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A STUDY OF THE ANTIMICROBIAL DRUG USAGE PATTERN AMONG IN-PATIENTS AND OUT-PATIENTS AT THE PAEDIATRICS DEPARTMENT AT TERTIARY CARE TEACHING HOSPITAL

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Abstract

Background: Antimicrobials are among the most frequently prescribed drugs in paediatric practice; however, their irrational and excessive use contributes to adverse drug reactions (ADRs), antimicrobial resistance, and increased healthcare costs. Drug utilisation studies (DUS) help evaluate prescribing patterns and support antimicrobial stewardship programmes. This study aimed to assess antimicrobial prescribing patterns and monitor ADRs among paediatric inpatients and outpatients using WHO core prescribing indicators.

Methods: A 12-month cross-sectional observational study was conducted in the Departments of Paediatrics and Pharmacology at ACSR Medical College and Government Hospital. A total of 1200 paediatric patients aged 1–18 years were included through simple random sampling (OPD: 900; IPD: 300). Prescriptions were analysed using WHO prescribing indicators. ADRs were assessed using the WHO-UMC causality assessment scale and Hartwig's severity assessment scale. Statistical analysis was performed using SPSS version 19.

Results: Among the 1200 patients, 59% were males. Respiratory disorders (19.6%) and gastrointestinal disorders (15.3%) were the most common indications for antimicrobial use. Antimicrobials were prescribed in 63.9% of cases. Cephalosporins (33.3%), penicillins (16.7%), and aminoglycosides (13.3%) were the most commonly prescribed antimicrobial classes. The average number of drugs prescribed per encounter was 3.56. Injectable drugs were used in 53.7% of cases, while 78.5% of prescriptions were written using generic names. All antimicrobials were prescribed from the National Essential Drug List. ADRs occurred in 11.3% of patients, predominantly due to cephalosporins (67.6%), and ranged from mild to severe.

Conclusion: The study highlights overuse of injections and broad-spectrum antibiotics, with incomplete adherence to WHO prescribing indicators. Rational prescribing practices and strengthened antimicrobial stewardship are essential to reduce resistance and improve paediatric treatment outcomes.

Keywords: Antimicrobials, Paediatrics, Drug Utilisation Study, Adverse Drug Reactions, WHO Prescribing Indicators, Antimicrobial Resistance, Rational Drug Use, Antimicrobial Stewardship.

INTRODUCTION

In India, infectious infections account for a significant percentage of hospital admissions, especially in children and are a major source of morbidity and mortality. Therefore, both in the community and in hospitals, antibiotics and other antimicrobials make up a significant class of medications. There is strong evidence that the indiscriminate use of antibiotics causes pathogenic

organisms susceptibility patterns to change and frequently results in frank resistance [1]. The rational use of antibiotics is fraught with difficulties, ranging from general ignorance and inadequate personal hygiene and environmental sanitation to a lack of surveillance mechanisms for tracking antimicrobial use and resistance [2,3,4]. Antimicrobials may make up half of all pharmaceutical sales in India, while other surveys have found different rates of antimicrobial use [5]. As antibiotics are used more frequently, resistance also becomes more common. In both inpatient and outpatient settings, the usage of antimicrobial drugs has been linked to resistance [6, 7]. Another issue with the use of antibiotics is the occurrence of adverse drug reactions (ADRs) [8]. According to a comprehensive review that was published a while back, the incidence of paediatric adverse drug reactions (ADRs) was 9.5%, accounting for 2.1% of hospital admissions, of which 39.3% were life-threatening [9].

According to a study on the prevalence of ADRs in children in Southern India, antibiotics were frequently linked to ADRs, which were more common in newborns [10]. Therefore, ongoing surveys of antimicrobial usage and associated ADR monitoring are necessary for the long-term rational use of antibiotics [11]. Drug utilisation is defined by the WHO as "the marketing, distribution, and prescription use of drugs in society with special emphasis on the resulting medical, social, and economic consequences"[11]. In order to monitor, assess, and encourage rational drug therapy, drug utilisation studies have advised identifying inappropriate or redundant medication use [12]. Antimicrobials are chemical products derived from living microorganisms that, at very low concentrations, either completely stop or prevent the growth of bacteria or kill them [13]. Antimicrobials are a product produced by one microorganism, which specifically prevent the growth of another microorganism [14].

The treatment of infectious diseases depends on antimicrobials. antibiotic-resistant bacteria are an inevitable consequence of long-term antibiotic use, which raises the need for new drugs [15]. A thorough understanding of microbiological and pharmacological elements as well as good clinical judgement are essential for the wise selection of antimicrobial medications [16]. Therefore, the worldwide problem of antibiotic overuse and misuse can be addressed through appropriate prescribing practices [17]. According to the WHO, almost half of all pharmaceuticals are either sold, delivered, or given incorrectly. In India, 37% of antimicrobials are used improperly[18]. According to a study, 50% and 85% of children in the USA and Canada, used antibiotics improperly. Medication errors are more common in infants and young children than in adults. In general, children utilise antimicrobial medications at a very high rate; upper respiratory tract infections account for around 70% of all prescribed antimicrobial medications [19]. "Choosing the right antimicrobials is a difficult process that calls for careful clinical judgement." The WHO has created a set of basic drug use indicators that assess the effectiveness of healthcare workers, the knowledge. This evaluation will improve the development of prescription guidelines, pinpoint problems with patients' understanding of consultants' advice, and potentially lessen the financial burden on patients [20,21]. The Global Antibiotic Resistance Partnership estimates that over 190,000 baby fatalities occur in India each year due to diseases, with over 30% of these instances being caused by antibiotic resistance [22]. "A set of standard guidelines for the treatment of infectious diseases based on local culture sensitivity data is known as antibiotic guidelines" [23]. The WHO states that the appropriate medication should be administered at the appropriate time, at the appropriate dose, and at the lowest feasible cost when using antimicrobials [24]. The assessment of medication use is essential for financial, educational, and diagnostic purposes [25.] Only a small number of drug utilisation studies have been conducted on paediatric patients; the majority have been undertaken on geriatric patients [26]. The discovery of penicillin by Alexander Fleming in 1926 marked the beginning of the antimicrobial era. Penicillin is a chemical produced by bacteria that has the ability to stop bacterial development. Edward Chain and Howard Florey conducted additional research on penicillin in 1939 before testing it on people [27,28]. The development of antimicrobials was made possible by the efforts of Florey, Fleming, and Chain, who were awarded the Nobel Prize in 1945 [29]. It includes research on the relationship between drug use and its effects, whether positive or negative, as well as medical and non-medical factors that influence drug use [30]. Clinical trial evidence is expected to have a major role in medical practice. However, a specific amount of time must pass following a study in order to allow for sufficient therapeutic improvements [31]. Both sides of the Atlantic have seen an increase in interest in human studies since the early 1960s [32]. The scope of antimicrobial studies has expanded due to a number of factors, including improved marketing of new antimicrobials, significant changes in drug prescription and consumption patterns, growing concerns about delayed adverse drug reactions, and ongoing worries about expensive medications, as evidenced by rising sales and prescription volume [33]. Drug usage can be assessed on a population of people according to age, sex, socioeconomic status, and other factors in drug utilisation studies [34].

Drug utilization data can be used to construct and dispensation planning, evaluate medication expenditures, and provide approximate estimations of disease [35]. The description of drug utilisation can be enhanced by correlating prescription data with the underlying cause for medication prescribed [36]. Consequently, they can record

the magnitude of improper medicine prescriptions (e.g., antimicrobials, NSAIDs) and the related unfavorable diagnostic, ecological, and financial repercussion[37]. The existing databases of drug utilization researches can be categorized into non- diagnosis-linked and diagnosis-linked types [38]. Data on drug evaluation can be obtained directly from the population through health surveys, includes national surveys or small surveys conducted in specific settings such as among university students, female population or elderly outpatients [39]. Drug utilization study encompasses a diverse array of descriptive and analytical methods aimed at quantifying, understanding, and evaluating the processes involved in prescribing, dispensing, and consuming medications, also assessing interventions designed to renovate the property of these processes [40]. Drug utilization and pharmacoepidemiology are closely related.

But it is time-consuming, and large-sample data collections are seldom possible. It also knowing that parents and school children report symptoms and treatment of allergic diseases differently [41]. "Antibiotic guidelines are defined as set of standard guidelines based on local culture sensitivity data for the therapy of infectious diseases [42]. Drug utilization significantly aids the healthcare system in understanding, interpreting, and enhancing the prescribing, administration and utilization of medications [43]. The irrational use of antimicrobials is associated with increased treatment costs and a higher incidence of adverse drug reactions [44].

MATERIALS AND METHODS

Materials

Type of study: Cross-sectional observational hospital based study

Site of study: This study was conducted in the pharmacology and Pediatrics department at A.C.S.R. GOVERNMENT MEDICAL COLLEGE Nellore, Andhra Pradesh.

Study duration: 06 months after receiving ethical approval from the institutions.

Study Population and Sampling Technique: A conventional random sampling method was used. Paediatric patients who met the inclusion criteria and were either admitted to the IPD or attended the OPD throughout the study period were enrolled. Based on the average monthly patient attendance in the paediatric department during the previous year, enrolment was completed sequentially on all working days until the necessary sample size was reached, keeping an OPD:IPD ratio of roughly 3:1. This made sure that both inpatient and outpatient cases were fairly represented.

Ethical approval: This study was approved by the Institutional Ethics committee, A.C.S.R. GOVERNMENT MEDICAL COLLEGE (Reference No: SU/2021/1029 dated 24/11/2025).

Before enrolment, all participants' parents or legal guardians provided written consent form. Additionally, children seven years of age and older gave their consent after being informed in age-appropriate terms about the study's goals, methods, possible dangers, and advantages. Participants were allowed to discontinue participation at any time without having their medical care impacted, and participation was completely voluntary. Patient information was kept completely confidential. No personal identifiers were included in the final dataset, and each participant was given a distinct research identification code. Electronic data was kept on password-protected computers that were only accessible by the investigators, while hard copy proformas were kept in a secured cabinet within the Department of Pharmacology.

Sample size: 1200

The sample size was calculated based on single population proportion formula preposition a p – value of 0.5, 95% of confidence level (Z= 1.96) and margin of error (d) of 3% (0.03).

Based on this formula, $n = z^2pq/d^2$.

Sample size (N) = $(1.96)^2 \times 0.5 \times (1 - 0.5)$ / $(0.03)^2$

Where

n= Desired sample size (when the population >10,0000)

Z= Level of confidence according to the standard normal distribution or statistic for a level of confidence (for 95% level of confidence, z value is 1.96)

P= Estimated proportion of the population exhibiting the characteristics (when unknown we use P=0.5) or expected prevalence or proportion

d= tolerated margin of error for example we want to know the real proportion within 5% or precision (considered as 5% in medical studies)

q=1-p (proportion in the target population not having the particular characteristics)

N = 1066, Rounded off to 1200

Inclusion Criteria

- Patients between 1-18 were selected for the study.
- All genders of patients
- Patients admitted to the pediatrics ward
- Patients visiting outdoor pediatrics department

Exclusion Criteria

- Patients who are older than 18 and younger than 1 year
- Patients admitted in Neonatal, pediatric ICU
- Patients make referrals to higher facilities
- Patients who are referred to& from another department.

This study's structured questionnaire was created using departmental standards, WHO prescribing indicators, and other research. A panel of three senior faculty members from the departments of paediatrics and pharmacology evaluated its content validity.

Procedure for data collection: The Principal investigator and a qualified research assistant collected the data.

Following the pediatrician's prescription, data for OPD patients was gathered the same day of the appointment. Data was gathered for IPD patients within 24 hours of admission, and they were monitored every day until they were released. Antimicrobial usage, dosage, route, duration, and WHO core prescribing parameters were recorded by reviewing prescriptions. Any adverse drug reactions (ADRs) that the patient or guardian reported or that medical personnel seen were mentioned in the proforma's ADR reporting section. A pre-made, verified questionnaire was used to collect all the data.

Data collection schedule: Every day (Monday through Saturday), data was gathered during IPD rounds (10:00 AM and 5:00 PM) and OPD hours (9:00 AM to 2:00 PM). November of 2025 to March 2026 was the duration of the study. While IPD patients were monitored every day until they were discharged, data from OPD patients was gathered on the same day of consultation.

Data Storage and Confidentiality: No personal identifiers (name, address, or phone number) were included in the final dataset; instead, each patient was given a unique research identification code. The Department of Pharmacology kept hard copy proformas in a secured cabinet. Microsoft Excel was used to enter electronic data, which was then stored on a password-protected computer that only the investigators could access.

METHODOLOGY

Patients were recruited for the study based on inclusion and exclusion criteria after the institutions granted ethical approval. Before the children were enrolled in this study, their parents or guardians gave their informed consent. Data was gathered using semi-structured and pre-designed questionnaires. Every medication prescribed both indoors and outdoors was documented, along with the demographic profile, average number of prescriptions, percentage of prescriptions for antimicrobials, percentage of prescriptions using generic names, percentage of prescriptions for injections, percentage of prescriptions from the essential drug list, dosage, route, and dosage form of each medication, frequency of administration, and indication for which the medication was prescribed. Antimicrobial adverse drug reactions (ADRs) were tracked during medication delivery, and patient side effects were noted during ward visits.

The **Hartwigand Siegel Severity Assessment Scale** was used to gauge the severity of ADRs, and the WHO-UMC Causality Assessment Scale was used to determine their causality. The following factors were examined:

- The patient's demographic information.
- Type of patient (inpatient/outpatient).

The diagnosis

The following drug indicator use were assessed using the WHO guidelines

- Encounter of average drugs prescription
- Percentage of encounters with antimicrobials
- Average number of Antimicrobials prescribed by their generic name & Essential Drug List
- Percentage of antimicrobials with injections
- Percentage of Antimicrobials prescribed fromApart from these adverse drug reaction associated with specific drugs were also assessed.

RESULTS

When the age distribution of the paediatric patients was examined, it was discovered that 18% of the prescriptions were for patients under the age of four, followed by 19.33% for those between the ages of five and eight, 20.66% for those between the ages of nine and twelve, 21.66% for those between the ages of thirteen and sixteen, and 20.33% for those over the age of seventeen and eighteen.

Table 01: Age wise Distribution of Patients Attending paediatrics department

Age	No. of patients prescribed (%) (n=1200)	Percentage (%)
< 4	216	18
5-8	232	19.33
9-12	248	20.66
13-16	260	21.66
17-18	244	20.33

The study on gender classification shows that 59% of male patient were and 41% were female.

Table 02: Gender wise Distribution of Patients Attending Pediatrics Department

Gender	No.of cases (N=1200)	Percentage (%)
Male	708	59
Female	492	41
Total	1200	100

The most prevalent illness was respiratory disease (19.66%), which was followed by gastrointestinal disease (15.33%), bronchopneumonia (12.66%), urinary tract infection (13%), dermatological disease (7.83%), typhoid fever (7.66%), sepsis (5.33%), meningitis (4%) and other (15%). Out of the 1200 patients, 300 were inpatients (IPD) and 900 were outpatients (OPD).

Table 03: Distribution of Pediatric Diagnosis among Patients Visiting the Pediatric Department

Diagnosis	Total Patients (N=1200)	Percentage (%0)	Outpatients (N=900)	Inpatients (N=300)
Bronchopneumonia	146	12.16	110	36
Gastrointestinal Disease	184	15.33	140	44

Respiratory Disease	236	19.66	180	56
Typhoid Fever	92	7.66	70	22
Sepsis	64	5.33	40	24
Dermatological Disease	94	7.83	40	14
Meningitis	48	4.00	20	28
Urinary Tract Infection	156	13.00	120	36
Others	180	15.00	140	40
Total	1200	100	900	300

According to the study, cephalosporins accounted for approximately 33.33% of all antimicrobial medications prescribed to patients, followed by pencillins (16.66%), aminoglycosides (13.33%), carbapenem (8.33%), and fluroquinolone (1%), antiprotozoal (3.33%), and antifungal (3.33%).

Table 04: Antimicrobials Preference

Antibiotic Class	No. of patients prescribed (%) (n=1200)	Percentage (%)
Cephalosporin	400	33.33
Penicillin	200	16.66
Aminoglycosides	160	13.33
Carbapenem	100	8.33
Macrolide	70	5.83
Glycopeptide	56	4.66
Sulfonamide	50	4.16
Imidazole	20	1.66
Tetracycline	20	1.66
Lincosamide	18	1.5
Oxazolidinone	14	1.16
Fluroquinolone	12	1
AntiProtozoal	40	3.33
Anti Fungal	40	3.33

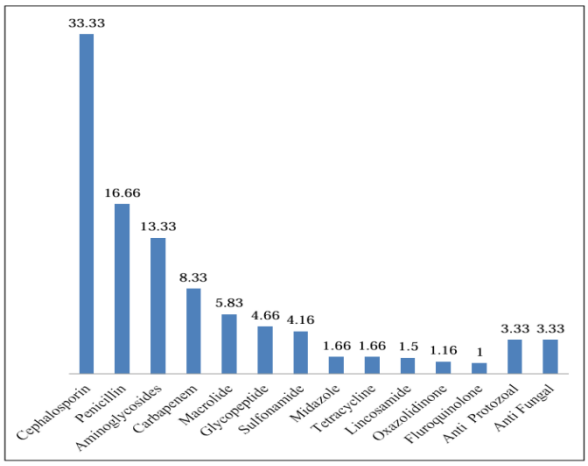

Figure 01: Antimicrobials Preference

Majority of drugs were given by oral route 33.66% followed by parenteral 53.60% and least were 12.60% by nasal route.

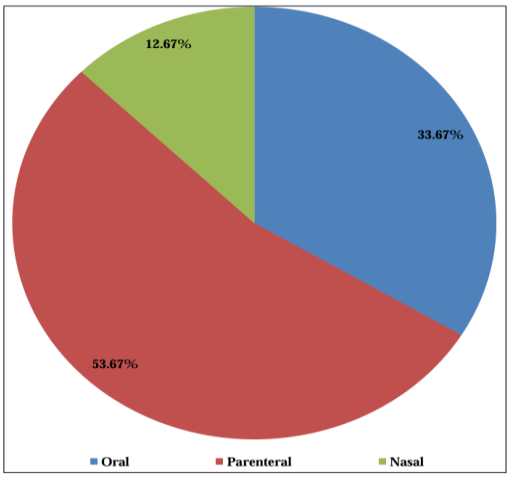

Figure 02: Distribution of Dosage Forms of Medicines Used

The majority of patients received only one antibiotic during treatment, with 692 receiving one antibiotic, 356 receiving two antibiotics, 136 receiving three antibiotics, and just 16 receiving four antibiotics.

Table 05: Distribution of Number of Drugs Prescribed Per Prescription among Patients Attending Pediatrics Department

No. of antimicrobials	No. of total medicine	No. of patients prescribed	Percentage (%)
1	3	692	57.66
2	4	356	29.666
3	5	136	11.33
4	6	16	1.33
1876	4276	1200	100

In my study majority of drugs were given by generic name 1473(78.51) followed by brand name 403(21.48).

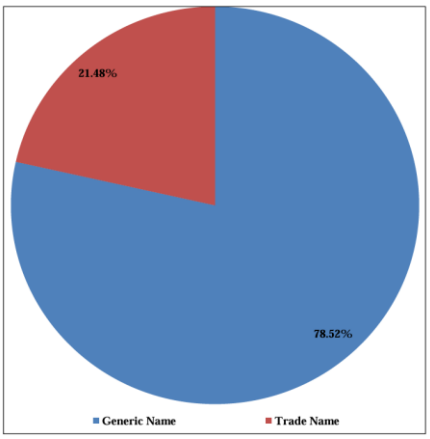

Figure 03: Antimicrobials Prescribed By Generic Names

Single antimicrobial therapy was predominant across all age groups, especially in children aged <4 years. The use of multiple antimicrobials increased progressively with age,

peaking in the 17–18 years group, which showed the highest overall antimicrobial exposure. Younger children were primarily managed with monotherapy, whereas older children and adolescents more frequently received combination therapy.

Table 06: Antimicrobials Use with Age

	Number of antimicrobials			
Age	Number of patients	1 antimicrobials	2 antimicrobials	>2 antimicrobials
< 4	216	132	44	4
5-8	232	108	52	36
9-12	248	112	64	36
13-16	260	124	72	28
17-18	244	216	124	48

Adverse drug reactions based on age group showed that the patients who were at an age group of 17-18 years were mostly affected to about 44.11% followed by 13-16 years at 26.47 %and patients at an age group 5-8 years were least affected by the adverse reactions to antimicrobials which constituted to only about 8.82%.

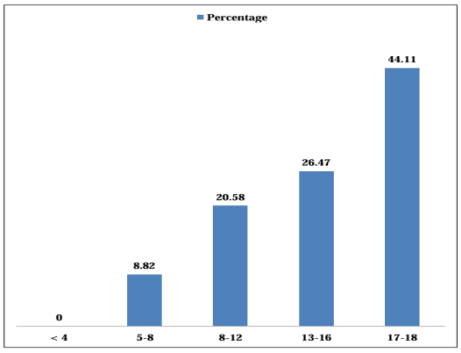

Figure 04: ADR Based On Age Group Paediatrics Department

On the basis of severity level, mild reactions accounted for 55.88%, moderate reaction accounted for 44.11% and no serious reaction were observed or reported in of any patients.

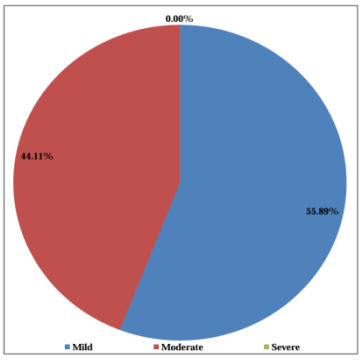

Figure 05: Adverse Drug Reaction Based On Severity Level (N=136)

SUMMARY AND CONCLUSION

The most commonly prescribed antimicrobial class was cephalosporins (33.33%), followed by penicillins. Antimicrobial sensitivity patterns revealed that *Klebsiella pneumoniae* was highly susceptible to amikacin and imipenem, *Escherichia coli* was susceptible to piperacillin/tazobactam, *Enterococcus faecalis* was susceptible to piperacillin/tazobactam, gentamicin, and ofloxacin, while *Staphylococcus aureus* was susceptible to ceftriaxone. The most common adverse drug reactions (ADRs) observed in the paediatric population included thrombophlebitis, eosinophilia, constipation, itching, haemolytic anaemia, giddiness, vomiting, and abdominal pain. ADRs can be minimized through appropriate monitoring during drug administration and by educating healthcare professionals regarding commonly occurring adverse reactions. Drug interactions can be reduced by reviewing prescriptions using the Micromedex drug database prior to dispensing.

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CONFLICT OF INTEREST

Not declared

INFORMED CONSENT AND ETHICAL STATEMENT

Informed consent was obtained from all study participants, and the study was approved by the Institutional Ethics Committee of A.C.S.R. Government Medical College (Reference No. SU/2021/1029; dated 24/11/2025).

AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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