A Study on The Patterns of Drugs Used in Pediatric Patients

Shivani Kumari
Department of Pharmacy
Practice, Bansal College of Pharmacy, Bhopal, Madhya Pradesh, India

***Abstract*—Background: Children are a pharmacologically vulnerable population whose unique developmental physiology fundamentally alters how drugs are absorbed, distributed, metabolized, and excreted. Despite constituting nearly 30% of India's population, pediatric patients remain poorly represented in clinical drug trials, leaving clinicians to navigate treatment decisions with limited age-specific evidence.**

Objective: This review critically appraises the published literature on drug use patterns in pediatric patients, focusing on WHO prescribing indicators, off-label and unlicensed drug use, adverse drug reactions (ADRs), polypharmacy, and antimicrobial prescribing, with particular emphasis on evidence from Indian tertiary care settings.

Methods: A comprehensive, narrative synthesis of prospective observational studies, systematic reviews, and drug utilization reports published between 2014 and 2026 was performed. Key databases including PubMed, Google Scholar, and IndMED were searched using MeSH terms related to pediatric pharmacotherapy, drug utilization, off-label prescribing, and antimicrobial stewardship. Key Findings: Anti-infective agents, particularly beta-lactam antibiotics, consistently dominate pediatric prescriptions, with antibiotic prescribing rates in Indian settings ranging from 36% to over 90%—substantially exceeding the WHO benchmark of less than 30%. Off-label drug use affects 42%–70% of prescribed medications, driven predominantly by dose modifications and use outside approved age ranges. ADRs occur in 10%–26% of hospitalized children, most frequently involving antibiotics and the gastrointestinal system. Polypharmacy is prevalent in inpatient settings, affecting up to 52% of patients and correlating with prolonged hospitalization and intensive care admission. Conclusion: Significant gaps remain between current pediatric prescribing practices and evidence-based standards. Implementing pediatric antimicrobial stewardship programs, strengthening pharmacovigilance infrastructure, promoting generic prescribing, and integrating clinical pharmacists into care teams are critical steps toward safer and more rational drug use in children.

Index Terms—pediatric pharmacotherapy; drug utilization study; off-label prescribing; antimicrobial stewardship; adverse drug reactions; polypharmacy; WHO prescribing indicators

I. INTRODUCTION

Pharmacotherapy in children demands a level of precision and caution that distinguishes it from adult medicine in fundamental ways. Children are not, as the old clinical aphorism reminds us, simply small adults; they are physiologically dynamic individuals whose organ systems, enzyme pathways, and body composition evolve continuously from the neonatal period through adolescence. These developmental changes exert profound effects on drug disposition and response, making the pharmacological management of pediatric illness both scientifically fascinating and clinically challenging.

In India, the pediatric population — broadly defined as individuals under 15 years of age — accounts for approximately 30% of the national population. This demographic significance stands in stark contrast to the evidence base available to guide treatment decisions for these patients. Historically, children have been excluded from pharmaceutical clinical trials for ethical and logistical reasons, resulting in a situation where many medicines routinely prescribed to children carry no specific approval for pediatric use. Clinicians are consequently left to extrapolate dosing and safety information from adult data, a practice that is at best imprecise and at worst potentially harmful.

Drug utilization studies (DUS) provide a systematic means of documenting and evaluating how medicines are prescribed and used within defined patient populations. By benchmarking prescribing practices against established standards — most notably the World Health Organization (WHO) core prescribing indicators — DUS can identify patterns of irrational drug use, quantify the extent of off-label prescribing, and generate evidence to support targeted quality improvement interventions. In pediatric settings, where the consequences of irrational prescribing can be particularly severe, the value of well-designed DUS cannot be overstated.

This review synthesizes the current evidence on drug use patterns in pediatric patients, drawing on prospective observational studies and systematic reviews published predominantly from Indian and global tertiary care contexts. The review is organized around five key dimensions of pediatric pharmacotherapy: prescribing patterns and WHO indicator compliance, off-label and unlicensed drug use, adverse drug reactions, polypharmacy, and antimicrobial stewardship.

II. DEVELOPMENTAL PHARMACOLOGY: THE PHYSIOLOGICAL BASIS FOR PEDIATRIC DOSING

Understanding why pediatric prescribing is inherently complex requires an appreciation of how developmental changes across the four pharmacokinetic processes — absorption, distribution, metabolism, and excretion (ADME) — alter drug behavior in children of different ages.

2.1.Absorption

The gastrointestinal absorption of drugs in neonates and young infants differs substantially from that observed in older children and adults. Gastric pH in neonates ranges from approximately 6 to 8 — considerably higher than adult values — and does not approximate adult levels until around the age of two to three years. This alkaline gastric environment enhances the bioavailability of drugs that are weak bases while impairing the absorption of weak acids such as phenobarbital. Delayed gastric emptying, reduced intestinal surface area, and immature biliary function further complicate enteral drug delivery in early life.

2.2.Distribution

Body composition changes dramatically across childhood. Neonates have a significantly higher proportion of total body water (approximately 75%–80% of body weight, compared with 55%–60% in adults) and substantially lower body fat. These differences translate into a larger volume of distribution for hydrophilic drugs, which may necessitate higher weight-adjusted doses to achieve therapeutic plasma concentrations. Conversely, plasma protein binding is reduced in neonates due to lower albumin levels and the presence of fetal albumin variants with diminished drug-binding capacity, resulting in a higher free fraction of highly protein-bound drugs and an increased risk of pharmacological effect and toxicity.

2.3.Metabolism

Hepatic drug metabolism is perhaps the most clinically consequential area of developmental pharmacology. The cytochrome P450 (CYP) enzyme system, which is responsible for the Phase I metabolism of the majority of clinically important drugs, undergoes age-dependent maturation. CYP3A4 — the predominant CYP enzyme in adults, responsible for metabolizing more than 50% of all drugs — is expressed at low levels at birth but increases rapidly, reaching adult activity by approximately one year of age. CYP1A2, in contrast, matures slowly and does not reach full adult activity until late childhood or adolescence.

Phase II conjugation reactions, particularly glucuronidation mediated by uridine diphosphate glucuronosyltransferases (UGTs), are markedly deficient in neonates. The clinical consequence of this immaturity is exemplified by the gray baby syndrome caused by chloramphenicol, in which inadequate glucuronidation leads to toxic drug accumulation in neonates. Similarly, the prolonged half-life of morphine in preterm neonates reflects immature hepatic glucuronidation capacity.

2.4.Renal Excretion

The glomerular filtration rate (GFR) in neonates is only 30%–40% of adult values when corrected for body surface area. While GFR increases rapidly in the first months of life and approximates adult levels by 6–12 months, tubular secretion matures more slowly. These differences have important clinical implications for renally cleared drugs such as aminoglycosides and vancomycin, where reduced clearance increases the risk of toxicity and necessitates careful dose adjustment and therapeutic drug monitoring.

Table 1 summarizes the key pharmacokinetic differences between pediatric patients and adults, along with their clinical implications.

Process	Key Pediatric Characteristics	Clinical Implications
Absorption	Elevated gastric pH in neonates; delayed gastric emptying; immature biliary function	Altered oral bioavailability; unpredictable drug absorption in early infancy
Distribution	Higher total body water (75–80%); lower body fat; reduced plasma protein binding	Larger volume of distribution for hydrophilic drugs; elevated free fraction of protein-bound agents
Metabolism	Immature CYP450 and UGT enzymes; age-dependent enzyme maturation trajectories	Prolonged drug half-lives; risk of accumulation; gray baby syndrome with chloramphenicol
Excretion	Reduced GFR (30–40% of adult values at birth); immature tubular secretion	Prolonged elimination of renally cleared drugs; dose adjustment and TDM required

Table 1. *Key Pharmacokinetic Differences Between Pediatric Patients and Adults. GFR = glomerular filtration rate; TDM = therapeutic drug monitoring; CYP = cytochrome P450; UGT = uridine diphosphate glucuronosyltransferase.*

III. WHO CORE PRESCRIBING INDICATORS IN PEDIATRIC SETTINGS

The WHO core prescribing indicators were developed to provide a standardized, internationally comparable framework for evaluating drug use quality in primary and secondary care settings. Five indicators form the core battery: the average number of drugs per prescription, the proportion of drugs prescribed by generic name, the proportion of encounters in which an antibiotic was prescribed, the proportion of encounters with an injection prescribed, and the proportion of drugs prescribed from the essential medicines list (EML). WHO reference values for each indicator represent aspirational benchmarks rather than absolute thresholds, but deviations from these values signal areas warranting prescriber education, formulary management, or regulatory intervention.

Across Indian pediatric studies published over the past decade, consistent deviations from WHO benchmarks have been documented. The average number of drugs per prescription — which WHO recommends should be 1.6 to 1.8 — has ranged from 1.9 in primary care outpatient clinics to over 5.0 in tertiary care inpatient settings. The higher figures in hospital-based studies reflect the greater severity and complexity of illness among admitted children, particularly those requiring intensive care management.

Generic prescribing — ideally 100% of prescriptions — shows wide variation depending on healthcare sector. Government hospital studies have reported generic prescribing rates approaching 70%–75%, while private sector institutions have documented rates as low as 4%–5%. This dichotomy reflects the influence of hospital formulary policies and commercial prescribing incentives on drug selection practices. Beyond cost implications, brand-name prescribing can contribute to confusion during dispensing and medication errors when a patient transitions between healthcare providers.

Antibiotic prescribing rates in Indian pediatric settings are a particular concern. A systematic review encompassing over 28,000 patient encounters at Indian primary health centers reported a pooled antibiotic prescribing prevalence of 65%, more than twice the WHO benchmark of less than 30%. Even in relatively well-regulated tertiary care settings, antibiotic prescribing rates of 36%–43% are commonly reported. Such high rates are partially explained by the high burden of infectious diseases in the Indian pediatric population — respiratory tract infections and acute gastroenteritis account for more than 60% of pediatric hospital visits in most series — but also reflect diagnostic uncertainty, patient and caregiver expectations, and limited microbiological support.

The proportion of encounters involving injectable medications, which WHO recommends should remain below 15%, frequently exceeds 25%–30% in inpatient pediatric studies. While intravenous administration is clinically necessary in severe infections and acute dehydration, unnecessarily prolonged parenteral therapy — when oral therapy would be equally efficacious and safer — contributes to increased healthcare costs, risk of catheter-associated infections, and patient discomfort. Early intravenous-to-oral switch programs have been shown to reduce antibiotic duration and hospital stay without compromising clinical outcomes.

Table 2 presents a comparative summary of WHO prescribing indicator findings from representative Indian pediatric studies.

WHO Indicator	WHO Standard	Aasani et al. (2016)	Mandal et al. (2022)	Jorige et al. (2023)	Typical Range (India)
Average drugs per prescription	1.6–1.8	5.17	2.66	1.92	1.9–5.2
Generic prescribing (%)	100%	71%	74%	N/A	4%–97%
Antibiotic prescribing (%)	<30%	N/A	36.8%	N/A	36%–92%
Injection prescribing (%)	<15%	N/A	N/A	N/A	15%–35%
EML adherence (%)	100%	N/A	N/A	N/A	57%–67%

Table 2. *Comparison of WHO Core Prescribing Indicators Across Indian Pediatric Studies. EML = essential medicines list; N/A = not available.*

IV. OFF-LABEL AND UNLICENSED DRUG USE IN PEDIATRIC PRACTICE

4.1.Definitions and Prevalence

The term "off-label" refers to the use of a licensed medicine in a manner that falls outside the conditions specified in its marketing authorization. This encompasses use in an unapproved age group, at a dose or frequency not recommended in the product label, for an indication not included in the licensed summary of product characteristics, or via a route of administration not listed in the license. "Unlicensed" use describes medicines for which no marketing authorization has been granted for any indication, including extemporaneously prepared formulations compounded from adult dosage forms.

Off-label and unlicensed drug use are virtually unavoidable in pediatric practice given the chronic underrepresentation of children in pharmaceutical clinical trials. The European Medicines Agency has estimated that more than 50% of medicines used in children lack pediatric-specific approval. In India, the situation is exacerbated by the absence of a dedicated pediatric drug regulatory framework and the limited availability of age-appropriate formulations.

Reported prevalence rates vary considerably across studies, ranging from approximately 30% to 80% of all prescribed medications depending on the patient population, hospital setting, and classification system used. Landmark European work by Conroy and colleagues documented that 46% of drug prescriptions in pediatric wards were either off-label or unlicensed. Indian studies have reported broadly similar figures, with Saiyed et al. identifying off-label use in 70% of medications prescribed to pediatric inpatients and Vadher et al. documenting rates of 42.5% off-label and 13.7% unlicensed in a tertiary care setting.

4.2.Categories and Predictors of Off-Label Use

The most commonly reported categories of off-label use in Indian pediatric studies are dose modification — where a drug is used at a weight-adjusted dose not explicitly stated in its approved label — and use outside the approved age range. Saiyed et al. found that dose differences accounted for 63% of off-label uses and restricted age limits for 19.8%. Vadher et al. similarly identified dose modification as the leading category. This pattern reflects the fundamental inadequacy of adult-derived dosing information when applied to the full spectrum of pediatric developmental stages.

Drug class influences off-label prescribing risk. Respiratory drugs, anti-infective agents, and central nervous system medications consistently carry the highest off-label use proportions across published series. Saiyed et al. reported off-label rates of 82% for respiratory medicines, 73% for anti-infectives, and 53% for nervous system drugs. Anti-infectives occupy a large share of pediatric prescriptions overall, making the absolute number of off-label antibiotic exposures particularly high.

Patient age is a strong predictor of off-label prescribing: the youngest patients face the greatest exposure. Logistic regression analyses have identified age between 0 and 2 years as a significant

independent predictor of off-label prescribing, with an odds ratio of approximately 1.7. This finding reflects both the greater paucity of pharmacokinetic and efficacy data for this age group and the extreme physiological variability that characterizes the first two years of life.

4.3.Clinical Implications

Off-label prescribing is not inherently inappropriate. In many clinical scenarios, off-label use is supported by high-quality evidence from prospective trials, observational cohorts, or established clinical consensus, and represents the standard of care. However, the level of evidentiary support for off-label pediatric prescribing is often surprisingly low. A comprehensive review of off-label drug records found that strong evidence supported only 14% of off-label uses, while 37% of dosing recommendations relied on expert opinion or consensus in the absence of controlled trial data.

This evidentiary deficit has practical consequences. Suboptimal off-label dosing — whether due to dose extrapolation from adult data or to an absence of validated pediatric pharmacokinetic models — contributes to therapeutic failure when doses are too low, and to toxicity when doses are inappropriately high. The risk is greatest in neonates, where the combination of extreme physiological immaturity, rapid developmental change, and very small body size magnifies the consequences of dosing inaccuracies.

V. ADVERSE DRUG REACTIONS IN THE PEDIATRIC POPULATION

5.1.Incidence and Risk Factors

Adverse drug reactions represent a significant and often underrecognized source of pediatric morbidity. Published incidence rates in hospitalized children range from approximately 1.5% to 26%, with this wide variation reflecting differences in study design, ADR definitions, monitoring intensity, patient age distribution, and clinical setting. Prospective, active monitoring studies consistently report higher rates than retrospective chart reviews, suggesting that passive pharmacovigilance substantially underestimates the true burden.

Infants under one year of age bear a disproportionate share of the ADR burden. Patel and colleagues documented that 53% of ADRs in their prospective monitoring study occurred in infants below one year of age. A study from Andhra Pradesh reported an ADR incidence of 30% in this youngest age group, compared with an overall study incidence of 26%. This vulnerability reflects the convergence of immature drug metabolism, rapidly changing pharmacokinetics, high rates of off-label drug use, and reduced physiological reserve for managing drug-induced perturbations.

Other established risk factors for pediatric ADRs include polypharmacy, prolonged hospital stay, admission to intensive care settings, and the presence of genetic polymorphisms affecting CYP enzyme activity. The dose-dependent nature of many ADRs means that the inaccuracies inherent in off-label dosing — particularly weight-based dose calculation errors — can precipitate or exacerbate adverse reactions.

5.2.Pattern of ADRs

Anti-infective agents, particularly antibiotics, are the most frequently implicated drug class in pediatric ADR series. Patel et al. attributed 89% of documented ADRs to antibiotics in their Gujarat study; a prospective study from Andhra Pradesh found antibiotics responsible for 48.6% of reactions. The gastrointestinal system is the most commonly affected organ system, with antibiotic-associated diarrhea and vomiting accounting for a large proportion of reactions. The high rate of gastrointestinal ADRs is mechanistically explained by antibiotic-induced disruption of the intestinal microbiome, a disturbance that has both short-term and potentially long-term immunological consequences in developing children.

Dermatological reactions, particularly drug-induced hypersensitivity syndromes, represent a smaller but clinically important category of pediatric ADRs. Severe cutaneous adverse reactions (SCARs) — including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) — are rare but potentially life-threatening and require immediate drug discontinuation and specialized management. A retrospective analysis of pediatric SCAR cases from Southern India identified Stevens-Johnson syndrome and toxic epidermal necrolysis as the predominant diagnoses (70.3%), with antiepileptics and sulfonamide-containing antimicrobials as the most common causative agents.

5.3.Preventability and Causality Assessment

A particularly striking finding from several Indian pediatric ADR studies is the high proportion of reactions classified as probably preventable. Patel et al. classified 57.6% of documented ADRs as probably preventable using the Schumock and Thornton preventability scale. This finding implies that a majority of ADR-related morbidity could be reduced through better prescribing practices, including more rigorous adherence to contraindication checking, more careful dose calculation, and more systematic therapeutic drug monitoring for narrow therapeutic index agents.

Causality assessment using validated tools such as the WHO-UMC scale and the Naranjo algorithm is essential for attributing ADRs to specific drugs in the complex polypharmacy environment of pediatric inpatient care. Most ADRs in published pediatric series are classified as probable or possible rather than certain, reflecting the difficulty of establishing definitive drug causality when multiple agents are co-administered and rechallenge is ethically impermissible.

Table 3 summarizes ADR characteristics from selected Indian pediatric studies.

Study	Setting	ADR Incidence	Top Implicated Drug Class	Top Organ System	% Preventable
Patel et al. (2021)	Gujarat, India (Inpatients)	N/A (66 ADRs)	Antibiotics (89%)	GI – diarrhea/vomiting (56%)	57.6%

Andhra Pradesh Study (2025)	Inpatients, 100 patients	26%	Antibiotics (48.6%)	GI (31.4%); Dermatology (25.7%)	N/A
Kuzhali et al. (2024)	Emergency Dept., South India	N/A	Antibiotics	GI system	N/A

Table 3. *Summary of Adverse Drug Reaction Studies in Indian Pediatric Populations. GI = gastrointestinal; N/A = not available or not reported.*

VI. POLYPHARMACY IN PEDIATRIC PATIENTS

6.1.Definition and Prevalence

Polypharmacy in children is commonly defined as the concurrent use of five or more medications, although some outpatient definitions lower this threshold to three or more drugs per prescription given the generally lower baseline medication burden in ambulatory pediatric patients. A systematic scoping review of polypharmacy prevalence across pediatric settings found that inpatient studies reported a median prevalence of 50.3%, compared with 38.8% in outpatient studies — a difference attributable to the greater disease severity and complexity of hospitalized children.

Neonatal and pediatric intensive care units represent the highest-risk environment for polypharmacy-related harm. A comprehensive pharmacotherapy evaluation from South India reported an average of 9.76 ± 3.81 medications per patient in the pediatric intensive care unit (PICU), with anti-infectives accounting for the largest drug category. Emergency department studies have similarly documented polypharmacy prevalence of approximately 52%, reflecting the acute, multisystem nature of emergency presentations in children.

6.2.Clinical Consequences of Polypharmacy

The clinical consequences of polypharmacy in children mirror those documented in adult populations but carry additional developmental dimensions. Drug-drug interactions are an important pharmacokinetic hazard: Kuzhali and colleagues reported that 92.7% of drug-drug interactions identified in their pediatric emergency cohort were of moderate severity. This high rate of moderate interactions is attributable to the use of multiple medications that share common CYP metabolic pathways — pathways that are themselves age-dependently expressed and may not follow predictable adult-based interaction predictions in younger children.

Polypharmacy also amplifies medication error risk. Weight-based dosing calculations — which must be performed for each drug individually — become exponentially more error-prone as the number of concurrently prescribed medications increases. Dosing errors, incorrect drug selection, and infusion rate errors are the most common error types in pediatric inpatient settings, and their frequency is directly correlated with prescription complexity. A large medication error analysis

from 2026 found that antimicrobials (24.5%) and opioids (10.5%) were the most commonly implicated drug classes, with administration errors (56.9%) and prescribing errors (38.7%) as the predominant error categories.

From a clinical pharmacology perspective, polypharmacy in neonates is particularly hazardous. The convergence of immature and variable CYP enzyme activity, reduced renal clearance, limited protein binding capacity, and altered volume of distribution creates a pharmacokinetic milieu in which drug accumulation and drug-drug interactions are genuinely unpredictable. Therapeutic drug monitoring for aminoglycosides and vancomycin — the most commonly prescribed antibiotics in neonatal intensive care — is an established safety practice precisely because conventional dose-interval regimens based on adult pharmacokinetics are unreliable in this population.

VII. ANTIMICROBIAL PRESCRIBING AND STEWARDSHIP IN PEDIATRIC SETTINGS

7.1.The Antibiotic Prescribing Problem

Antibiotics occupy a uniquely prominent position in pediatric prescribing. Infectious diseases — particularly respiratory tract infections and acute gastroenteritis — are the leading causes of childhood morbidity and mortality in low- and middle-income countries, and antibiotics are among the few pharmacological agents with proven efficacy against serious bacterial infections. However, the high burden of pediatric infection has led to widespread and frequently indiscriminate antibiotic use, including prescription for viral infections against which these agents have no therapeutic benefit.

The consequences of antibiotic overuse extend far beyond the individual patient. Antibiotic use exerts a selective pressure on commensal and pathogenic bacterial populations that drives the emergence and spread of antimicrobial resistance (AMR). The WHO has identified AMR as one of the top ten global public health threats. Pre-pandemic estimates attributed 700,000 deaths annually to AMR; modelling projections suggest this toll could reach 10 million annually by 2050 if current trends in antibiotic use continue unabated. Children — through high antibiotic exposure rates and their role as community reservoirs for resistant organisms — are central actors in the AMR crisis.

7.2.The WHO AWaRe Classification

The WHO AWaRe (Access, Watch, Reserve) classification, introduced in 2017 and updated in subsequent WHO essential medicines list revisions, provides a practical framework for monitoring and optimizing antibiotic use at the point of care. Access group antibiotics are first- and second-line agents with a narrow spectrum and low resistance selection potential, suitable for most common infections; they should constitute at least 60% of total antibiotic consumption. Watch group antibiotics have higher resistance potential and broader spectra, and their use should be restricted to specific, confirmed indications. Reserve group agents are last-resort antibiotics for pan-resistant infections and should be used only in exceptional circumstances under specialist supervision.

Application of the AWaRe framework to Indian pediatric antibiotic prescribing data reveals a consistent pattern: Access group antibiotics predominate but often fall short of the 60% target, while Watch group agents — particularly third-generation oral cephalosporins, macrolides, and fluoroquinolones — account for a substantial and often inappropriate proportion of prescriptions. Mandal et al. documented that 47.4% of antibiotics prescribed to pediatric outpatients in Eastern India belonged to the Access group, with 38.4% classified as Watch. Azithromycin, frequently prescribed for viral upper respiratory tract infections and acute otitis media despite limited bacteriological evidence, is consistently the most overprescribed Watch group antibiotic in pediatric practice.

7.3.Antimicrobial Stewardship Programs

Pediatric antimicrobial stewardship programs (pASPs) represent the most evidence-based intervention for improving antibiotic prescribing quality in hospital settings. Core pASP components include prospective audit and feedback — in which a clinical pharmacist or infectious disease specialist reviews antibiotic prescriptions and provides direct prescriber feedback — preauthorization requirements for broad-spectrum Watch and Reserve group agents, decision support tools embedded in electronic prescribing systems, and prescriber education programs covering diagnostic stewardship and antimicrobial prescribing principles.

Published evidence from pASP implementation studies demonstrates significant and clinically meaningful improvements in prescribing quality: reduced broad-spectrum antibiotic use, increased Access group prescribing, shorter antibiotic courses, and — in some studies — reduced infection-related mortality and Clostridioides difficile infection rates, with no evidence of adverse clinical outcomes attributable to stewardship-driven antibiotic de-escalation. Despite this evidence base, dedicated pASPs remain uncommon in Indian pediatric hospitals, particularly at the secondary and primary care levels where the majority of pediatric antibiotic prescribing occurs.

VIII. THE ROLE OF CLINICAL PHARMACISTS IN PEDIATRIC PHARMACOTHERAPY OPTIMIZATION

Clinical pharmacists are uniquely positioned to address the multiple dimensions of irrational drug use identified in pediatric DUS. Their specialized training in pharmacokinetics, drug interactions, dosing optimization, and medication safety — combined with their proximity to the clinical team — makes them effective agents of prescribing quality improvement across the hospital spectrum.

Specific roles for clinical pharmacists in pediatric care include medication reconciliation at admission and discharge (to identify discrepancies and reduce transition-of-care errors), pharmacokinetic consultation for narrow therapeutic index drugs requiring therapeutic drug monitoring, prospective prescription review to identify off-label uses requiring documentation and monitoring, ADR detection and reporting to pharmacovigilance programs, patient and caregiver counselling on medication administration and adherence, and participation in multidisciplinary antimicrobial stewardship teams.

Evidence from hospitals that have integrated clinical pharmacists into pediatric inpatient teams' documents significant reductions in prescribing errors, medication-related adverse events, and Length of hospital stay. A systematic review of clinical pharmacist interventions in pediatric settings found that pharmacist participation in inpatient rounds was associated with a 66% reduction in preventable adverse drug events.

IX. EVIDENCE-BASED RECOMMENDATIONS FOR IMPROVING PEDIATRIC DRUG USE

Based on the evidence reviewed, the following priorities are recommended for healthcare institutions, policymakers, and educators committed to improving pediatric pharmacotherapy:

1. Establish and resource dedicated pediatric antimicrobial stewardship programs at all tertiary care hospitals, incorporating prospective audit and feedback, prescriber education, and diagnostic stewardship components.
2. Implement hospital formulary systems that mandate generic prescribing for all drugs with therapeutic bioequivalence, accompanied by pharmacist-led prescriber education programs emphasizing the cost and quality benefits of generic medicines.
3. Develop and disseminate institution-specific pediatric dosing references aligned with national formulary standards, with particular attention to neonatal and infant dosing — the age groups where evidence gaps are greatest and consequences of errors most severe.
4. Strengthen pharmacovigilance infrastructure for pediatric ADR detection, reporting, and signal generation. Clinical pharmacists should be designated as pharmacovigilance coordinators in all pediatric departments, with standardized ADR reporting forms and structured causality assessment protocols.
5. Promote early intravenous-to-oral antibiotic switch programs where clinically appropriate, reducing injection prescribing rates toward the WHO benchmark and decreasing both iatrogenic infection risk and drug costs.
6. Integrate clinical pharmacists into pediatric multidisciplinary teams, with defined roles in medication reconciliation, dose optimization, ADR monitoring, and stewardship.
7. Advocate at the regulatory level for incentivized pediatric clinical trial requirements for new medicines, accelerating the generation of age-appropriate pharmacokinetic and efficacy data.
8. Conduct regular, institution-level drug utilization audits benchmarked against WHO prescribing indicators, with findings reported to prescribers and hospital quality committees as part of a continuous quality improvement cycle.

X. CONCLUSION

Pediatric pharmacotherapy in India and globally is characterized by a complex interplay of clinical necessity, evidentiary deficit, and systemic challenges that together create fertile conditions for irrational drug use. The evidence reviewed in this paper paints a consistent picture: antibiotic

prescribing substantially exceeds WHO benchmarks, off-label use is near-universal in hospitalized children, ADRs affect up to one in four inpatients, and polypharmacy is the rule rather than the exception in critical care settings. All five WHO core prescribing indicators deviate significantly from recommended standards in the majority of published Indian studies.

These findings are not merely descriptive. They represent a call to action for all stakeholders involved in pediatric healthcare — prescribers, pharmacists, hospital administrators, regulators, and policymakers. Improving pediatric prescribing quality is achievable through evidence-based, multifaceted interventions. Antimicrobial stewardship programs, generic prescribing promotion, integrated clinical pharmacy services, and strengthened pharmacovigilance systems have all been shown to produce meaningful improvements in prescribing quality when properly resourced and implemented.

The ultimate measure of success must be clinical: fewer treatment failures, fewer preventable ADRs, lower rates of antimicrobial resistance, and better outcomes for the children in our care. Meeting this standard requires moving beyond description toward action — and recognizing that the rational, evidence-based pharmacotherapy of children is not merely a quality improvement priority, but a fundamental obligation of pediatric medicine.

Conflicts Of Interest

The author declares no conflicts of interest.

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