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EVALUATION OF PRESCRIBING PATTERN AND FACTORS ASSOCIATED WITH ANTIBIOTIC PRESCRIBING IN PEDIATRIC PATIENTS OF TERTIARY CARE HOSPITAL

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ABSTRACT

The aim of the study is to determine the prescribing pattern and factors associated with antibiotic prescribing among pediatric patients. A prospective and observational study was carried out for three months. A total of 56 patients were included in the study. A data collection form was prepared to collect patient's details. A questionnaire was prepared to evaluate the prescriptions and the prescribing pattern was assessed using WHO prescribing indicators. The antibiotics were classified based on WHO AWaRe classification to evaluate and monitor use of antibiotics. Descriptive statistics was used to summarize patients' characteristics. Chi-square test was done using SPSS version 22.0 to determine significant association between potential risk factors and drug-drug interactions. A p value of ≤ 0.05 was considered to be statistically significant. Cephalosporins (54%) were most prescribed class of antibiotic. The prevalence of antibiotic prescribed among patients is 76.79%. Ceftriaxone was most involved in monotherapy or combination therapy. Half of the patients (50%) were prescribed with only one antibiotic per prescription. Antibiotics were commonly administered intravenously (80.33%). 26.23% and 60.66% of antibiotics prescribed belonged to ACCESS and WATCH category respectively. 52.5% of drugs prescribed belonged to essential drug list or formulary. Number of drugs prescribed per patient was found to be statistically significant ($p = 0.000$) factor associated with antibiotic prescribing among pediatric patients.

Keywords: Antibiotics, formulary, pediatrics, patients, statistics

INTRODUCTION

Rational use of medicines is one of the core element in effective treatment of a patient. The World Health Organisation (WHO) defines rational use of medicines as "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." The causes of irrational use of medicines are inappropriate prescribing, dispensing, selling of medicines and failure of the patient to take them correctly. This leads to overuse, underuse or misuse of medicines which therefore result in several adverse drug reactions, complications, diseases, various health hazards etc. Some of the examples of irrational use of medicines include: failure to prescribe in accordance with clinical guidance, inappropriate use of antimicrobials, inappropriate self-medication, non-adherence to dosing regimens etc. WHO reports that more than half of the medicines are inappropriately prescribed, dispensed or sold **[1]**.

The differences of pharmacokinetic and pharmacodynamic data between adults and pediatrics make pediatrics a special population. In fact, the distribution, metabolism, elimination, and safety of drugs vary not only between adults and pediatrics but also among pediatric age groups. Pediatrics are those age groups less than 19 years including premature (born before 37 weeks), neonates (from birth to 28 days), infants (1 month to 1 year), children (above 1 year to 12 years), and adolescent (13 to 18 years). Being a special population, pediatrics is known to have a complex process of drug prescribing involving several steps of calculation, verification, preparation and administration of doses which is also an error prone process **[2]**. The paucity of pharmacokinetic, pharmacodynamic, safety and efficacy data for these patients, ethical, financial and regulatory limitations and lack of provider training in pediatric pharmacotherapy makes it exceptionally necessary to monitor the prescribing pattern in pediatric population **[3]**.

Antimicrobial drugs are defined as the drugs that are designed to inhibit/kill the infecting organism and to have no/minimal effect on the recipient. Antibiotics, which are a type of antimicrobials, are the drugs produced by microorganisms, which selectively suppress the growth of or kill other microorganisms at very low concentrations. In 20th century, therapeutics have extensively expanded due to the constant development of antimicrobial drugs. This class of drugs is one of the most commonly used and misused drugs **[4]**. In India, about 37% of inappropriate use of antimicrobial drugs were reported **[5]**.

The problems that arise from lack of judicious use of antibiotics are toxicity,

hypersensitivity reactions, drug resistance etc in adults[4]. Pediatric population are no exception to hazards of inappropriate use of antibiotics. For example, in African region various hazards related to overuse and misuse of antibiotics and occurrence of adverse drug reactions were reported to be widely prevalent among pediatric patients[3]. Antibiotics are commonly prescribed in viral respiratory tract infections and urinary tract infections in pediatrics. This constant use of antibiotics in such infections has further worsened the scenario by rising the number and types of resistant bacteria resulting in antibiotic resistance as a global threat **[6]**. Therefore, it is crucial that prudent monitoring of prescription of drugs especially antibiotics is done in order to curtail aforementioned threats among pediatric patients.

Information about prescribing trends especially use of antibiotics among pediatrics remains inadequate **[5]**, hence, this study will expand the existing body of data thereby promoting the rational use of antibiotics in order to provide better healthcare for pediatric patients.

Aims and objectives:

1. To assess the prescribing pattern of antibiotics among pediatrics

2. To determine the factors associated with antibiotics prescribing among pediatrics

3. To promote rational use of antibiotics among pediatrics

MATERIALS AND METHODS

Study design and subjects:

A prospective and observational study was carried out at Nilofer Hospital, Hyderabad for three months. The source population included all the hospitalized pediatric patients; however, the study population was based on the inclusion and exclusion criteria. Inclusion criteria included patients below 19 years, willing to participate, in-patient (IP) ward, with or without chronic illness, with or without comorbidities and with discharge summary. A total of 56 patients were included in the study. Exclusion criteria included patients of out-patient (OP) and dermatology wards, admitted in Intensive Care Unit (ICU) /Neonatal Intensive Care Unit (NICU) and emergency wards, those not discharged or discharged before collecting or cross-checking the data.

Data collection:

A data collection form was prepared to collect patient data such as

- Sociodemographic details: age, gender, past medical history, past medication history
- Clinical details: diagnosis along with comorbid conditions and with or without chronic illnesses.
- Drug therapy details: all the drugs prescribed with dose, dosage regimen,

route of administration, duration of treatment.

A questionnaire was prepared to evaluate the prescriptions and the prescribing pattern was assessed using WHO prescribing indicators **[7]**. The antibiotics were classified based on WHO AWaRe classification to evaluate and monitor use of antibiotics. Based on AWaRe classification, the antibiotics are classified into Access, Watch and Reserve groups.

- Access group included those antibiotics that have activity against a wide range of pathogens and also show low resistance potential. They are recommended as first or second choice empiric treatment options for infectious syndromes and are listed to improve access and promote appropriate use.
- Watch group included those antibiotics that have higher resistance potential and recommended as first or second choice empiric treatment options for a limited number of specific infectious syndromes. They are listed to carefully watch for resistance potential.
- Reserve group included those antibiotics and antibiotic classes that are reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms. Reserve group antibiotics should be treated as "last resort" options. These antibiotics should be accessible, but their use should be tailored to highly specific patients and settings, when all alternatives have failed or are not suitable **[8]**.

Statistical analysis:

Descriptive statistics were used to summarize patients' demographic and clinical characteristics. Frequency tables along with their percentages were calculated using MS excel. A one-tailed Fisher's exact test or Chi-square test was used wherever appropriate to find a significant association between potential risk factors and antibiotic prescribing. Odds ratio (OR) and confidence interval (CI) of 95% were used to see the strength of association. Haldane-Anscombe correction for odds ratio was applied wherever appropriate. p value ≤ 0.05 was considered to be statistically significant. The collected data were checked and assessed every day for completeness and accuracy before processing. Data were entered and statistical analysis was done using SPSS version 22.0 (copyright IBM Corporation and other(s) 1989, 2013).

RESULTS

Out of 56 pediatric patients, the maximum number of patients were in the age group of children (above 1 year to 12 years) which was 31 patients (55.36%). The mean ± SD (standard deviation) for age of 56 pediatric patients is 9.3±5.8. Simultaneously, the maximum number of pediatric patients that

were prescribed with antibiotics (n=43) were also found in the same age group of children (above 1 year to 12 years) which was 24 (42.85%) pediatric patients with mean ± SD (standard deviation) of 8.6±5.8. Male pediatric patients were found to be in majority [41 (73.21%)]. The percentages of presence of chronic illness, comorbidities, past medical history, and past medication history of pediatric patients was found to be 27 (48.21%), 25 (44.64%), 29 (51.79%) and 15 (26.79%) respectively. A total of 31 (55.36%) pediatric patients had a single disease diagnosed. A majority of 34 (60.71%) pediatric patients were prescribed with ≥6 drugs. 37 (66.07%) patients had no drug-drug interactions and the remaining had ≥1 interaction.

Based on total number of drugs prescribed (n = 339), antibiotics were prescribed 61 times (17.99%) and when based on number of pediatric patients prescribed with antibiotics (n = 56), antibiotics were prescribed among 43 pediatric patients (76.78%). This gives the prevalence of antibiotic use (43/56*100) as 76.79%.

Figure 1 shows the various classes of antibiotics prescribed in the study population (n = 61). Cephalosporins were prescribed majority number of times [33 (54%)], followed by Beta-lactamase inhibitors [11 (18%)].

Out of total number of antibiotics (n = 61), total number of antibiotics given in monotherapy were 21 (34.43%) and total number of combinations of antibiotics were 42 (68.85%). The most common antibiotic prescribed in monotherapy was Ceftriaxone [10 [16.39%)] followed by Cefotaxime [7 (11.48%)]. Ceftriaxone was majorly involved in combination therapy of antibiotics, 16 (38.10%). A combination of Ceftriaxone and Tazobactam [6 (9.84%)] was most commonly prescribed as combination therapy of antibiotics **(Figure 2)**.

Distribution of pediatric patients based on number of antibiotics prescribed per patient (n = 56) showed that single antibiotic was prescribed among half of the pediatric patients 28 (50%) followed by 12 pediatric patients (21.43%) with two antibiotics prescribed. They were 13 (23.21%) pediatric patients that were not prescribed with any antibiotics **(Figure 3)**. The mean ± SD (standard deviation) for number of antibiotics prescribed per patient is 1.42±0.63.

Various parameters when analysed statistically to determine the potential risk factors of antibiotics prescribing determined that number of drugs prescribed per patient (p = 0.000) was found to be statistically significant **(Table 1)**.

As shown in **Table 2**, based on AWaRe classification of antibiotics, a total of 16 antibiotics (26.23%) belonged to Access category, 37 antibiotics (60.66%) belonged

to Watch category and no antibiotics belonged to Reserve category.

Prescribing pattern among pediatric patients was evaluated using WHO prescribing indicators as shown in **Table 3**. Average number of drugs per encounter was found to be 6.05. Out of 339 drugs, percentages of drugs prescribed by generic name and essential drugs list (EDL) was found to be 27.13% and 52.5% respectively. Out of 56 pediatric patients, percentages of encounters with antibiotics and injections prescribed was found to be 76.79% and 85.71% respectively.

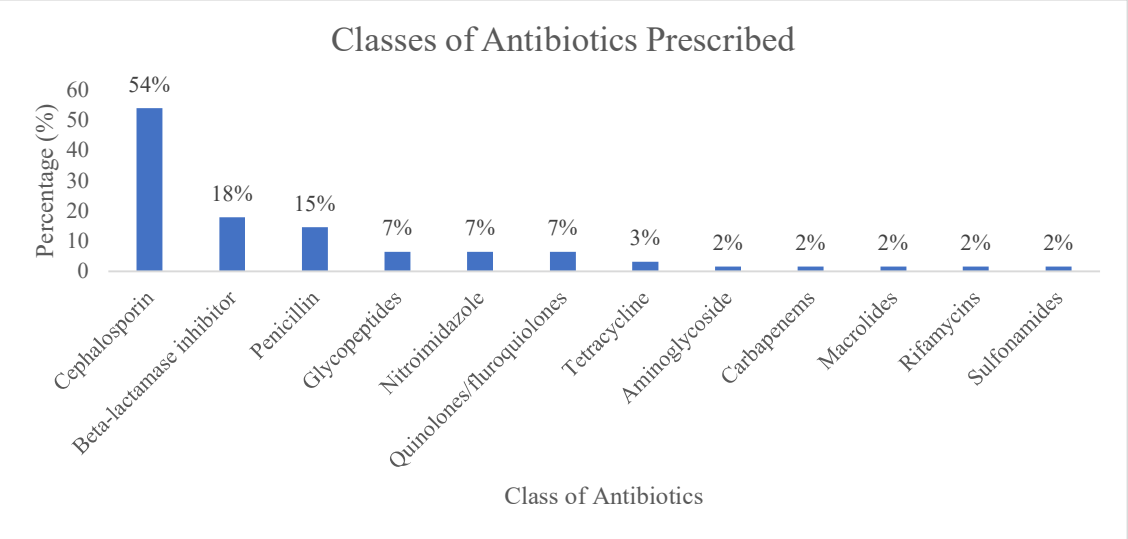

Figure 1: Classes of antibiotics prescribed

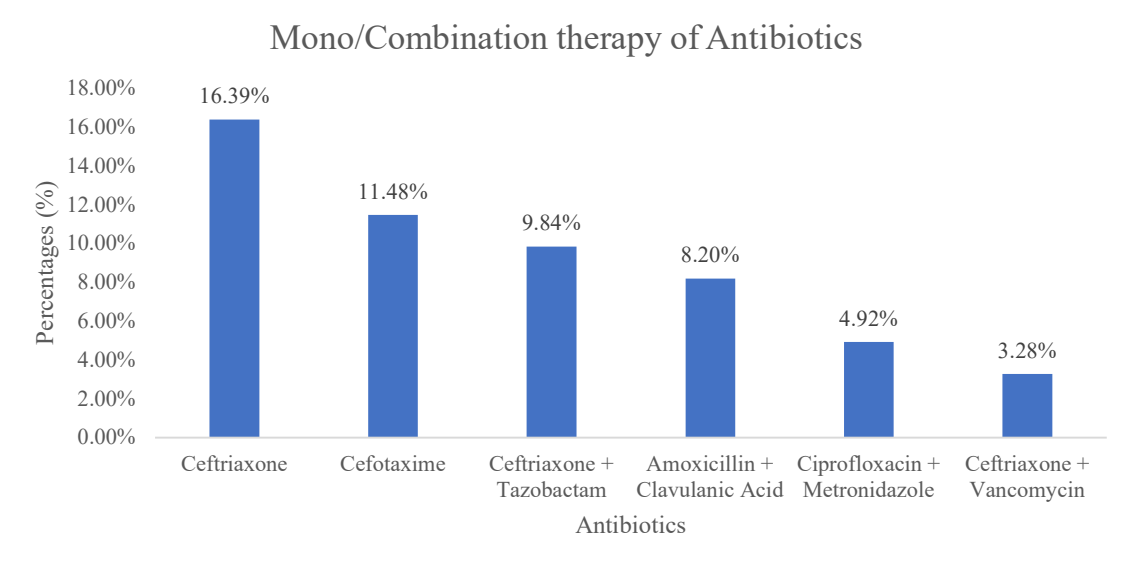

Figure 2: Mono/combination therapy of antibiotics

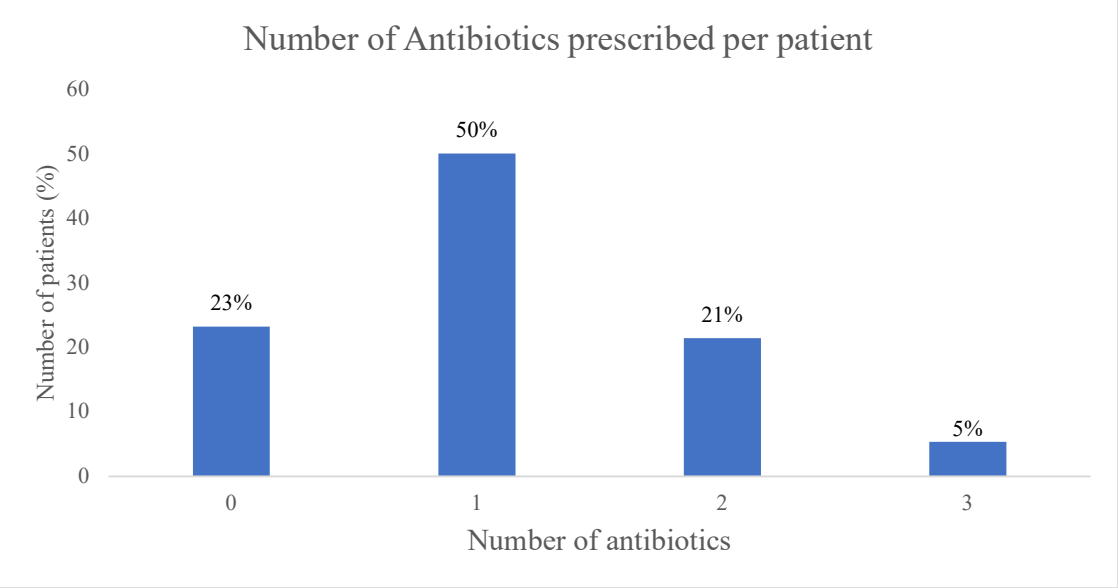

Figure 3: Number of antibiotics prescribed per patient

Table 1: Potential Risk Factors of Antibiotics Prescribing

Factor	Antibiotics prescribed		OR (CI)[a]	*p* value
	Yes	No		
Age				
upto 12 years	**29**	**7**	**1.776 (0.502 - 6.280)**	**0.370**
13 to 18 years	**14**	**6**		
Gender				
Male	**34**	**7**	**3.238 (0.869 - 12.060)**	**0.072**
Female	**9**	**6**		
Chronic Illness				
Yes	**20**	**7**	**0.745 (0.215 - 2.587)**	**0.643**
No	**23**	**6**		
Comorbidity				
Yes	**19**	**6**	**0.924 (0.266 - 3.209)**	**0.900**
No	**24**	**7**		
Past medical history				
Yes	**20**	**9**	**0.386 (0.103 - 1.449)**	**0.151**
No	**23**	**4**		
Past medication history				
Yes	**10**	**5**	**0.485 (0.129 - 1.820)**	**0.278**
No	**33**	**8**		
Number of drugs prescribed per patient				
1 to 5 drugs	**13**	**12**	**0.036 (0.004 - 0.307)**	**0.000[b]**
≥ 6 drugs	**30**	**1**		
Number of diseases diagnosed				
1 disease	**24**	**7**	**1.083 (0.312 - 3.762)**	**0.900**
>1 disease	**19**	**6**		
Drug-drug interactions				
0 interaction	**27**	**10**	**0.506 (0.121 – 2.117)**	**0.346**
≥ 1 interaction	**16**	**3**		

[a] OR – Odds ratio with a 95% confidence interval (CI); [b] Statistically significant (p ≤0.05)

Table 2: AWaRe Classification of Antibiotics

ACCESS Category	Frequency n = 61 (%)
Amikacin	1 (1.64%)
Amoxicillin	2 (3.28%)
Amoxicillin/Clavulanic Acid	4 (6.56%)
Ampicillin	1 (1.64%)
Doxycycline	1 (1.64%)
Metronidazole	3 (4.92%)
Metronidazole	3 (4.92%)
Sulfamethoxazole + Trimethoprim	1 (1.64%)
WATCH Category	Frequency n = 61 (%)
Azithromycin	1 (1.64%)
Cefixime	1 (1.64%)
Cefotaxime	8 (13.11%)
Ceftriaxone	15 (24.59%)
Ciprofloxacin	4 (6.56%)
Meropenem	1 (1.64%)
Piperacillin + Tazobactam	1 (1.64%)
Rifaximin	1 (1.64%)
Ticarcillin	1 (1.64%)
Vancomycin	4 (6.56%)
RESERVE Category	TOTAL n = 61 (%)
None	-

Table 3: Who Prescribing Indicators

PRESCRIBING INDICATORS	TOTAL DRUGS/ ENCOUNTERS	AVERAGE/ PERCENT	WHO STANDARDS
Average number of drugs per encounter	339	6.05	1.6 – 1.8
Percentage of drugs prescribed by generic name (n = 339)	92	27.13%	100%
Percentage of encounters with an antibiotic prescribed (n = 56)	43	76.79%	20% - 26.8%
Percentage of encounters with an injection (n = 56)	48	85.71%	13.4% - 24.1%
Percentage of drugs prescribed from essential drugs list or formulary (n = 339)	178	52.5%	100%

DISCUSSION

In our study, the maximum number of pediatric patients were found in the age group of children (above 1 year to 12 years). This result was similar to a number of previous studies **[9–12]** but varying results were also found in several other previous studies **[3, 13, 14]**. The mean and standard deviation was found to be 9.3±5.8 which was different from results found in earlier studies **[9, 14]**. Simultaneously, the maximum number of pediatric patients that were prescribed with antibiotics were also found in the same age group of children (above 1 year to 12 years). Similar results were seen in previous studies **[5, 6, 15]**, but contrasting result was established in a study conducted by Mustafa ZU *et al*. where maximum number of pediatric patients that received antibiotics were found in the age group of infants (1month to 1 year) **[12]**. The mean and standard deviation of the pediatric patients prescribed with antibiotics was found to be 8.6±5.8, which was almost similar to a few previous studies **[5, 16]**.

Assessing overall pediatric patients based on gender, our study resulted in maximum number of male pediatric patients. A wide range of prior studies established a similar outcome **[3, 10–14, 16–18]**. Male pediatric patients were in majority when the pediatric patients prescribed with antibiotic therapy

were distributed based on gender. This result was comparable to prior studies **[5, 6, 15, 18]**. Out of total number of pediatric patients, majority of the patients had comorbidities, however this outcome was in contrast with a study conducted by Kitt E *et al*. **[17]**

The prevalence of antibiotic prescribing per patient was found to be 76.79% which was lower than the prevalence established in a few prior studies **[12, 14]**. The most commonly prescribed class of antibiotics was Cephalosporins. This outcome was similar in a wide variety of prior studies **[5, 6, 9, 11–13, 17]**.

Majority of the antibiotic prescriptions were prescribed as monotherapy. Ceftriaxone was most common antibiotic prescribed in monotherapy which was found similar in a few prior studies **[15, 16]**. Assessing the combination therapy of antibiotics, Ceftriaxone was also majorly prescribed in combination therapy which was found similar in several prior studies **[12, 15–17]** and found differing in several other studies **[10, 14]**. The most common combination of antibiotic therapy in our study was Ceftriaxone and Tazobactam, however this outcome was different in a few prior studies **[15, 16]**.

Based on number of antibiotics prescribed per patient, our study showed that maximum number of patients were prescribed with single antibiotic, which was comparable to outcome of various prior studies **[6, 11, 17]**. However, a study conducted by Mustafa ZU *et al*. showed varying results with maximum number of pediatric patients prescribed with two antibiotics per patient **[12]**. The mean and standard deviation of number of antibiotics prescribed per patient was found to be 1.42±0.63, which was similar to a study conducted by Miao R *et al*. **[6]** A few previous studies showed contrasting results **[5, 12]**.

Potential risk factor for antibiotic prescribing such as number of drugs prescribed per patient ($p = 0.000$) was found to be statistically significant in our study. This outcome was comparable to a few previous studies **[19, 20]** and contrasting in a few other previous studies where age, gender and diagnoses of patients were significantly associated with antibiotic prescribing **[19, 21, 22]**.

AWaRe classification of antibiotics revealed that the percentage of antibiotics belonging to Access category were less than that of percentage of antibiotics belonging to Watch category. This trend was similar to that of previous studies **[12, 17, 18]**. There were no antibiotics belonging to Reserve category, however this outcome was in contrast in a few previous studies **[12, 18]**.

Various WHO prescribing indicators were used to evaluate the prescribing pattern in pediatric patients. In our study, average number of drugs prescribed per patient was found to be 6.05 which was slightly greater

in a few prior studies **[5, 13]** slightly lower in a few other prior studies **[10, 11]** and contrasting in several previous studies**[3, 9]**. Percentage of drugs prescribed by generic name was determined to be almost similar to a few prior studies **[5, 9]** but several studies showed contrasting results **[3, 10, 11, 13, 15]**. The percentage of patients that were prescribed with antibiotics in our study was found to be slightly lower or greater in a few earlier studies **[3, 10, 11]** but differing in other earlier studies **[5, 9, 13]**. Assessment of percentage of patients prescribed with injectables was found to be almost similar with the outcome of a study conducted by Mathew R *et al*. **[5]** but a wide range of studies showed varying outcomes**[3, 10, 11, 13, 15]**. The comparison of percentage of drugs prescribed from EDL (Essential Drug List) with prior studies revealed differing outcomes **[3, 5, 9–11, 13, 15]**.

CONCLUSION

Our study revealed that more than half of the sample size were prescribed with antibiotics which emphasizes a need for monitoring antibiotic prescribing pattern in pediatric patients. To evaluate and monitor use of antibiotics, antibiotics were classified based on AWaRe classification which revealed that majority of antibiotics belonged to Watch category and therefore had higher resistance potential. The prescribing pattern in our study was not satisfactory, as the results were not optimal as per WHO prescribing standards. The number of drugs prescribed per patient was ascertained as potential risk factor associated with antibiotic prescribing. Therefore, a better understanding of antibiotic prescribing pattern and their associated factors was established in the study area, thereby promoting awareness for a need of monitoring of antibiotic prescriptions in pediatric patients. As information about antibiotic prescribing trends among pediatrics remain inadequate, this study expands the existing body of data and hence emphasizes the need for rational use of antibiotics in order to provide a better therapeutic plan for pediatric patients.

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