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Original Article

Drug-Related Problems and Pharmacist Interventions in Paediatric In-Patients at a Tertiary Care Teaching Hospital: A Prospective Observational Study

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ABSTRACT

Background: Paediatric in-patients are particularly vulnerable to Drug-Related Problems (DRPs) owing to physiological immaturity, weight-based dosing, and widespread off-label medicine use. **Objectives:** To identify and categorise DRPs, evaluate prescribing patterns and rationality against standard guidelines, assess pharmacist intervention outcomes, and perform a cost analysis of drug therapy in paediatric in-patients at a tertiary care teaching hospital. **Materials and Methods:** A six-month prospective observational study was conducted in the PICU, NICU, and General Paediatric wards of a tertiary care teaching hospital. A total of 135 in-patients aged 18 years or younger were enrolled. Prescriptions were reviewed daily; DRPs were classified using the Strand classification; rationality was assessed against Indian Academy of Paediatrics (IAP) recommendations. The chi-square test was applied, with significance set at $p<0.05$. **Results:** Of 135 patients, lower respiratory tract infection was the most frequent diagnosis (25.9%). Overall, 71.85% of prescriptions were rational and 28.15% irrational. A total of 139 DRPs were identified, predominantly drug-drug interactions (38.1%) and adverse drug reactions (20.9%). Polypharmacy occurred in 84.4% of patients and accounted for 79.1% of DRPs. Of 139 pharmacist suggestions, 46.8% were accepted by physicians, resulting in a change of therapy in 36.0% of cases. **Conclusion:** The high burden of DRPs and irrational prescribing supports routine clinical pharmacist participation in paediatric care. Physician receptiveness to suggestions demonstrates the clinical relevance of these services.

Keywords: Clinical Pharmacy Services, Drug-Related Problems, Paediatrics, Polypharmacy, Prescription Rationality.

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INTRODUCTION

Clinical pharmacy is a discipline within the health sciences in which pharmacists deliver patient-focused care aimed at improving medication outcomes, supporting wellness, and reducing the burden of illness (Houghton, 2007). Over recent decades, such services have moved from the periphery to the centre of multidisciplinary healthcare delivery, spanning activities such as reconciling medication histories, monitoring therapeutic drug levels, tracking adverse effects of medicines, and contributing to ward-round discussions (Society of Hospital Pharmacists of Australia, 2013). The underlying goal is to reduce the hazards associated with medicine use while improving outcomes at every stage of the medication pathway.

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Children make up roughly one-fifth to one-quarter of the world's population and present a unique set of medication-safety concerns (Parthasarathi *et al.*, 2004). The Kefauver-Harris amendments of 1962 made proof of both safety and efficacy mandatory before a drug could be approved; an unintended consequence was that manufacturers became less willing to pursue formal paediatric approvals, leaving children as so-called 'therapeutic orphans' for whom robust evidence of safe medicine use is often lacking (Parthasarathi *et al.*, 2004). A combination of immature drug-handling physiology, the need for weight-based dose calculations, frequent off-label use, and reliance on caregivers for administration leaves children disproportionately exposed to medication-related harm. Children have been reported to experience medication errors at roughly three times the rate seen in adult patients (Fortescue *et al.*, 2003).

Evidence indicates that pharmacist participation in ward rounds meaningfully lowers the occurrence of adverse drug events. Fortescue *et al.* (2003) found that pharmacists embedded within paediatric wards averted roughly four out of five potentially harmful prescribing errors. Krupicka *et al.* (2002) observed that

the bulk of pharmacist contributions in a paediatric intensive care unit involved dosage adjustment and drug-information support, with these activities yielding tangible cost savings. Joseph and LaRochelle (2012), working in a similar intensive-care environment, recorded close to 900 pharmacist interventions across a two-month window, with prescribers acting on more than 95% of them. In a randomised trial, paediatric patients assigned to pharmacist-led input experienced a shorter hospital stay and better adherence to prescribed regimens than those who did not, with no corresponding rise in treatment expenditure (Zhang *et al*., 2012).

Problems arising from drug therapy-such as treating a condition without a clear indication, leaving an existing condition untreated, adverse reactions, harmful drug-drug interactions, dosing that is too low or too high, and unnecessary duplication of therapy-collectively contribute to avoidable illness, longer hospital admissions, and higher healthcare spending (Lagnaoui *et al*., 2000; Winterstein *et al*., 2002). Systematically identifying and addressing such problems has been shown to make a tangible difference to both patient outcomes and the economics of care (Davey *et al*., 2005; Jamtvedt *et al*., 2006).

Clinical pharmacy practice is still at a relatively early stage of development locally compared with western healthcare systems, and paediatric units in particular often function without dedicated pharmacist oversight of prescribing. Against this background, the present study was designed to evaluate the prescribing pattern among paediatric in-patients; to identify, categorise, and quantify drug-related problems and the resulting pharmacist interventions; and to perform a cost analysis of the prescribed drug therapy in a tertiary care teaching hospital.

MATERIALS AND METHODS

Study Design, Site, and Duration

This prospective observational study was conducted over a period of six months in the Paediatric Intensive Care Unit (PICU), Neonatal Intensive Care Unit (NICU), and General Paediatric wards of S. Nijalingappa Medical College and H.S.K. Hospital and Research Centre, Bagalkot, Karnataka-a tertiary care teaching hospital affiliated to Rajiv Gandhi University of Health Sciences.

Ethical Approval

The study protocol was reviewed and approved by the Institutional Ethics Committee of S. Nijalingappa Medical College, Bagalkot (Reference No. SNMC/IECHSR/2014-15/A-04d-1.1). Written informed consent was obtained from the parent or legal guardian of each enrolled child.

Study Population and Selection Criteria

Paediatric in-patients of either sex aged 18 years or younger, admitted to the PICU, NICU, or General Paediatric wards during the study period, were included. Paediatric out-patients and patients older than 18 years were excluded. Following International Council for Harmonisation (ICH) guidance, four age bands were used for analysis: newborns (0-29 days), infants and toddlers (29 days to 2 years), children (2-12 years), and adolescents (12-18 years).

Data Collection

Information was drawn from each patient's case file, treatment chart, laboratory reports, prescription record, adverse drug reaction notification forms, and discharge summary, and was logged prospectively onto a structured data-collection proforma. Every enrolled patient was followed daily for the entire length of admission, with data captured on demographics, diagnosis, drug history, route and dose of administration, and any drug-related problem encountered.

Identification and Classification of Drug-Related Problems

All prescriptions were independently reviewed by the intervening Pharm.D students in consultation with the academic clinical pharmacist of the Department of Pharmacy Practice. Drug-related problems were categorised according to the classification proposed by Strand *et al*. (1990), comprising the following categories: drug use without indication, untreated indication, improper drug selection, sub-therapeutic dosage, overdosage, adverse drug reaction, drug interaction, drug duplication, class duplication, and failure to receive a prescribed drug.

Assessment of Prescription Rationality

The rationality of each prescription was assessed against the treatment recommendations of the Indian Academy of Paediatrics (IAP), with each prescription classified as rational or irrational based on the appropriateness of drug selection, dose, and duration relative to the diagnosis.

Pharmacist Intervention and Outcome Documentation

Each identified DRP was brought to the attention of the treating physician, together with an appropriate suggestion, at the earliest opportunity. Suggestions were categorised as a change in dosage form, change in drug dose, addition of a drug, cessation of a drug, substitution of a drug, change in route of administration, change in frequency of administration, change in duration of therapy, or monitoring of a drug-drug interaction. The acceptance status of each intervention (accepted or not accepted) and the resulting change, if any, in drug therapy were recorded. The level of pharmacist involvement in therapeutic decision-making was further classified using the Hepler-Strand intervention model.

Drug Interaction Severity Classification

Identified drug-drug interactions were graded according to standard severity classifications (contraindicated, major,

moderate, and minor) based on the potential clinical consequence of concurrent administration.

Cost Analysis

The cost of drug therapy for each patient was calculated using the hospital pharmacy price list; where a particular formulation was unavailable in that list, the Current Index of Medical Specialities (CIMS) or the Indian Drug Review (IDR) was used as the reference source. The average drug cost per prescription and the proportion of cost attributable to injectable formulations were computed.

Statistical Analysis

Findings were summarised using frequencies and percentages. Differences in the proportion of rational versus irrational prescriptions between the PICU/NICU and the general wards, and differences in polypharmacy occurrence between male and female patients, were examined using the chi-square test, with statistical significance set at $p<0.05$.

RESULTS

A total of 135 paediatric in-patients were enrolled during the six-month study period, comprising 75 males (55.6%) and 60 females (44.4%).

Demographic Profile

The age-wise distribution of patients according to ICH age bands is presented in Table 1. The largest proportion of patients belonged to the 29 days-2 years age group (47.5%), followed by the 2-12 years group (39.2%).

Disease Pattern

Lower respiratory tract infections (including bronchopneumonia, wheeze-associated lower respiratory tract infection, and bronchiolitis) constituted the most frequent diagnostic category (25.9%), followed by seizure disorders (9.6%) and hepatitis (6.7%) (Table 2).

Route of Drug Administration

A combination of oral and parenteral therapy was prescribed for 122 patients (90.3%), while parenteral-only and oral-only therapy were prescribed for 8 (5.9%) and 5 (3.8%) patients, respectively. The predominance of combined oral-parenteral therapy reflects the acuity of patients managed in the PICU and NICU settings.

Assessment of Prescription Rationality

Based on IAP recommendations, 97 of 135 prescriptions (71.85%) were classified as rational, while 38 (28.15%) were classified as irrational. Irrationality was chiefly attributed to inappropriate antimicrobial choice for the diagnosis, the omission of guideline-directed adjunct agents (for example, diuretics in nephrotic syndrome or hepatoprotectants in viral hepatitis), and avoidable co-prescription of two or more drugs from an identical therapeutic class.

On stratifying rationality by location of care, prescriptions in the PICU and NICU were more often rational (21 of 24, 87.5%) than those in the General Paediatric wards (76 of 111, 68.5%). Although this difference suggests closer prescribing scrutiny in critical-care areas, it did not reach statistical significance ($\chi^2=3.534$, $p=0.060$) (Table 3 and Figure 1).

Drug-Related Problems

A total of 139 DRPs were identified among the 135 study patients Figure 2. Drug-drug interactions were the most common category (38.1%), followed by adverse drug reactions (20.9%) and untreated indications (13.7%) (Table 4).

Among the 53 drug-drug interactions identified, the majority were of major severity (43.4%), followed by moderate (34.0%), with minor and contraindicated interactions each accounting

Table 1: Distribution of disease categories among paediatric in-patients.

Disease category	Number of patients	Percentage (%)
Lower respiratory tract infections	35	25.9
Seizure disorders	13	9.6
Hepatitis	9	6.7
Urinary tract infection	5	3.7
Acute gastroenteritis	4	3.0
Meningitis	4	3.0
Nephrotic syndrome	4	3.0
Hyperreactive airway disease	4	3.0
Retroviral disease	3	2.2
Others*	54	40.0
Total	135	100.0

*Others include birth asphyxia, low birth weight, anaemia, malnutrition, congenital anomalies, and miscellaneous single-case diagnoses.

Table 2: Ward-wise assessment of prescription rationality.

Ward category	Rational, n	Irrational, n	Total, n
PICU and NICU	21	3	24
General wards (A, B, C)	76	35	111
Total	97	38	135

Chi-square = 3.534; $p=0.060$ (not significant at $\alpha = 0.05$).

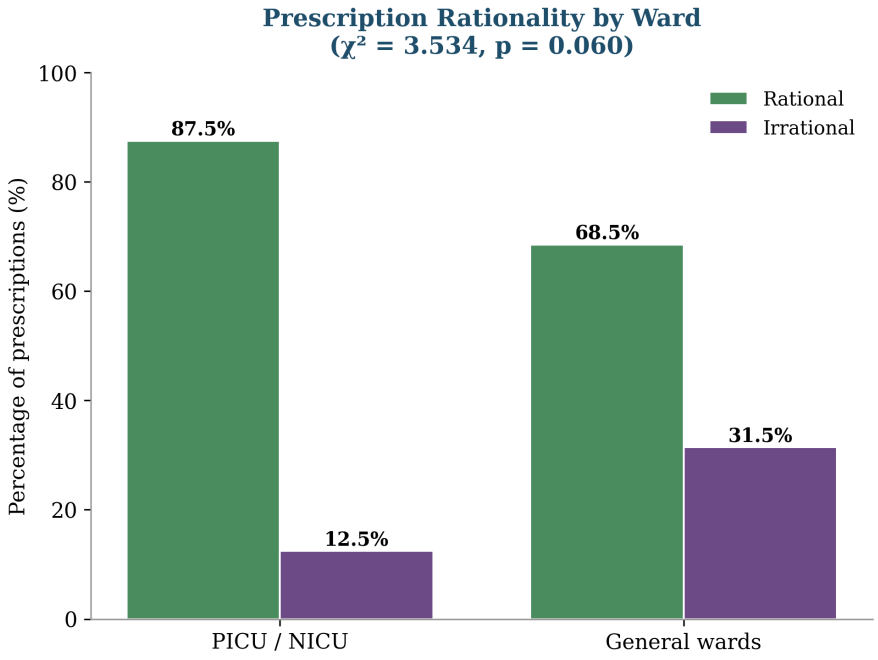

Figure 1: Ward-wise comparison of prescription rationality. A higher proportion of rational prescriptions was observed in the PICU/NICU than in the general wards; the difference was not statistically significant ($\chi^2 = 3.534$, p=0.060).

Table 3: Distribution of drug-related problems identified among paediatric in-patients.

Type of drug-related problem	Number (%)
Drug-drug interaction	53 (38.1)
Adverse drug reaction	29 (20.9)
Untreated indication	19 (13.7)
Improper drug selection	11 (7.9)
Drug duplication	11 (7.9)
Class duplication	5 (3.6)
Drug use without indication	5 (3.6)
Overdose	4 (2.9)
Sub-therapeutic dose	1 (0.7)
Failure to receive a prescribed drug	1 (0.7)
Total	139 (100)

for 11.3%. The most frequently observed interacting drug pairs included calcium supplements with levofloxacin, amikacin with amoxicillin-clavulanate, and the concurrent use of two or more antiepileptic agents (phenytoin, phenobarbital, and valproic acid). Organ-system analysis revealed that the central nervous system (20.1%), cardiovascular system (19.4%), and gastrointestinal system (17.2%) were most frequently implicated in DRPs.

Polypharmacy

Polypharmacy (concurrent use of ≥5 medications) was observed in 114 patients (84.4%), comprising 60 males and 54 females, while the remaining 21 patients (15.6%) were prescribed fewer than 5 medications; the difference between genders was not statistically significant (χ^2=2.538, p=0.111). Notably, 110 of the 139 DRPs (79.1%) occurred among patients receiving ≥5 drugs, compared with only 29 (20.9%) among those on fewer than 5 drugs-a pattern pointing to polypharmacy as a major driver of medication-related problems in this cohort.

Prescribing Indicators and Cost Analysis

On average, each patient was prescribed 7.67 drugs (1036 drugs across 135 patients), and intravenous formulations were administered to 131 patients (97.04%). Per-patient drug expenditure averaged ₹549.07 (total ₹74,124 across 135 patients), with injectable formulations contributing ₹36,713-nearly half (49.53%) of the overall cost. Acetaminophen (101 prescriptions), multivitamin preparations (55), and ceftriaxone (44) topped the list of agents prescribed.

Pharmacist Interventions and their Outcomes

Of the 139 suggestions provided by the intervening Pharm.D students, monitoring of drug-drug interactions was the most frequent (38.1%), followed by substitution of drugs (32.4%) and addition of an indicated drug (13.7%) (Table and Figure 3). Overall, 65 interventions (46.8%) were accepted by the treating physicians, while 74 (53.2%) were not accepted; a corresponding change in drug therapy occurred in 50 cases (36.0%).

Classifying interventions by the pharmacist's level of involvement in therapeutic decision-making showed that Level 2 (corrective) involvement-where the pharmacist actively challenged a

prescription in an effort to bring about change-accounted for the largest share (41.8%), while Level 1 (annotative) involvement, in which an issue was flagged without an explicit request for modification, made up 20.9%. For evidence sources underpinning these interventions, secondary references such as Micromedex and the MSD Merck Manual for Healthcare Professionals were consulted most often (61.1%), with tertiary textbook sources (21.7%) and primary research literature (17.2%) used less frequently.

DISCUSSION

Children living with complex or ongoing health conditions are widely regarded as needing more from the healthcare system than children generally do, and embedding pharmacists within paediatric care teams has repeatedly been linked to fewer dispensing errors and better caregiver comprehension of how prescribed medicines should be used (American Academy of Pediatrics, 2005; Joseph and LaRochelle, 2012).

Males formed a slight majority of the cohort (55.6% versus 44.4%), echoing the gender split reported in earlier work on paediatric prescribing patterns (Joseph and LaRochelle, 2012). That the largest age band was 29 days to 2 years fits with the well-recognised susceptibility of very young children to infections and nutritional problems, and corresponds with the disease profile seen here, in which lower respiratory tract infection topped the diagnosis list-an observation echoed in other tertiary paediatric settings (Rajan *et al.*, 2016).

The high proportion of patients (90.3%) receiving a combination of oral and parenteral therapy reflects the acuity of admissions to the PICU and NICU, where intravenous access is often required for rapid therapeutic effect or when oral intake is not feasible. The most frequently prescribed agents-ceftriaxone, amoxicillin-clavulanate, and acetaminophen-are consistent with the predominance of infectious and febrile illnesses in the cohort, and mirror prescribing patterns reported from other tertiary-care paediatric settings (Sharma and Gupta, 2017).

Roughly one in four prescriptions (28.15%) failed to meet IAP-recommended standards. Other government teaching hospitals have reported irrational-prescribing rates in paediatric settings spanning a similar range, the exact figure depending on the criteria applied (Mirza *et al.*, 2009). Critical-care areas in the present study (PICU/NICU) showed numerically fewer irrational prescriptions than the general wards; although this difference did not reach statistical significance, it is consistent

Table 4: Type and frequency of pharmacist suggestions provided during the study.

Type of pharmacist suggestion	Number (%)
Monitor drug-drug interaction	53 (38.1)
Substitution of drug	45 (32.4)
Addition of drug	19 (13.7)
Cessation of drug	13 (9.4)
Change in drug dose	5 (3.6)
Change in dosage form	2 (1.4)
Change in frequency of administration	2 (1.4)
Total	139 (100)

Of 139 suggestions, 65 (46.8%) were accepted and 74 (53.2%) were not accepted; therapy was changed in 50 cases (36.0%).

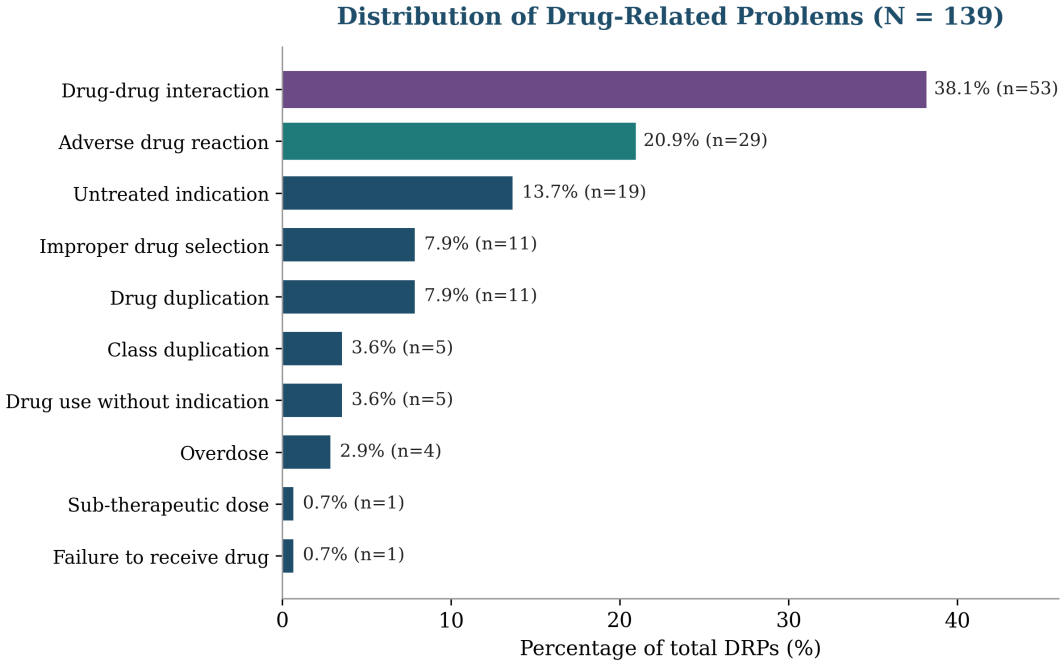

Figure 2: Distribution of Drug-Related Problems (DRPs) identified among the 135 paediatric in-patients (*n*=139). Drug-drug interactions and adverse drug reactions were the two most frequent categories.

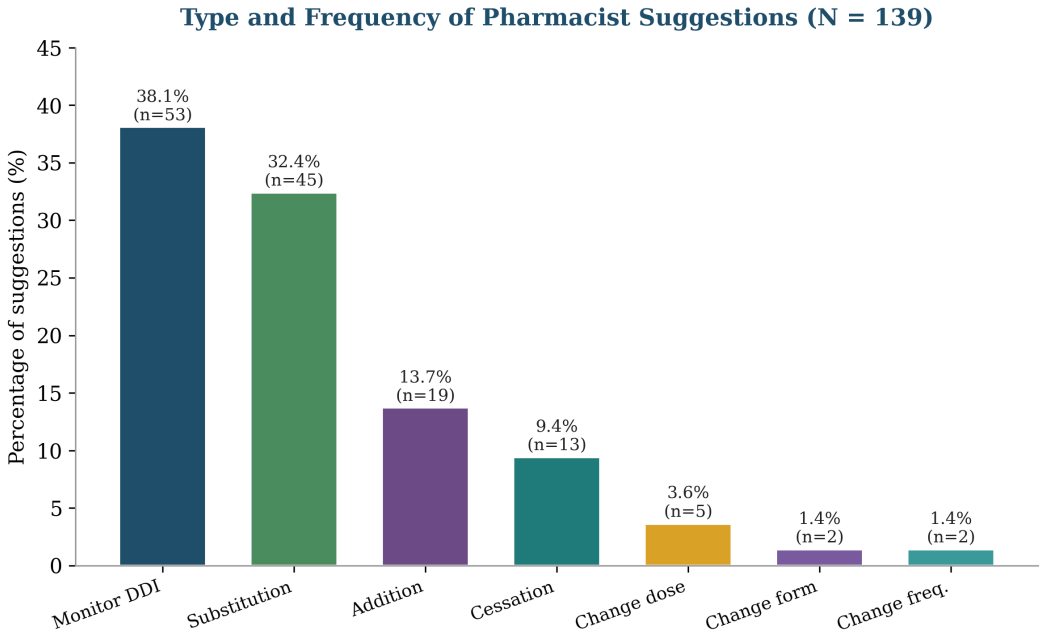

Figure 3: Type and frequency of clinical pharmacist suggestions provided during the study (*n*=139). Monitoring of drug-drug interactions and drug substitution were the most frequent recommendations.

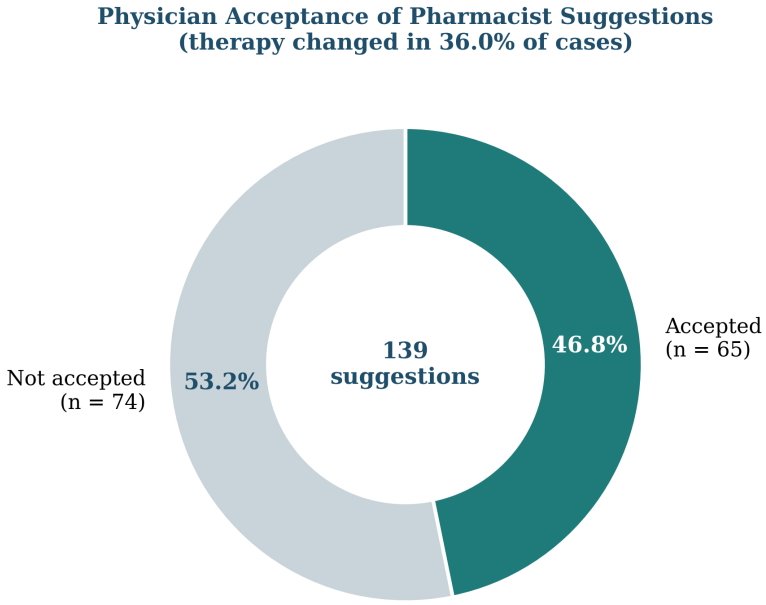

Figure 4: Physician acceptance of pharmacist suggestions. Of 139 suggestions, 65 (46.8%) were accepted, resulting in a change of therapy in 36.0% of cases.

with the heightened consultant oversight and more frequent case discussions typical of intensive-care settings-a pattern also noted in a study of neonatal antibiotic prescribing, where most prescriptions in intensive care were found to be appropriate (Shinde and Jadhav, 2016).

With 139 DRPs spread across 135 patients-just over one per child-drug-drug interactions (38.1%) emerged as the leading category, the majority carrying major clinical significance. Other paediatric cohorts have likewise found drug interactions to be the single largest contributor to DRP burden (Easton *et al.*, 2009). Recurring and largely preventable patterns included combining multiple antiepileptics (Phenytoin, Phenobarbital, Valproic acid) and pairing calcium supplements with fluoroquinolones, the latter risking reduced fluoroquinolone absorption through chelation. Adverse drug reactions made up a further 20.9%

of DRPs, with cephalosporin antibiotics the most commonly implicated agents-a finding mirrored in adverse drug reaction surveillance work from other hospitals (Blix *et al.*, 2004).

Nearly 80% of all DRPs in this study occurred among the 114 patients (84.4%) receiving five or more concurrent medications, underscoring polypharmacy as a recurring and modifiable contributor to medication-related harm in children-a link also reported elsewhere (Birarra *et al.*, 2017). With patients in this cohort averaging close to eight drugs each, and injectables consuming nearly half of total drug spending, there appears to be room for rationalising therapy-for instance, switching to oral formulations sooner where clinically feasible-with potential benefits for both patient safety and cost in resource-constrained settings (Thirthopu and Reddy, 2018).

Of particular relevance to the feasibility of introducing clinical pharmacy services, nearly half (46.8%) of the suggestions made by the intervening Pharm.D students were accepted by treating physicians, resulting in an actual change of therapy in over one-third of cases. This acceptance rate compares favourably with intervention-acceptance rates reported during the early phase of pharmacist-led services in other teaching hospitals, where acceptance during initial implementation has often ranged between 40% and 60% before improving with sustained pharmacist presence (Chandrakanth and Reddy, 2015). The predominance of Level 2 (corrective) interventions, in which the pharmacist actively sought a change to the prescription, indicates that the intervening students were not merely passive observers but were engaging substantively with the prescribing process-a pattern considered indicative of a maturing clinical pharmacy service (American Academy of Pediatrics, 2005).

LIMITATIONS

This study was conducted at a single centre over a six-month period, and the findings reflect prescribing practices documented during the study window. As this was an observational study without a comparator group, the direct causal impact of the pharmacist intervention on clinical outcomes could not be established. Rationality and DRP assessments, although performed against established criteria and cross-checked with an academic clinical pharmacist, involve an element of reviewer judgement and are subject to potential observer bias. Future controlled before-and-after studies at this institution would help to quantify the clinical and economic impact of these services more definitively.

CONCLUSION

This work documents a substantial burden of drug-related problems among paediatric in-patients at a tertiary teaching hospital. Around one in four prescriptions fell short of IAP standards, and 139 drug-related problems-chiefly drug-drug interactions and adverse drug reactions-were identified across the 135-patient cohort, with polypharmacy standing out as a major contributing factor. That close to half of the pharmacist team's suggestions were taken up by physicians, even at this early stage, points to the practical value such involvement can add to paediatric care from the outset. Taken together, these results make a case for embedding clinical pharmacists more widely within paediatric healthcare teams, particularly where systematic medication review has not yet become standard practice.

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ABBREVIATIONS

ADR: Adverse drug reaction; **CIMS:** Current Index of Medical Specialities; **CNS:** Central nervous system; **DRP:** Drug-related problem; **IAP:** Indian Academy of Paediatrics; **ICH:** International Council for Harmonisation; **IDR:** Indian Drug Review; **LRTI:** Lower respiratory tract infection; **NICU:** Neonatal Intensive Care Unit; **PICU:** Paediatric Intensive Care Unit; **UTI:** Urinary tract infection; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FUNDING

The authors received no specific funding for this work.

DECLARATION OF ARTIFICIAL INTELLIGENCE USE

The authors declare that artificial intelligence was not used for the generation of the case report, tables, results or any scientific data. Artificial intelligence was used solely to assist with formatting and language refinement (improving wording and readability). All clinical data, tables and results presented in this manuscript are original, genuine and derived directly from the patient's records, and the authors take full responsibility for the accuracy, integrity and authenticity of the entire content.

AUTHOR CONTRIBUTIONS

All authors contributed to this work in accordance with the ICMJE authorship criteria. Raghavendra Shivaram Hegde conceived and designed the study, supervised data acquisition and analysis, and drafted and critically revised the manuscript. Sowmya and Ramya Sree contributed to data collection, pharmacist interventions, and data analysis. Ajeet Singh Rathod contributed to data collection and interpretation. Mallappa Shalavadi supervised the study and critically reviewed the manuscript. Mudakappa Keshannavar

contributed to data analysis and manuscript preparation. All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

SUMMARY

This prospective study of 135 paediatric in-patients identified a significant burden of drug-related problems (139 DRPs), primarily driven by polypharmacy (84.4% of patients). Drug-drug interactions were the most frequent DRP (38.1%), and nearly 30% of prescriptions were deemed irrational based on IAP guidelines. Clinical pharmacist interventions were well-received, with a 46.8% physician acceptance rate, suggesting that embedding pharmacists in paediatric teams can enhance medication safety and rationality.

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