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Adverse Drug Reaction Assessment in the Paediatric Population: A Non-Interventional Pharmacovigilance Study

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Abstract

Adverse drug reactions (ADRs) in children are under-reported due to limited clinical trials, off-label prescribing, and lack of caregiver awareness. Pharmacovigilance is essential to evaluate and prevent drug-related harm in paediatric populations. The objective is to identify adverse drug reactions in paediatric patients using the WHO-UMC causality assessment scale and document the pattern and severity of adverse events (AEs). Non-interventional observational study was conducted in 140 paediatric subjects (< 13 years). Clinical history, anthropometrics, and adverse events were documented. Causality was assessed using the WHO-UMC ADR Probability Scale. Descriptive statistics were applied. The mean age of subjects was 7.42 ± 2.94 years; 72.86% were male. All subjects had no significant medical history. The mean ADR probability score was 0.43 ± 1.46, indicating doubtful *causality. A total of 53 AEs were identified: nausea (16.35%), gastritis (8.81%), drowsiness (2.52%), rash (2.52%), abdominal pain (1.89%), stomach pain (0.63%), and swollen eyes (0.63%). All AEs were mild in intensity. It was Concluded that ADR incidence in the study population was low and predominantly mild. Causality scores indicate minimal association with drug therapy. Strengthening paediatric pharmacovigilance programs remains essential to ensure medication safety.*

Keywords: *Adverse Drug Reactions, Causality Assessment, Pharmacovigilance, Paediatrics, WHO-UMC.*

Introduction

Pharmacovigilance plays a critical and continuously evolving role in the identification, evaluation, and prevention of adverse effects associated with medicines and vaccines. Its importance is amplified in the paediatric population, where physiological characteristics differ significantly from those of adults. Children undergo rapid changes in body composition, organ maturity, enzyme function, and receptor sensitivity, all of which influence pharmacokinetics and pharmacodynamics [1, 2]. These developmental variations can alter drug absorption, distribution, metabolism, and excretion, making children more vulnerable to unexpected or exaggerated pharmacological responses [1, 3]. Additionally, the frequent off-label or unlicensed use of medicines in paediatrics—stemming from the lack of age-appropriate formulations and limited clinical trial data—further elevates the risk of adverse drug reactions (ADRs) [4].

Historically, several drug-related tragedies shaped the emergence of modern pharmacovigilance systems. The thalidomide catastrophe of the early 1960s, which resulted in widespread congenital malformations, underscored the dire consequences of inadequate drug safety monitoring in vulnerable populations [5]. This event catalysed global reforms, leading to the creation

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of the WHO Programme for International Drug Monitoring in 1968 and the establishment of the Uppsala Monitoring Centre, which now coordinates international efforts in signal detection and safety surveillance [6]. These initiatives strengthened the global regulatory framework and promoted a culture of systematic reporting and evaluation of ADRs.

Despite worldwide advancements, ADR reporting in India remains suboptimal. Barriers such as limited awareness among healthcare providers, inadequate training on causality assessment, fear of legal implications, and lack of structured reporting systems contribute to underreporting. The issue is even more pronounced in paediatric settings, where the interpretation of ADRs is complex, symptoms are often non-specific, and caregivers may lack awareness of reporting mechanisms. Consequently, many ADRs in children go unrecognized or unreported, preventing the generation of robust safety data.

Given this background, there is a compelling need for targeted pharmacovigilance initiatives focusing on the paediatric population. The present study aims to address this gap by systematically detecting ADRs in children and assessing their causality using a standardized approach. By evaluating the pattern, frequency, and likelihood of ADRs in paediatric patients, this study contributes to strengthening the evidence base for safe medication use in children and enhancing the overall effectiveness of pharmacovigilance systems.

Materials and Methods

Study Design and Subjects

A non-interventional, observational study was carried out to identify adverse drug reactions (ADRs) in paediatric patients and assess their causality using the WHO–UMC criteria. A total of 140 paediatric subjects, aged below 13 years, were enrolled. Written informed consent was obtained from each participant's parent or legal guardian before inclusion. The study adhered to the principles of the Declaration of Helsinki and followed the predefined inclusion and exclusion criteria [7-8].

Inclusion Criteria [9-10]:

Children were eligible for participation if they met the following criteria:

1. Male or female subjects younger than 13 years
2. Undergoing clinical treatment for any medical condition at the time of enrolment
3. Parents or guardians willing to provide accurate past and current medical history
4. Parents or guardians able and willing to provide written informed consent
5. Parents willing to comply with study procedures and assessments

Exclusion Criteria [11-12]:

Subjects were excluded from the study if they exhibited:

1. A known history of chronic medical conditions such as:
   - Diabetes mellitus (Type 1 or Type 2)
   - Thyroid disorders
   - Asthma
   - Hypertension
   - Cardiovascular diseases
   - Epilepsy
   - Any other long-term illness requiring chronic therapy
2. Current use of medications for chronic diseases
3. Inability or unwillingness of caregivers to complete consent or required study documentation

Study Procedures [13-14]

All eligible subjects underwent a comprehensive screening evaluation, which included:

1. Detailed medical and medication history
2. Demographic data collection (age, gender, height, weight)
3. Physical examination (head-to-toe assessment)

4. Vital signs (temperature, blood pressure, heart rate, respiratory rate)
5. Documentation of any pre-existing adverse events (AEs)

Following screening, subjects were enrolled and assigned a unique study identification number. During the observational period, any newly occurring AEs were recorded using standardized reporting forms. Each AE was assessed for causality using the WHO–UMC Causality Assessment System, which classifies events as certain, probable, possible, unlikely, conditional/unclassified, or unassessable/unclassifiable.

Primary Outcome [15-16]

1. **Identification and documentation of adverse drug reactions (ADRs)** occurring in the paediatric study population.

Secondary Outcomes

1. **Pattern, frequency, and type of reported adverse events (AEs)**
2. **Severity classification** of AEs into mild, moderate, and severe categories
3. **Causality assessment outcomes** using WHO–UMC methodology

Data Analysis [17-18]

Data collected were compiled into case report forms (CRFs) and subsequently entered into a validated database for analysis. Descriptive statistical methods were employed:

1. Continuous variables were expressed as mean ± standard deviation (SD).
2. Categorical variables (e.g., types of AEs, severity) were summarized as frequency and percentage.
3. AEs were stratified based on severity (mild, moderate, severe) and causality (WHO–UMC categories).

No inferential statistics were required, as the study aimed primarily to describe ADR patterns in the paediatric population.

Results

Demographics

A total of 140 subjects were enrolled in the study, and the data were analyzed descriptively. Overall average age of enrolled subjects is 7.4286 Yrs. Out of the 140 subjects enrolled 102 (72.86 %) subjects were male and 38 (27.14 %) subjects were female; all are Asian race. The overall average height of enrolled subjects was 114.2536 cm, and the overall average weight was 20.8429 kg. There were no significant medical history and concurrent medical conditions for all enrolled subjects as per the data collected. The demographic distribution of Subjects can be observed in Table 1 below

Table 1. Summary Statistics of Demographics of All Subjects

Parameter	**Count (N= 140)**
Age (Years)	
N	140
Mean	7.4286
Standard deviation	2.9483
Minimum	3
Maximum	17
Gender, n (%)	
N	140
Male	102 (72.86 %)
Female	38 (27.14 %)
Weight (KG)	
N	140

Mean	20.8429
Standard deviation	8.7828
Minimum	6
Maximum	56
Height (Cm)	
N	140
Mean	114.2536
Standard deviation	15.3977
Minimum	90
Maximum	162
Significant Medical History and Concurrent Medical Conditions	
Subject with NO Diabetes (Type 1/Type 2)	140 (100 %)
Subject with NO Thyroid	140 (100 %)
Subject with NO Cardiovascular Disease	140 (100 %)
Subject with NO Hypertension	140 (100 %)
Subject with NO Coronary Artery Disease	140 (100 %)
Subject with NO Asthma	140 (100 %)
Subject with NO Epilepsy	140 (100 %)
Subject with NO Drug Allergy	140 (100 %)
Subject with NO Others	140 (100 %)

As part of Data Collection, Adverse Drug Reaction Probability Scale was employed to identify ADRs of subjects. It was evident from Table 2 that, the Mean total score of adverse drug reaction probability scale was 0.435714 (SD 1.4603), indicating that the reaction was doubtful whether the ADR is likely related to factors other than a drug.

Table 2. Summary Statistics of Adverse Drug Reaction Probability Scale

Parameter	**Count (N= 140)**
Total Score	
N	140
Mean	0.435714
Standard deviation	1.4603
Minimum	-3
Maximum	4

As part of data collection, Knowledge based questionnaires were employed to record the knowledge of subject's family members about the Adverse Events. It was evident from Table 3 that, around 5 (3.57 %) members had excellent knowledge, 70 (30%) had good knowledge, 53 (37.86%) had moderate knowledge and 12 subjects had poor knowledge regarding the definition of ADR. Out of 140, about 50 (35.71 %) members had poor knowledge, 67 (47.86 %) members had moderate knowledge, and 23 (16.43 %) members had good knowledge on differentiating whether the adverse drug reaction and ADR the Same. Out of 140, 60 (42.86 %) members had poor knowledge, 71 (50.71 %) had moderate knowledge, 7 (5 %) members had good knowledge and only 2 (1.43 %) members had excellent knowledge on who can report ADRs. Out of 140 subjects, 69

(49.29 %) members had poor knowledge, 63 (45 %) members had moderate knowledge, 7 (5 %) members had good knowledge and only 1 (0.71%) member had excellent knowledge on what is meant by Pharmacovigilance. Out of 140 members, all of them had poor knowledge on which method is commonly used for causality assessment of ADR and on what type of medication can cause ADRs.

Out of 140, 101 (72.14 %) subjects had poor knowledge, 37 (26.43 %) subjects had moderate knowledge, 1 (0.71 %) subject had good knowledge and 1 (0.71 %) subject had excellent knowledge on whether the collection of information on ADRs contribute to improving patient safety. Out of 140, 93 (66.43 %) subjects had poor knowledge, 43 (30.71 %) subjects had moderate knowledge, 3 (2.14 %) subjects had good knowledge and 1 (0.71 %) subject had excellent knowledge on how important do you they it is for the public to report ADRs. Out of 140, 118 (84.29 %) subjects had poor knowledge, 21 (15 %) subjects had moderate knowledge, 3 (2.14 %) and only 1 (0.71 %) subject had good knowledge on considering reporting suspected ADRs in future. Out of 140, 132 (94.29 %) subjects had poor knowledge, 7 (5 %) subjects had moderate knowledge, and only 1 (0.71 %) subject had good knowledge on where to find more information on ADR reporting. Out of 140, 119 (85 %) subjects had poor knowledge, and 21 (15 %) subjects had moderate knowledge, on where to find more information on to whom can they report ADRs. Out of 140 members, all of them had poor knowledge on how can ADRs be reported and on what type of ADRs should be reported.

Table 3. Summary Statistics of Knowledge Based Questionnaries

Parameter	**Count (N= 140)**
Define ADR	
Excellent	5 (3.57 %)
Good	70 (50 %)
Moderate	53 (37.86 %)
Poor	12 (8.57 %)
Are adverse drug reaction and ADR the Same?	
Excellent	0 (00.00 %)
Good	23 (16.43 %)
Moderate	67 (47.86 %)
Poor	50 (35.71 %)
Who can Report ADR?	
Excellent	2 (1.43 %)
Good	7 (5 %)
Moderate	71 (50.71 %)
Poor	60 (42.86 %)
What is meant by Pharmacovigilance	
Excellent	1 (0.71 %)
Good	7 (5 %)
Moderate	63 (45 %)
Poor	69 (49.29 %)
Which method is commonly used for causality assessment of ADR?	
Excellent	0 (00.00 %)

Good	0 (00.00 %)
Moderate	0 (00.00 %)
Poor	140 (100 %)
What type of medication can cause ADRs?	
Excellent	0 (00.00 %)
Good	0 (00.00 %)
Moderate	0 (00.00 %)
Poor	140 (100 %)
Does the collection of information on ADRs contribute to improving patient safety?	
Excellent	1 (0.71 %)
Good	1 (0.71 %)
Moderate	37 (26.43 %)
Poor	101 (72.14 %)
How important do you think it is for the public to report ADRs?	
Excellent	1 (0.71 %)
Good	3 (2.14 %)
Moderate	43 (30.71 %)
Poor	93 (66.43 %)
Would you consider reporting suspected ADRs in future?	
Excellent	0 (00.00 %)
Good	1 (0.71 %)
Moderate	21 (15 %)
Poor	118 (84.29 %)
Where can you find more information on ADR reporting?	
Excellent	0 (00.00 %)
Good	1 (0.71 %)
Moderate	7 (5 %)
Poor	132 (94.29 %)
To whom can ADRs be reported?	
Excellent	0 (00.00 %)
Good	0 (00.00 %)
Moderate	21 (15 %)
Poor	119 (85 %)
How can ADRs be reported?	
Excellent	0 (00.00 %)
Good	0 (00.00 %)
Moderate	0 (00.00 %)
Poor	140 (100 %)
What type of ADRs should be reported?	
Excellent	0 (00.00 %)
Good	0 (00.00 %)
Moderate	0 (00.00 %)
Poor	140 (100 %)

It was evident from Table 4 that, out of 140 subjects, only 3 (1.89 %) subjects were reported with Mild Abdominal pain, 4 (2.52 %) subjects were reported with Mild Drowsiness, 14 (8.81 %) subjects were reported with Mild Gastritis, 26 (16.35 %) subjects were reported with Mild Nausea, 4 (2.52 %) subjects were reported with Mild Rashes, 1 (0.63 %) subject was reported with Mild Stomach pain, 1 (0.63 %) subject was reported with Mild Swollen eyes.

Table 4. Summary Statistics of AE List

Parameter	**Count (N= 140)**
Abdominal Pain	**3 (1.89 %)**
Mild	3 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)
Drowsiness	**4 (2.52 %)**
Mild	4 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)
Gastritis	**14 (8.81 %)**
Mild	14 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)
Nausea	**26 (16.35 %)**
Mild	26 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)
Rashes	**4 (2.52 %)**
Mild	4 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)
Stomach Pain	**1 (0.63 %)**
Mild	1 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)
Swollen eyes	**1 (0.63 %)**
Mild	1 (100 %)
Moderate	0 (00.00 %)
Severe	0 (00.00 %)

ADR Probability Assessment

Causality assessment of observed events was performed using the WHO–UMC Causality Assessment Scale, which evaluates the likelihood of the relationship between a drug and an adverse event. The mean WHO–UMC causality score among the subjects was 0.435 ± 1.46, with individual scores ranging from –3 to +4. This wide variation reflects diverse clinical presentations; however, the overall mean score falls into the “doubtful” category, indicating

that most adverse events were *unlikely to be directly attributable to drug therapy*. This finding suggests that the majority of AEs noted during the study likely arose from non-pharmacological factors, underlying illness, or incidental conditions rather than from medication exposure. The low causality scores also align with the mild nature of all reported adverse events.

Discussion

In this observational paediatric pharmacovigilance study, we observed a low frequency of ADRs, and importantly, all reported adverse events were mild. The average WHO–UMC causality score (~0.435) fell into the "doubtful" category, suggesting that most AEs were unlikely to be directly attributable to medication. These findings align with several prior Indian studies, reinforcing the notion that, despite biological vulnerability, paediatric ADR burden in real-world settings may often be limited.

For instance, a prospective observational study from a tertiary care hospital reported an ADR incidence of 2.9% in children, emphasizing that while ADRs in children exist, many are preventable or mild. Similarly, a large dataset from Odisha showed that although serious ADRs do occur, they constitute a smaller proportion of pediatric reports, with gastrointestinal ADRs being relatively uncommon. These parallels strengthen our confidence in the external validity of our findings.

Nature of ADRs: Gastrointestinal Predominance

The predominance of gastrointestinal events (notably nausea and gastritis) in our cohort is noteworthy. While such events can frequently be attributed to medications like antibiotics, analgesics, or symptomatic therapy, they are also common in children due to non-pharmacologic causes (diet, underlying illness, etc.). Studies from other Indian centres corroborate gastrointestinal involvement.

However, cutaneous ADRs often dominate other paediatric ADR literature (e.g., rash is frequently reported in hospital-based settings). The relative absence of skin reactions in our data may reflect differences in prescribing patterns, drug classes used, or even under-recognition/underreporting of dermatological AEs in our observational setting.

Implications of Mild ADRs

The fact that no moderate or severe ADRs were detected in our sample is encouraging, as it suggests that current prescribing practices in our setting are relatively safe and well-monitored. Yet, the absence of severe ADRs does not negate the importance of pharmacovigilance. Even mild ADRs can adversely affect compliance, quality of life, and long-term therapy, especially in chronic or recurrent paediatric conditions.

Moreover, doubtful causality does not necessarily imply zero risk. Low causality scores may result from limitations in detection (e.g., transient AEs missed between clinical assessments), or from under-reporting of subtle symptoms by caregivers. This underscores the need for vigilant, continuous monitoring rather than occasional checks.

Challenges in Paediatric Pharmacovigilance

Our findings also reflect broader systemic challenges. Under-reporting of ADRs is a pervasive problem in India. Previous research has identified lack of awareness, insufficient training, fear of legal fallout, and heavy clinical workload as key barriers to spontaneous ADR reporting. Without robust reporting mechanisms and active surveillance, even mild ADRs may go unnoticed.

Additionally, age-related pharmacokinetic and pharmacodynamic variability in children (e.g., organ maturation, enzyme capacity) complicates causality assessment. These

factors make signal detection more challenging in paediatric populations compared to adults, emphasizing the value of standardized causality tools like the WHO–UMC scale.

Strengths and Limitations

Strengths:

1. **Real-world setting:** Our non-interventional study reflects routine prescribing and monitoring practices.
2. **Standardized causality assessment:** Use of WHO–UMC scale ensures methodological rigor.
3. **Focus on mild ADRs:** Often underemphasized but clinically relevant.

Limitations:

1. **Lack of active surveillance:** As an observational study without regular follow-ups, some transient or delayed ADRs may have been missed.
2. **No control group:** Without a comparator, it is difficult to distinguish drug-related events from illness-related symptoms.
3. **Limited sample size and drug variety:** With 140 subjects, the spectrum of drugs and ADRs may not represent all paediatric prescribing scenarios.

Conclusion

1. The paediatric population in this study demonstrated a low burden of adverse drug reactions, with all reported events categorized as *mild* in nature. The WHO–UMC causality assessment further indicated that most events had minimal or doubtful association with drug exposure, suggesting that the observed symptoms were likely attributable to underlying illness or non-pharmacological factors.
2. Despite the low ADR frequency, these findings underscore the critical importance of sustained pharmacovigilance efforts in paediatric healthcare. Children remain a vulnerable population due to developmental differences in drug handling, and even mild ADRs can influence adherence, recovery, and quality of care.
3. To improve detection and reporting of ADRs, ongoing education and sensitization of caregivers as well as healthcare professionals is essential. Strengthening awareness, simplifying reporting pathways, and integrating routine ADR monitoring into clinical practice will contribute significantly to a safer paediatric medication environment. Continuous engagement with national pharmacovigilance programs will also support more robust data generation and early identification of potential safety signals in this sensitive group.

Ethical Considerations

This study is conducted according to ICH-GCP, ICMR guidelines, ISO 14155 and other government regulations and Institutional research policies and procedures.

Data Availability

Due to the sensitive nature of pharmacovigilance and patient-related data, the datasets are not publicly available. De-identified data may be provided upon reasonable request and subject to ethical approval.

Author Contributions

Krishna Priyanka conceptualized the study, prepared the research design, performed data collection and pharmacovigilance analysis contributed to interpretation of pediatric ADR findings. Bharghava Bhushan Rao P reviewed the manuscript, provided critical revisions, and supervised the overall work. All authors read and approved the final manuscript.

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