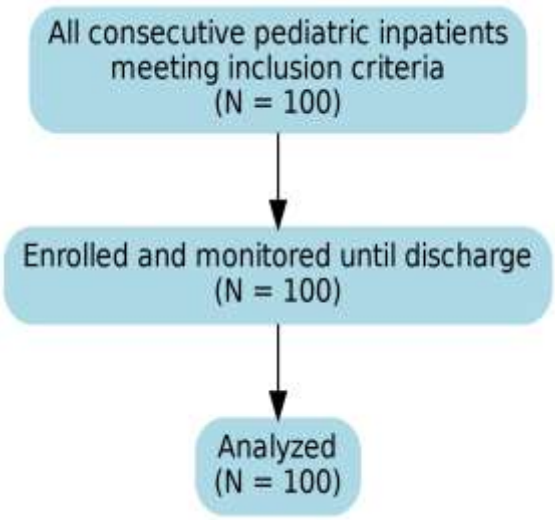


**Figure 1. Participant Flow Diagram**

Out of 100 pediatric patients enrolled, 26 (26%) experienced at least one adverse drug reaction (ADR), with a total of 35 ADRs documented. The highest incidence was observed in infants aged <1 year (30.0%), followed by children aged 1–5 years (27.5%) and 6–12 years (22.5%). A slight male predominance was noted, with ADRs occurring in 27.6% of boys compared to 23.8% of girls (Table 1).

**Table 1. Demographic Characteristics and Incidence of Adverse Drug Reactions (N = 100)**

| Variable | Category | Patients n (%) | Patients with ADRs n (%) | ADR Incidence (%) |
|---|---|---|---|---|
| **Age group** | <1 year | 20 (20.0) | 6 (6.0) | 30.0 |
| | 1–5 years | 40 (40.0) | 11 (11.0) | 27.5 |
| | 6–12 years | 40 (40.0) | 9 (9.0) | 22.5 |
| **Gender** | Male | 58 (58.0) | 16 (16.0) | 27.6 |
| | Female | 42 (42.0) | 10 (10.0) | 23.8 |
| **Total** | | 100 (100) | 26 (26.0) | 26.0 |

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The majority of ADRs were associated with antibiotics (48.6%), which was the most frequently implicated drug class, followed by antiepileptics (20.0%), NSAIDs (14.3%), antipyretics (8.6%), and other agents including vaccines (8.6%) (Table 2). These findings underscore the predominant role of antimicrobials and centrally acting agents in pediatric ADR profiles.



**Table 2: Drug Classes Implicated in Adverse Drug Reactions (n = 35)**

| Drug Class | Number of ADRs | Percentage (%) |
|---|---|---|
| Antibiotics | 17 | 48.6 |
| Antiepileptics | 7 | 20.0 |
| NSAIDs | 5 | 14.3 |
| Antipyretics | 3 | 8.6 |
| Others (e.g., Vaccines etc.) | 3 | 8.6 |

In terms of the affected organ systems, gastrointestinal (31.4%) and dermatological (25.7%) manifestations were most common, followed by adverse effects involving the central nervous system (17.1%), respiratory system (14.3%), and other systems (11.5%) (Table 3). The most frequently reported gastrointestinal ADRs included vomiting and diarrhea, while dermatological reactions comprised rash and urticaria.

**Table 3: Organ Systems Affected by Adverse Drug Reactions (n = 35)**

| System Affected | Number of ADRs | Percentage (%) |
|---|---|---|
| Gastrointestinal | 11 | 31.4 |
| Dermatological | 9 | 25.7 |
| Central Nervous System | 6 | 17.1 |
| Respiratory | 5 | 14.3 |
| Others | 4 | 11.5 |

Regarding severity, most ADRs were mild (65.7%) in nature, followed by moderate (28.6%), and severe (5.7%). Causality assessment using WHO-UMC criteria categorized 14 ADRs (40.0%) as *possible*, 13 (37.1%) as *probable*, and 8 (22.9%) as *certain* (Table 4). All ADRs were managed conservatively, and no mortality or long-term sequelae were reported. Most reactions resolved within 72 hours of drug withdrawal or symptomatic treatment.

**Table 4: Severity and Causality Assessment of ADRs (n = 35)**

| Category | Number of ADRs | Percentage (%) |
|---|---|---|
| Mild | 23 | 65.7 |
| Moderate | 10 | 28.6 |
| Severe | 2 | 5.7 |
| Certain | 8 | 22.9 |
| Probable | 13 | 37.1 |
| Possible | 14 | 40.0 |

## Discussion

This prospective observational study evaluated the incidence, clinical patterns, and causality of adverse drug reactions (ADRs) among hospitalized pediatric patients in a tertiary care setting. The overall incidence of ADRs was 26%, which falls within the higher range reported in similar hospital-based pediatric studies employing active surveillance methods [7]. This notable frequency underscores the pressing need for systematic ADR monitoring in routine pediatric clinical practice.

A higher incidence of ADRs was observed in children under one year of age (30%), reaffirming previous findings that infants are particularly vulnerable due to immature hepatic

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and renal function, limited enzymatic capacity, and unpredictable pharmacokinetics [8]. Additionally, a predominance of ADRs among male children, although not statistically tested in this study, aligns with previously published demographic trends in pediatric pharmacovigilance literature [9].

Antibiotics emerged as the most frequently implicated drug class (48.6%), followed by antiepileptic drugs and NSAIDs. These findings are consistent with global data identifying antimicrobials and neurologically active agents as common culprits, especially in hospital settings where empirical prescribing is widespread [10]. The empirical use of broad-spectrum antibiotics, often in the absence of definitive culture sensitivity, likely contributes to this pattern.

Gastrointestinal symptoms such as vomiting and diarrhea, along with dermatological reactions like rashes, were the most common clinical manifestations. These findings are in concordance with prior reports highlighting these systems as the most frequent targets of pediatric ADRs due to their rapid turnover and immunologic sensitivity [11]. The majority of ADRs were mild to moderate in severity and resolved either with discontinuation of the offending agent or supportive therapy, emphasizing the importance of early recognition to prevent escalation into serious outcomes [12]. Causality assessment using the WHO-UMC scale revealed that 40% of ADRs were classified as 'possible', while 37.1% and 22.9% were categorized as 'probable' and 'certain', respectively. This distribution reflects challenges inherent in pediatric settings, especially when multiple drugs are administered simultaneously, making it difficult to definitively attribute causality [13]. The use of standardized causality and severity tools enhances the objectivity and reproducibility of pharmacovigilance data and should be integrated into routine hospital practice.

## Generalizability

The findings of this study, though derived from a single tertiary care hospital, apply to similar pediatric inpatient settings in India and other low- and middle-income countries where antibiotic use is common and pharmacovigilance systems are still evolving. The patterns of drug classes implicated, age-related vulnerability, and predominance of mild to moderate reactions mirror those reported in international literature, suggesting that the results have reasonable external validity. However, caution is needed when extrapolating to outpatient or community populations, where drug exposure profiles and monitoring practices may differ.

## Conclusion

This prospective observational study highlights a notable incidence of adverse drug reactions (ADRs) among hospitalized pediatric patients, with antibiotics being the most commonly implicated drug class. The majority of ADRs were mild to moderate in severity and affected the gastrointestinal and dermatological systems. Younger children, particularly those under one year of age, exhibited a higher susceptibility. Most ADRs were categorized as possible or probable based on the WHO-UMC causality assessment. These findings underscore the critical need for active pharmacovigilance, early recognition, and rational prescribing practices in pediatric care. Implementing structured ADR monitoring systems can significantly enhance drug safety in this vulnerable population.

## Limitations

This study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings to broader pediatric populations. The exclusion of outpatients and short-stay admissions may have underestimated the overall ADR burden. Additionally, causality assessment relied on clinical judgment and available tools, which are inherently subjective. Lack of follow-up after discharge might have missed delayed or long-term ADRs. No inferential statistics were applied to determine associations.

## Recommendations

To improve drug safety in pediatric practice, routine implementation of active pharmacovigilance systems within hospitals is essential. Clinicians should receive regular training on early recognition, documentation, and reporting of adverse drug reactions (ADRs). Establishing multidisciplinary ADR monitoring committees, including pediatricians and clinical pharmacologists, can enhance causality assessment and intervention strategies. Emphasis should be placed on rational prescribing, especially with antibiotics and high-risk medications. Integrating electronic medical record alerts and decision-support tools can aid real-time detection. Larger multicentric studies with longer follow-up are recommended to capture delayed ADRs and validate the findings across diverse pediatric populations.

## Acknowledgements

The authors express their sincere gratitude to the Department of Pediatrics, Santhiram Medical College, Nandyal, for providing the necessary support and

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https://doi.org/10.51168/sjhrafrica.v6i6.2005
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infrastructure to conduct this study. We thank all the pediatric patients and their caregivers for their participation and cooperation. Special appreciation is extended to the clinical and nursing staff for their assistance in data collection and monitoring. We also acknowledge the Institutional Ethics Committee for approving the study protocol and guiding the ethical conduct of the research.

## Abbreviations

**ADR** – Adverse Drug Reaction
**WHO-UMC** – World Health Organization–Uppsala Monitoring Centre
**NSAIDs** – Nonsteroidal Anti-Inflammatory Drugs
**CNS** – Central Nervous System

## Source of funding:

The study had no funding.

## Conflict of interest:

The authors declare no conflict of interest.

## Author contributions:

**DCS**-Concept and design of the study, results interpretation, review of literature
Sure, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.
**SSR**-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript, revision of the manuscript.

## Data availability:

Data Available

## Author Biography

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His primary interests include pediatric infectious diseases, neonatal care, and pharmacovigilance in children. He has mentored numerous student research projects and clinical audits, contributing to safer pediatric prescribing and

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**https://doi.org/10.51168/sjhrafrica.v6i6.2005**
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improved patient outcomes. **ORCID ID**: https://orcid.org/0009-0003-4342-7020



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**https://doi.org/10.51168/sjhrafrica.v6i6.2005**
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**PUBLISHER DETAILS.**



**Student's Journal of Health Research (SJHR)**
**(ISSN 2709-9997) Online**
**(ISSN 3006-1059) Print**
**Category: Non-Governmental & Non-profit Organization**
**Email: studentsjournal2020@gmail.com**
**WhatsApp: +256 775 434 261**
**Location: Scholar's Summit Nakigalala, P. O. Box 701432, Entebbe Uganda, East Africa**