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EVALUATION OF RATIONAL DRUG PRACTICES IN PEDIATRIC PATIENTS AT A TERTIARY CARE HOSPITAL IN INDIA

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ABSTRACT

Background and objectives

The irrational use of medication in pediatric patients is a widespread concern, particularly prevalent in developing countries. This study aimed to evaluate the rationality of drug use in the pediatric outpatient department of a tertiary care hospital in India.

Methods

The cross-sectional observational study involved data collection from 5401 prescriptions of patients attending pediatric outpatient department of a tertiary care hospital. Ethical approval and informed consent were obtained. The study included prescriptions for newly diagnosed or first-time patients under 18 years of age, each containing at least one drug. The World Health Organization's prescribing indicators were used to assess rational drug use.

Results

Patients aged 1-5 years comprised 30% of the sample, with a male-to-female ratio of 1.44. Respiratory tract infections were the most common condition (48.33%). A total of 12,818 drugs were prescribed, with syrups being the most frequent dosage form (38.48%). Fixed-dose combinations were prescribed the most (31.95%). Average number of drugs per prescription was 2.3. 35% drugs were written using generic names with 82% prescribed from the essential drug list. Average percentage of antibiotics per prescription was 19.83%. Patient

information was present in 96% of prescriptions, but many lacked complete patient history, allergy status, and doctor details. 68% of prescriptions were moderately legible, while 32% were fully legible.

Conclusion

Healthcare providers must be to encouraged and trained to adhere to clinical guidelines, use generics and write in capital letters or utilize typed prescriptions to promote rational therapeutics in pediatric settings. This study forms the foundation for policymakers and future interventions.

Keywords: prescription pattern, prescribing drug use indicators, children, generic, legibility, medication error

INTRODUCTION

Children constitute approximately 40% of the population in numerous developing countries, and they are particularly vulnerable to severe illnesses. Infants and young children under the age of five are especially susceptible to infectious diseases, which contribute to high mortality rates. In 2019 alone, nearly 5.2 million children under five years old died, mostly from treatable and preventable causes. India recorded 783 of these deaths, ranking second after Nigeria, which reported 844 deaths **[1]**. Given the heightened vulnerability of children and the limited data on the safety and efficacy of many medications for this age group, rational and judicious drug use is critically important during childhood. The lack of age-appropriate dosage forms can lead to the use of compounded medications, adjustments from adult dosages, and off-label drug use without adequate evidence.

The irrational use of medications in pediatric patients is a global challenge, with the highest prevalence observed in developing countries. Contributing factors include limited knowledge about medications, unethical promotional practices, and improper prescribing habits among healthcare providers **[2]**. Pediatric patients are particularly susceptible to medication errors and may experience more severe adverse drug reactions compared to adults due to differences in weight, body surface area, and variations in their ability to metabolize and eliminate medications **[3]**. Moreover, children may struggle to recognize and communicate early signs of adverse drug effects **[4]**. The irrational use of medications not only increases treatment costs but also leads to a higher incidence of adverse drug reactions.

Evaluating prescriptions using World Health Organization (WHO) prescribing drug use indicators is an effective strategy

to enhance the quality of prescribing and establish criteria for optimal drug use, thereby reducing medication errors **[5]**. Such studies provide a foundation for promoting rational and cost-effective therapeutic care **[2, 5, 6]**. Therefore, the present study was undertaken to assess the rational drug use in pediatric population of a tertiary care hospital serving to rural semi-urban population in Northern India.

MATERIAL AND METHODS

Study Design

This was a cross- sectional and observational study

Study Setting

The study was conducted in the pediatric outpatient department (OPD) of a multi-specialty, 810-bed tertiary care hospital in Northern India.

Sample Size

A total of 5401 prescriptions were analysed during the study. The sample size was determined using a convenience sampling method, based on the average number of patients attending the pediatric OPD daily.

Study Duration

The study was carried out over a 12-month period, from March 1, 2023, to March 1, 2024.

Ethical Consideration

The ethical clearance was obtained from the Institutional Ethics Committee (IEC-SGTCHRI/SGTCOLLEGEOFPHARMACY/2023/05). As the study was observational in nature and required data collection from the prescription of the patient, the patient was not subjected to any additional risk or harm during this study. Informed consent was obtained from all the participants. According to ICMR's National Ethical Guidelines for Biomedical Research involving children 2017, patients aged 12 years and above signed the assent form on their own and for patients below 12 years, the consent form was signed by their parent or caretaker **[7]**. The patient information sheet and consent forms were provided in both Hindi and English, where the study's purpose and details were explained in simple terms.

Inclusion Criteria

The study included prescriptions containing at least one drug from patients, under 18 years of age, who attended the pediatric OPD of the tertiary care hospital for the first time or were newly diagnosed. Only those patients willing to participate were included.

Exclusion Criteria

The study excluded patients and/or their caregivers/parents who refused to participate. Prescriptions that did not contain any prescribed drugs were also excluded.

Data Collection and analysis

Data was collected from patient prescriptions and recorded in a structured data collection form. The analysis focused

on determining the age and gender distribution of patients, type of pediatric diseases, pattern of drugs, fixed-dose combinations and dosage forms prescribed, WHO rational drug use prescribing indicators, completeness and legibility of prescriptions.

Statistical Analysis

Descriptive statistics, including frequency, averages, and percentages, were used to analyze the data.

RESULTS AND DISCUSSION

Evaluation of prescription patterns is a critical approach to promoting the rational use of drugs, particularly in pediatric patients who have unique pharmacokinetic and pharmacodynamic needs. Prescribing indicators are essential tools that assess and enhance prescribing practices, reducing the risks of adverse drug reactions, antibiotic resistance, and unnecessary healthcare costs in outpatient settings.

Sociodemographic characteristics of patients

In this study, the sociodemographic characteristics of the patients were analyzed to better understand the prescribing patterns. The age distribution of patients obtained from their prescriptions is illustrated in **Figure 1**. Among the patients, 1620 (30%) belonged to the age group of 1 to 5 years, with an average age of 7 years. The gender distribution showed that 3187 (59%) were male and 2214 (41% of patients) were female, resulting in male-to-female ratio of 1.44. Our findings are consistent with a previous study, where maximum patients (45%) were from age group 1-5 years **[8]**.

Pattern of diseases

The analysis of prescriptions revealed that respiratory tract infections were the most prevalent among pediatric patients, accounting for 2592 (48.33%) cases. Among these, cold was the most frequent accounting for 838 (32. 33%). Similar results indicating maximum prevalence of respiratory tract infections have been reflected in the past **[8-11]**. The prevalence of diseases among the pediatric patients studied is further illustrated in **Figure 2**.

Pattern of prescribed drugs including fixed dose combinations

In this study, 5401 prescriptions were analyzed, revealing a total of 12,818 drugs prescribed. Fixed dose combinations (FDC) were prescribed the maximum accounting for 1611 (31.95%), followed by non-steroidal anti-inflammatory drugs (NSAIDs) with 1602 (12.5%) and 1009 (7.87%) antacids. Chlorpheniramine meleate with Phenylephrine hydrochloride was the most commonly prescribed FDC (688)16.81%. Among the antibiotics, the beta-lactam FDC of Amoxicillin with Clavulanic acid was the most frequently prescribed, with 242 (32.77%) prescriptions, primarily for patients with fever and respiratory tract

infections. Miscellaneous drugs included carminatives, probiotics, diuretics, calamine lotion, artificial tears, urinary alkalizes, and cardiovascular drugs totaling up to 1584 (12.36%). Past studies have reported of antibiotics being the most prescribed drugs **[12, 13]**. The frequent use of FDCs and NSAIDs underscores the importance of monitoring prescribing trends to ensure the rational use of these medications. Additionally, the Indian regulatory agency, Central Standard Drug Control Organization (CDSCO), issued guidelines in 2023 advising against the use of Chlorpheniramine maleate and Phenylephrine Hydrochloride FDCs in children under 4 years of age **[14]**. A detailed breakdown of the most frequently prescribed drugs within each class is provided in **Table 1**, offering further insight into the prescribing habits observed.

Pattern of prescribed dosage forms

Out of 12818 drugs, 4932(38.48%) were prescribed in the form of syrups, 3610(28.16%) were tablets, 2160(16.85%) were drops, 724(5.64%) were injections, 531(4.14%) were nebulizers, 297(2.32%) were powdered dosage forms, 144(1.12%) were capsules, and 267(2.08%) were classified as miscellaneous, including sprays, suspensions and enemas. The dosage form was not specified for 153 drugs (1.2%). These findings are consistent with previous research, which also reported syrups as the most commonly prescribed dosage form (62.73%), followed by tablets (15.23%) **[15]**. The preference for syrups, particularly in pediatric patients, reflects the need for easily administrable and palatable dosage forms. Understanding the distribution of dosage forms is crucial for optimizing drug administration in children, ensuring adherence, and improving therapeutic outcomes.

Average number of drugs per prescription

Figure 3 illustrates the number of drugs per prescription. According to the World Health Organization (WHO), the ideal number of drugs prescribed per prescription should be less than 2, with an optimal range between 1.6 and 1.8. In 5401 prescriptions, a total of 12818 drugs were prescribed resulting in an average of 2.37 drugs per prescription, which is slightly on a higher side. A previous study reported an average of 1.8 drugs per prescription, aligning with WHO recommendations **[16]**. However, other studies have documented higher averages in pediatric populations, with 4.98 and 3.32 drugs per prescription **[11, 13]**. These higher averages suggest a trend toward polypharmacy, which is concerning as it significantly increases the risk of adverse drug reactions and drug interactions.

Antibiotics prescribed per prescription

A total of 1071 antibiotics, including FDC were prescribed. **(Figure 4)** WHO recommends that the percentage of antibiotic encounters should ideally fall within the range of 20.0% to 26.8%. In this study, the average percentage of antibiotics prescribed per prescription was 19.83%, which is within the recommended range. Our results were different from a past study with 33% antibiotics prescribed **[17]**. The inappropriate prescribing of antibiotics remains a significant concern, as it not only accelerates the development of antibiotic resistance but also subjects children to unnecessary side effects **[18]**. These findings underscore the importance of adhering to antibiotic stewardship guidelines to ensure rationality and to protect pediatric patients from the risks associated with over prescription.

Injections prescribed per prescription

There were 724 (13.4%) prescriptions with injection encounters. Among these, 162 (3%) contained a single injection, 90 (1.66%) had two injections, and 45 (0.83%) had three injections. Prescriptions with four and five injections each numbered 27 (0.50%). The average percentage of prescriptions with injection encounters was 13.4%. This finding is relatively close to the WHO-recommended optimal range of 13.4% to 24.1%, but still reflects a need for adherence to clinical guidelines. Our results contrasts sharply with 89.95% injection encounters per prescription in a past study **[11]**. Over-reliance on injections, especially when oral alternatives are available, reflects a lack of adherence to clinical guidelines and can lead to irrational drug use. In our study, injections were primarily prescribed for serious and emergency conditions, reflecting a more targeted use rather than routine or unnecessary administration.

Drugs prescribed by generic name

Out of 12818 drugs prescribed, 4486 (35%) were prescribed by generic names, whereas majority 8332 (65%) were written using trade names. The optimal value for the percentage of drugs prescribed by generic name should ideally be 100%, as recommended by clinical guidelines. Literature reports of studies with 60.2% and 79% of generic drugs prescribing **[9, 17]**. Prescribing by trade name can lead to higher treatment costs, reducing accessibility for economically disadvantaged families. Moreover, it contributes to the irrational use of medicines, as brand name prescriptions are often driven by commercial interests rather than clinical evidence. Therefore, it is highly recommended that pediatricians emphasize the use of generic names to promote cost-effective and evidence-based prescribing practices in the current setting.

Drugs prescribed from the Essential Drug List

10511 (82% of drugs) were prescribed from India's National List of Essential Medicines (NLEM) 2022. Medications listed in the Essential Drug List are known for their benefits in terms of cost, safety, and effectiveness. Ideally, 100% of drugs should be prescribed from them to ensure optimal therapeutic outcomes. The present result indicates a strong adherence to essential drug guidelines, supporting the goal of providing cost-effective and safe treatments. 76% and 23.3% of the drugs were prescribed from essential drug list in past studies **[19, 20]**.

Completeness of prescriptions

Table 2 illustrates the completeness of prescriptions concerning various components and essential drug information. The patient's details with date were printed at the time of registration, and was found to be in accordance with a past study **[17]**. Proper diagnosis is important to define the therapeutic goal of the treatment. The weight of the pediatric patient must be documented, as it is important for calculating the dose. Documentation of patient's history, allergies, chief complaints and physical examination can help prevent medication errors and form the basis for diagnosis and rational treatment. Our study shows that the essential information about the prescribed drugs including dose, frequency, quantity, route of administration especially duration was missing. Doctor's stamp and registration number was missing in more than half of the prescriptions. Similar result had been obtained in a past study **[21]**. Ensuring the completeness of prescription information regarding both patient and drug details is essential for enhancing patient safety and treatment effectiveness.

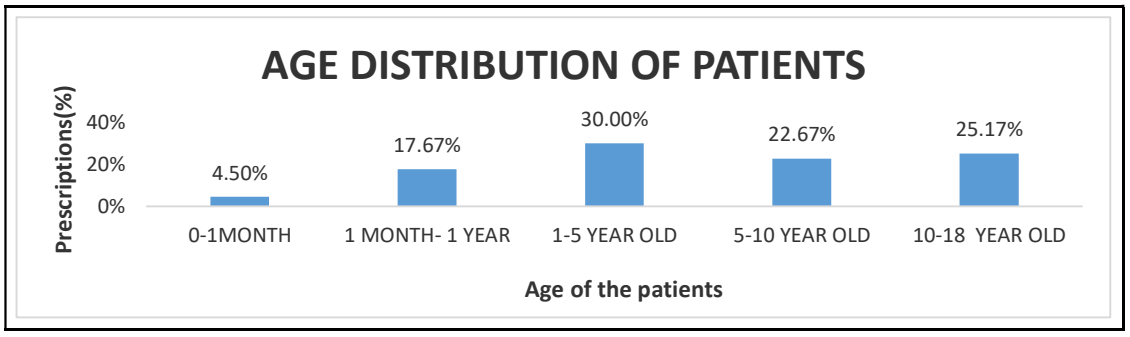

Figure 1: Age distribution of patients
#Number of patients=5401

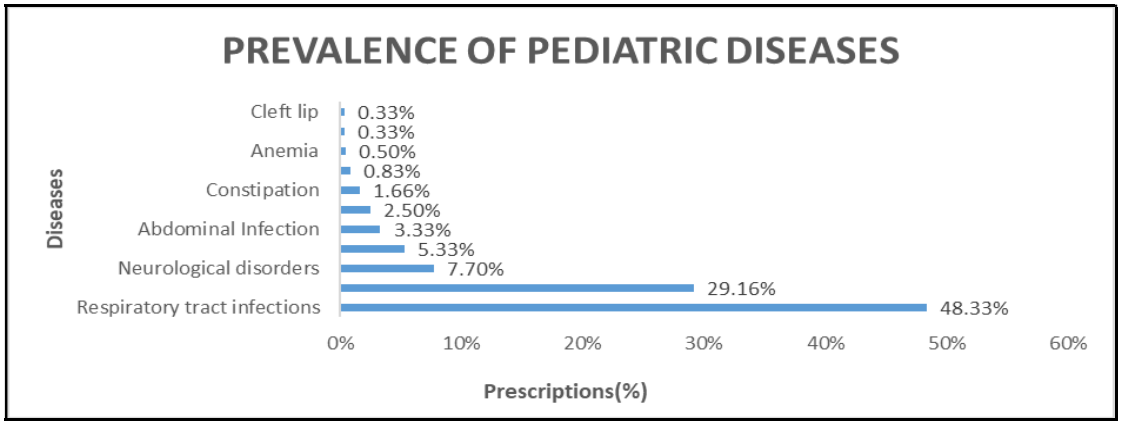

Figure 2: Prevalence of diseases in children
#Number of patients=5401

Table 1: Pattern of drugs prescribed to pediatric patients

Categories of drugs prescribed	Number and percentage of Total drugs prescribed (%)	Most prescribed drugs of each category	Number and percentage of most prescribed drug of each category (%)
Fixed Dose Combinations	(4095)31.95%	Chlorpheniramine meleate with Phenylephrine hydrochloride	(688)16.81%
NSAIDs	(1602)12.50%	Paracetamol with Ibuprofen FDC	(1497)93.40%
Antacids	(1009)7.87%	Lansoprazole	(549)54.39%
Anti-histamines	(936)7.30%	Levocitrizine	(389)41.53%
Anti-helminthics	(756)5.90%	Albendazole	(747)98.82%
Antibiotics	(738)5.76%	Beta-lactams	(242)32.77%
Vitamins and minerals	(549)4.28%	Fixed dose combination	(89)16.15%
Anti-epileptics	(441)3.44%	Sodium valproate and Levetiracetam	(159)36.36% each
Anti-emetics	(306)2.39%	Ondansetron	(274)89.47%
Anti-spasmodics	(197)1.54%	Dicyclomine	(147)74.35%
Laxatives	(197)1.54%	polyethylene glycol	(143)72.73%
Sedative-hypnotics	(188)1.47%	Clobazam	(108)57.14%
Bronchodilators	(162)1.26%	Levosalbutamol	(52)32.20%
Steroids	(117)0.91%	Budesonide	(78)66.67%

#Total number of drugs=12818

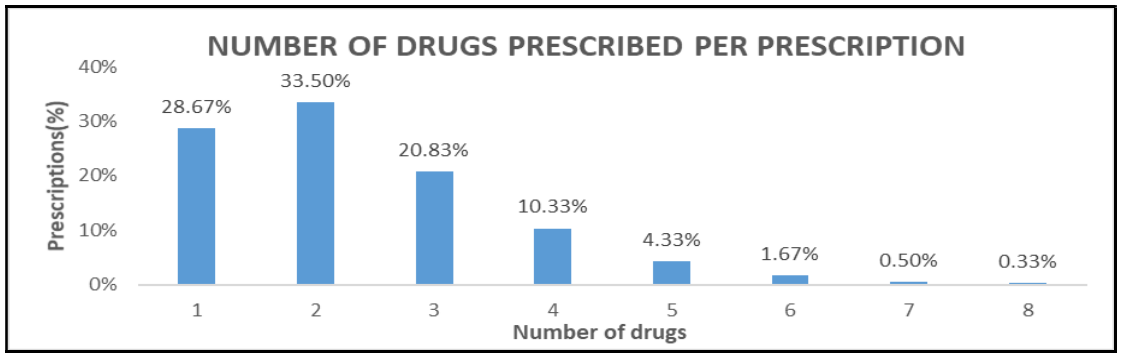

Figure 3: Number of drugs prescribed per prescription
 # Total number of drugs =12818

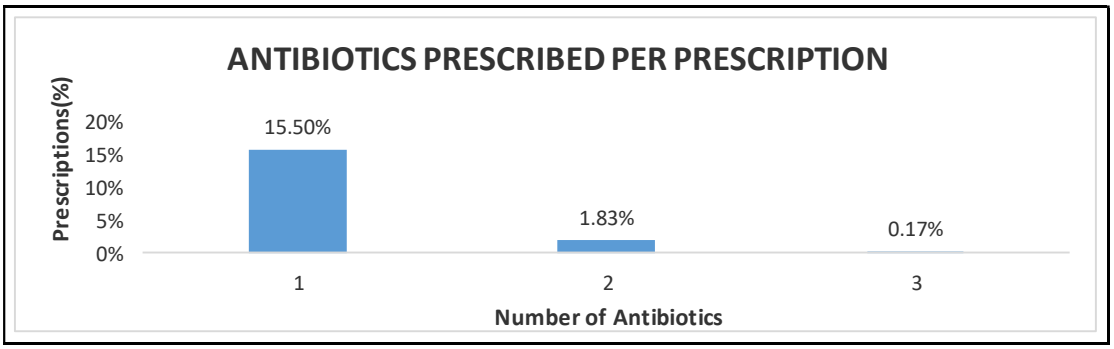

Figure 4: Percentage of antibiotics prescribed per prescription
 # Total number of prescriptions=5401

Table 2: Completeness of prescriptions

Information in prescriptions	Number and Percentage (%) of prescriptions with complete information
Patient related information	5167(95.67%)
Diagnosis	4861(90%)
Weight	5167(95.67%)
Chief complaints	2710(50.17%)
Physical examination	5185(96%)
Patients history	4672(86.5%)
Follow up advice	2286(42.33%)
Diet related advice	648(12%)
Special instructions	2430(45%)
Lab investigations advised	3106 (57.5%)
Doctor's stamp	2592(48%)
Doctor's signature	5184(96%)
Doctor's registration number	2583(47.83%)
Information about drugs in prescriptions	Number and Percentage (%) of drugs with complete information
Strength of prescribed drugs	11809(92.13%)
Duration of prescribed drugs	8551(66.71%)
Frequency of prescribed drugs	11711(91.36%)
Route of administration for prescribed drugs	12665(98.81%)

 # Total number of prescriptions=5401, Total number of drugs =12818

Legibility of prescriptions

Our study shows that 3428 (68% of prescriptions) had a legibility grade score of 3 indicating that the prescriptions were moderately legible. 1613 (32% of prescriptions) were found to have a legibility grade score of 4, where all the prescriptions were completely legible and written in capital letters. No prescriptions were graded as 1 or 2, which indicates that there were no illegible prescriptions. Switching to electronic prescribing systems can ensure prescriptions clarity and legibility and reduce errors.

CONCLUSION

Studying the prescription pattern is a helpful tool to ensure the rationality in prescriptions and establishing the criteria of optimum drug use and limiting medication errors. The findings demonstrate that rational prescribing practices are being followed to a certain extent. However, healthcare providers must be to encouraged and trained to adhere to clinical guidelines,

use generics and write in capital letters or utilize typed prescriptions to promote judicious drug use in pediatric care. Although, continuous monitoring of prescribing patterns is essential, patient education plays a crucial role in ensuring that parents and caregivers understand the importance of rational drug use, thereby reducing pressure on physicians to prescribe unnecessary medications. This study not only provides a foundation for policymakers and future intervention studies but also serves as a benchmark for promoting rational drug use, particularly in pediatric patients.

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