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Original Article

Drug Related Problems in Pediatric Patients: A Pharmacist Led Prospective Interventional Study

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ABSTRACT

Drug-Related Problems (DRPs) are common in hospitalized pediatric patients and may adversely affect therapeutic outcomes. The present study aimed to assess the prevalence and pattern of DRPs in pediatric inpatients and to evaluate the role of pharmacist-led interventions in optimizing drug therapy. A six-month prospective interventional study was conducted in the pediatric inpatient department of a tertiary care hospital. Clinical pharmacists reviewed patient medication profiles and identified DRPs using the Pharmaceutical Care Network Europe (PCNE) classification system. A total of 115 patients were included, of whom 87 (75.65%) experienced at least one DRPs, accounting for 165 DRPs. Drug choice problems (48.48%) were most frequent, followed by drug interactions (30.90%) and dosing problems (7.87%). Pharmacist interventions were proposed for 115 DRPs, primarily at the prescriber level (47.27%). The mean number of DRPs per patient was 1.89±1.3. The study highlights the critical role of clinical pharmacists in identifying and managing DRPs and improving medication safety in pediatric patients.

Keywords: Adverse drug reaction, Drug Interaction, Drug-related problems, PCNE Classification, Pediatrics, Pharmaceutical care, Interventions.

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INTRODUCTION

India is home to the largest child population in the world, significantly exceeding that of China. The country accounts for 20% of the global population of children aged 0-4 years. This relative demographic load is expected to remain high for the foreseeable future (UNICEF, 2011). Due to variations in developmental stages, physiological characteristics, and communication limitations, infancy and childhood present unique challenges in pharmacotherapy. Rapid phases of growth, differences in organ function, enzyme activity, and body systems that process drugs and dosages vary significantly over time (Pemmasani *et al*., 2018; Daniel *et al*., 2018). Pediatrics carries a distinctive risk profile, making children especially vulnerable to the consequences of inappropriate drug use. This is primarily due to the variability in pharmacokinetic and pharmacodynamics parameters which necessitate individualized therapeutic strategies based on developmental stages (Rashed *et al*., 2013; Birarra *et al*., 2017; Leopoldino *et al*., 2019). An improved understanding of the same has significantly enhanced the safety and efficacy of pediatric drug therapy (Kearns *et al*., 2003).

Patient safety remains a top priority in healthcare systems worldwide. A substantial number of patients are harmed each year due to medication errors, with estimates suggesting that one-third to one-half of these errors are preventable (Australian Commission on Safety and Quality in Health Care, 2002; Department of Health, 2001; Kohn *et al*., 2000). Experts agree that pediatric patients are at a greater risk of medication errors compared to adults for several reasons. In fact, the potential for Adverse Drug Events (ADEs) in hospitalized children is estimated to be approximately three times higher than in hospitalized adults (Kaushal *et al*., 2001). A study, the first to develop and assess a trigger tool for detecting ADEs in hospitalized pediatric patients-reported an 11.1% incidence of ADEs. Of these, 22% were deemed preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively (Takata *et al*., 2008; Institute of Medicine, 2007). Pharmaceutical care is critical in pediatrics to ensure safe, effective, and individualized treatment, while minimizing risks such as adverse drug reactions and medication errors (Nahata, 1999). This approach emphasizes a collaborative relationship between the patient and healthcare providers, with shared responsibility for treatment decisions to achieve optimal health outcomes (Hepler and Strand, 1990; Hepler and Grainger-Rousseau, 1995; Hersberger and Arnet, 2006). The Pharmaceutical Care Network Europe (PCNE) defines

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a Drug-Related Problem (DRP) as an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes (PCNE, 2006). DRPs can occur at any stage of the medication use process-from prescribing to treatment follow-up. They are especially common in hospitalized patients due to frequent changes in medication regimens. DRPs can significantly affect a patient's quality of life, increasing mortality, morbidity, and healthcare costs (Blix *et al.*, 2004). Addressing DRPs requires professional judgment and involves evaluation of patient, drug, and disease data to assess the appropriateness of each medication regimen (PCNE, 2006). Studies in developed countries have reported high rates of drug-related errors among hospitalized pediatric patients. However, limited research exists in developing countries like India, although existing studies suggest that pharmacist interventions can positively impact the reduction of DRPs and overall patient care (Bizuneh *et al.*, 2020; Mohammed *et al.*, 2017; Nori *et al.*, 2014). In India, the concept of pediatric pharmaceutical care is still in its early stages and requires stronger support from healthcare systems and professionals. Incorporating clinical pharmacists as part of multidisciplinary care teams is crucial to delivering effective pharmaceutical care. This study aims to assess the role of pharmacists in identifying and managing DRPs in pediatric patients.

MATERIALS AND METHODS

A prospective interventional study was conducted over a six-month period in pediatric inpatients in a tertiary care hospital in north Karnataka. Pediatric patients of either gender, admitted to general pediatric and pediatric intensive care unit for more than 24 hr. with age up to 18 years were included in the study through consecutive sampling method. The sample size was calculated to an estimate of at least 115 patients, recruited assuming a DRPs rate of 2.1 and a confidence level of 0.95 with margin of error at 5% (Blix *et al.*, 2004). The study was approved by Institutional Ethics Committee of the faculty of pharmacy. All study procedures and processes were conducted in accordance the ethical standards of the institutional research committee. Following the medical assessment of the patient after admission at selected wards the two-research pharmacist prospectively reviewed medication charts, laboratory reports, and clinical progress notes on a daily basis. Identified DRPs were classified using the PCNE V5.01 system. Pharmacist recommendations were verbally communicated to the treating pediatrician during ward rounds or case discussions and were simultaneously documented in the patient profile form. Prescriber acceptance was assessed based on modification, continuation, or rejection of the recommendation during follow-up reviews. Intervention outcomes were categorized as solved, partially solved, not solved, or unknown based on clinical documentation and patient response (Figure 1). The data collected was finally analyzed using descriptive statistics and expressed as frequencies, percentages, and mean±standard deviation. The analysis was limited to descriptive statistics as the primary objective of the study was to identify, classify, and describe DRPs and pharmacist interventions rather than to establish inferential associations.

RESULTS

Of the 115 pediatric patients included, 76 (66.08%) were male and 39 (33.92%) were female. The most common age group was 2-11 years (53.04%). A total of 750 medications were prescribed, with a mean of 6.52±1.5 medications per patient. The average length of hospital stay was 4.5±2 days. DRPs were identified in 87 patients (75.65%), with a total of 165 DRPs and a mean of 1.89±1.3 DRPs per patient (Table 1).

Table 1: Demographic and clinical characteristics of the study population *n*=115.

Demographic and Clinical Characteristics	Frequency	Percentage (%)
Gender		
Female	39	33.92
Male	76	66.08
Age Group (in years)		
<2 years	43	37.39
2-11 yrs	61	53.04
12-18 yrs	11	9.57
Diagnosis		
Respiratory	40	34.78
Viral/Bacterial	14	12.17
Haematology	13	11.30
Gastrointestinal	10	8.70
Hepatic	04	3.48
Central nervous system	04	3.48
Renal	04	3.48
Endocrine	02	1.74
Cardiovascular system	01	0.87
Others	23	20
Average length of hospital stay	4.5±2	-
Average medication prescribed	6.52±1.5	-
Average DRPs* Per Patient	1.89±1.3	-
No of actual DRPs	70	57.58
No of potential DRPs	95	24.34
DRPs in study population		
Number of patients with one or more DRPs	87	75.65
Number of patients without any DRPs	28	42.42

*DRPs: Drug Related Problems.

Among the observed DRPs; Drug choice problem had the highest frequency of 80 (48.48%), followed by drug interactions 51 (30.90%) and dosing problem 13 (7.87%), adverse reactions 8 (4.84%), drug use problem 2 (1.21%) and others 11 (6.66%) (Table 2). For all the reported DRPs (165), a total of 115 (69.7%) DRPs were found with the scope for pharmacist interventions. Most of the interventions were at the prescriber level 78 (47.27%) followed by patient level 37 (22.42%). There were clinically insignificant DRPs 50 (30.3%) which were either of self-limiting nature and/or does not require intervention (Table 3). The outcome of interventions in the resolution of the DRPs were reported as follows; DRPs solved 22 (19.13%), partially solved 8 (6.96%), not solved 64 (55.65%), and not known 21 (18.26%) (Table 4).

DISCUSSION

The present study evaluated Drug-Related Problems (DRPs) in 115 hospitalized pediatric patients, of whom males (66%) predominated and the most common age group was 2-11 years (53.04%) (Table 1). This age distribution is comparable with findings reported by Pemmasani *et al.*, (2018), who observed a higher burden of DRPs among younger pediatric age groups.

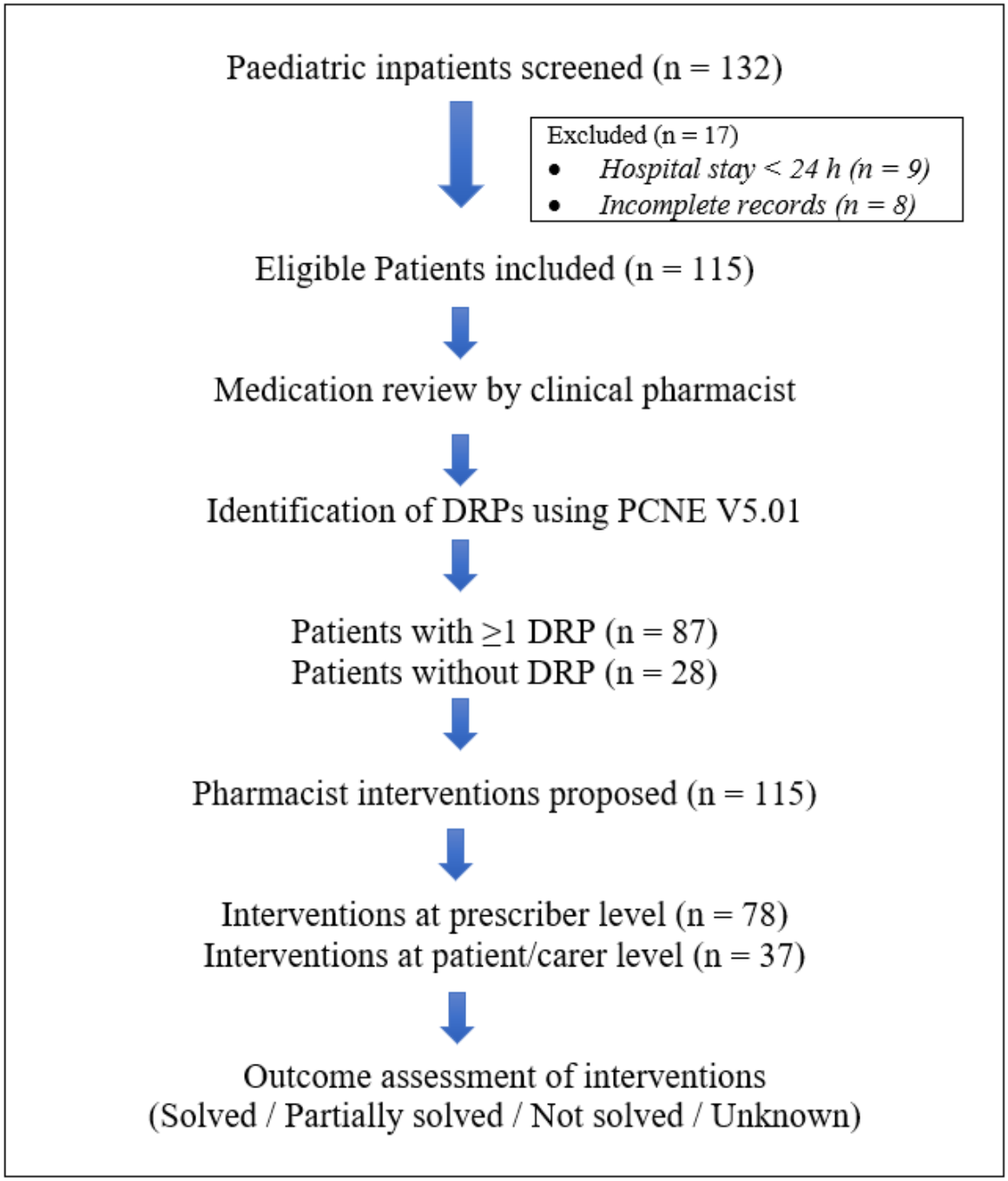

Figure 1: Study Flow Chart.

Table 2: Categorization and Incidence of DRPs (*n*=165).

Domain	Problem	Frequency	Percentage (%)
Adverse Reactions	Side effect suffered (non-allergic)	1	4.84
	Side effect suffered (allergic)	6	
	Toxic effects suffered	1	
Drug Choice Problem	Inappropriate drug (not most appropriate for indication)	7	48.49
	Inappropriate drug form (not most appropriate for indication)	8	
	Inappropriate duplication of therapeutic group or active ingredient	16	
	Contra-indication for drug (incl. Pregnancy/breast feeding)	4	
	No clear indication for drug use	12	
	No drug prescribed but clear indication	33	
Dosing Problem	Drug dose too low or dosage regime not frequent enough	2	7.88
	Drug dose too high or dosage regime too frequent	2	
	Duration of treatment too short	6	
	Duration of treatment too long	3	
Drug Use Problem	Drug not taken/administered at all	2	1.21
	Wrong drug taken/administered	0	
Drug Interactions	Potential interaction	17	30.91
	Manifest interaction	34	
Others	Patient is dissatisfied with therapy despite taking drug(s) correctly	1	6.67
	Insufficient awareness of health and diseases (possibly leading to future problems)	2	
	Unclear complaints. Further clarification necessary	4	
	Therapy failure (reason unknown)	4	

Most patients were diagnosed with a single clinical condition, and respiratory disorders were the most frequent indication for hospitalization (34.78%) (Table 1) similar to observations by Bizuneh *et al.*, (2020). The higher prevalence of respiratory illnesses in the present study may partly be attributed to the semi-arid geographic location and variable air quality of the study region.

Polypharmacy was common, with a mean of 6.52±1.5 medications per patient, and antibiotics constituted the major proportion of prescribed drugs (Table 1). Empirical and prophylactic antibiotic use contributed significantly to the occurrence of drug interactions and inappropriate drug selection. Overall, 75.65% of patients experienced at least one DRP, with a mean of 1.89±1.3 DRPs per patient (Table 1). Drug choice problems were the most frequently identified DRPs (48.48%), followed by drug interactions (30.90%) and dosing problems (7.87%) (Table 2). This pattern differs from the findings of Rashed *et al.*, (2013). where dosing problems were the predominant DRP, highlighting variability in prescribing practices across healthcare settings.

Table 3: Categorization of Proposed Interventions for Identified DRPs (*n*=165).

Interventions Proposed	Frequency	Percentage (%)
No Intervention scope	50	30.30
Interventions proposed at prescriber level	78	47.28
Interventions proposed at patient/ carer level	37	22.42

Drug choice problems in the present study were mainly related to omission of indicated therapy, drug use without valid indication,

Table 4: Categorization of Outcome of Proposed Interventions for DRPs (*n*=115).

Domain	Outcome of Intervention	Frequency	Percentage (%)
Not Known	Outcome intervention not known	21	18.26
Solved	Problem totally solved	22	19.13
Partially Solved	Problem partially solved	8	6.95
Not Solved	Problem not solved, lack of cooperation of patient	0	55.65
	Problem not solved, lack of cooperation of prescriber	32	
	Problem not solved; intervention not effective	26	
	No need or possibility to solve problem	6	

therapeutic duplication, inappropriate drug or dosage form, and use of contraindicated drugs (Table 2). Pediatric pharmacotherapy is inherently challenging due to diagnostic uncertainty, age-related physiological variability, and limited pediatric formulations, which often result in empirical prescribing and deviation from standard treatment guidelines. Therapeutic duplication observed in this study may be attributed to the availability of multiple branded formulations with look-alike or sound-alike names and the lack of generic prescribing.

The incidence of adverse drug reactions (4.84%) was relatively low, and most ADRs were mild to moderate and self-limiting (Table 2). Antibiotics and antiepileptic's were the most frequently implicated drug classes, consistent with previous reports. Dosing problems, though less frequent, included both sub therapeutic and supra therapeutic dosing and inappropriate treatment duration, emphasizing the need for careful dose individualization and monitoring in pediatric patients (Table 2).

Drug interactions were predominantly antibiotic-related, reflecting their extensive use in hospitalized children (Table 2). Drug use problems and other DRPs were infrequent and were mainly associated with delayed drug administration, inadequate patient or caregiver understanding, and healthcare system-related factors (Table 2).

Pharmacist-led interventions were proposed for 69.70% of identified DRPs, with most interventions directed at prescribers (Table 3). Although complete resolution was achieved in only a subset of cases, pharmacist involvement resulted in therapy modification, drug withdrawal, and improved medication safety. Variability in prescriber acceptance underscores the importance of strengthening interdisciplinary collaboration and integrating clinical pharmacists into pediatric healthcare teams. The outcomes of pharmacist interventions are summarized in Table 4.

The study is limited by its single-center design and reliance on descriptive analysis. However, it provides valuable evidence supporting the role of pharmacists in pediatric pharmaceutical care within Indian hospital settings.

Overall, the findings reinforce the necessity of structured pharmacist intervention models to identify and manage DRPs and enhance therapeutic outcomes in pediatric patients and deliverance of quality of pediatric pharmaceutical care.

CONCLUSION

The study reveals a greater incidence of one or more DRPs per patient requiring intervention from the pharmacist. Most of the interventions provided by the pharmacist were well received by the physicians by prompt implementations and improvisations. The role of the pharmacist in preventing DRPs arising during the course of therapy with or without the knowledge of the prescribers is significant and necessitates the need for conceptual pediatric pharmaceutical care practice involving a clinical pharmacist. There is considerable evidence that pharmaceutical care services provided by the pharmacist could reduce the impact of DRPs and can improve quality of life. The conception of an impeccable pharmaceutical care approach was possible only with the perfect blend of collaboration of pharmacists and the healthcare body.

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ABBREVIATIONS

PCNE: Pharmaceutical Care Network Europe; **DRPs:** Drug-related problems; **ADR:** Adverse drug reaction; **ADE:** Adverse drug event.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FUNDING

The study neither applied for nor received funding from any source.

SUMMARY

Pharmaceutical care is critical in pediatrics to ensure safe, effective, and individualized treatment while minimizing DRPs. The strategy involves a collaborative approach between the healthcare providers and clinical pharmacist for improved patient care. The study shows pharmaceutical care medicine management approach provided by the pharmacist is significant in the prevention of DRPs. Pediatric pharmaceutical care, therefore, promote quality medicine use practice.

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