

## Evaluation of prescription pattern of antimicrobials in the treatment of respiratory tract infections in pediatric patients attending a tertiary care hospital

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### ABSTRACT

**Background:** Irrational use of antimicrobials is a complex and multifactorial problem in developing countries. Prescriptions not adhering to the treatment guidelines, self-medication, inappropriate use of drugs by patients can inadvertently lead to development of antimicrobial resistance. An observational study was designed to evaluate antimicrobial use in pediatric population with respiratory tract infections and its adherence to national treatment guidelines.

**Methods:** This was a cross sectional observational study initiated after taking institutional ethics committee permission. The prescriptions of children diagnosed with upper respiratory tract infections and lower respiratory tract infections (LRTI) were screened. Their demographic profile and details of drugs prescribed were recorded.

**Results:** Out of 230 pediatric prescriptions, 155 (67%) were from outpatient department and 75 (33%) from those admitted in ward. Total 145 children were diagnosed with URTI whereas 85 had LRTI. In this study, 60 children with URTI received combination of amoxicillin and clavulanic acid (Co-amoxiclav) whereas 66 children with LRTI received Co-amoxiclav, 18 ceftriaxone (N=18), 6 vancomycin (N=6) and 18 were prescribed oseltamivir (N=18), either alone or in combination. Other drugs prescribed included, paracetamol for fever and cough syrups. Out of 195 drugs prescribed by brand names, 138 (70.8%) were antimicrobials. Fixed dose combination amoxicillin and clavulanic acid, paracetamol and cough syrups were available from hospital pharmacy. None of the prescriptions had polypharmacy.

**Conclusions:** URTI was treated using single antimicrobial whereas LRTI was treated with more than one antimicrobials or combination of antimicrobial and antiviral agent. The prescriptions were in accordance with the national treatment guidelines.

**Keywords:** Upper respiratory tract infections, Antibiotics, Lower respiratory tract infections, Antimicrobial, Infectious diseases

### INTRODUCTION

Antimicrobial agents are often prescribed in the pediatric population for treating various infections. The accurate determination of safety and efficacy of any drug being

prescribed to a child is rather different from adults as it is dependent on understanding pharmacokinetics and pharmacodynamics of a particular drug, as well as the clinical characteristics of the child being treated with that particular drug.<sup>1</sup> Prescribing antimicrobial agents not

adhering to the treatment guidelines, inappropriate use of medicines such as overuse, underuse and misuse, and self-medication can inadvertently lead to development of antimicrobial resistance.<sup>2</sup> Differences in antimicrobial drug use around the world reflects differences in local medication policies based on antimicrobial sensitivity, barriers to healthcare access, preferences of health-care providers and maternal attitude towards medication use. In developing countries the availability of antimicrobial agents without doctor's prescription, population growth, increase in antimicrobial consumption and poorly enforced laws to limit access to them are considered to play a role in development of antimicrobial resistance<sup>3,4</sup>. According to the latest report by Indian council of medical research (ICMR), Imipenem susceptibility of *E. coli* has dropped gradually from 86% in 2016 to 64% in 2021 and that of *Klebsiella pneumoniae* dropped from 65% in 2016 to 43% in 2021. Resistance to carbapenems in *Acinetobacter baumannii* was recorded as 87.5% in the year 2021, limiting the utility of available treatment options<sup>5</sup>. Study by Youngster et al reported the substantial differences of up to 7.5-fold in pediatric antimicrobial use across several industrialized countries from Europe, Asia, and North America.<sup>6</sup> Also, study conducted by Baidya et al in eastern region of India concluded that the selection of antimicrobial agents is mostly empirical as use of antimicrobial agent after determining the sensitivity pattern is time consuming, expensive and may cause delay in the treatment offered.<sup>7</sup> Therefore, it is imperative to adhere to the guidelines and strategies so as to restrict the unnecessary and inappropriate use of antimicrobial agents.

Upon realizing the increasing threat of antimicrobial resistance, department of health research, ICMR developed the evidence based treatment guidelines 'National treatment guidelines for antimicrobial use in infectious diseases' published in 2016 with the objective of rationalizing the use of antimicrobial agents in the country.<sup>8</sup> Drug utilization studies are useful in obtaining information with regards to the drug use patterns and for identifying the adherence to treatment guidelines by the prescribers. The practicing physicians are one of the key stakeholders playing a decisive role in controlling inappropriate use of the antimicrobial agents. Hence, the present study was proposed to assess the antimicrobial use in children diagnosed with respiratory tract infections with respect to appropriateness to the indication and adherence to national guidelines.

## METHODS

This was a cross sectional observational study conducted in department of pharmacology in collaboration with department of pediatrics over a period of 6 months, from June to November 2018 at a tertiary care teaching hospital. It was performed in accordance with the Declaration of Helsinki and institutional ethics committee approval was obtained before initiation of the study. Written informed consent from the parent of each child who met the

inclusion criteria was taken after explaining the purpose of the study and before screening their prescriptions. Assent was obtained from the children between 12 to less than 18 years of age along with their parents' written informed consent. Pediatric patients diagnosed with respiratory tract infection having age more than 2 and less than 18 years attending pediatric outpatient department (OPD) or admitted in pediatric ward or pediatric intensive care unit were included in the study. Children suffering from malaria, tuberculosis, HIV/AIDS or other immunodeficiency diseases, congenital heart diseases, and cancer, necessitating long-term antibiotic treatment or prophylaxis, were excluded. The demographic details of each selected pediatric patient, diagnosis, and details of drugs prescribed such as, name of the drug, generic or brand name, its strength/dose, route of administration, frequency of use, average number of drugs per prescription, number of fixed dose combinations (FDCs), and duration of treatment were recorded in the case record form.

## Statistical analysis

The data was analyzed with the help of statistical software SPSS, version 22 for windows. Descriptive statistic was used and the collected data was expressed in terms of numbers and percentages.

## RESULTS

Total 230 pediatric prescriptions were analysed of which 116 (50.43%) were boys and 114 (49.57%) were girls with ratio of 1.02. Out of 230 children, 155 (67%) were screened from OPD and 75 (33%) from those admitted in the ward. Number of children diagnosed with URTI was 145, whereas 85 children had LRTI. Total 93 (40.4%) children belonged to age less than 5 years and 137(59.6%) were between the age range of 5-18 years. On analysis of 145 prescriptions with URTI, it was found that 60 children were prescribed Co-amoxiclav, a fixed dose combination (FDC) of amoxicillin and clavulanic acid and azithromycin was prescribed to 4 children. Paracetamol for fever and cough syrups containing antiallergic, antitussives and expectorants were also prescribed for symptomatic relief (Table 1).

Children diagnosed with LRTI (N= 85), were prescribed either antimicrobials or antivirals or both. Out of total antimicrobials prescribed (N=76), 49 (64.5%) were prescribed Co-amoxiclav alone, 8 were prescribed Co-amoxiclav in combination with Inj. Ceftriaxone (N=8, 10.5%) and 9 were treated with Co-amoxiclav in addition to oseltamivir (N=9, 11.8%), 6 (7.9%) children were prescribed ceftriaxone and vancomycin and only Inj. Ceftriaxone was prescribed to 4 (5.3%) children. Oseltamivir was prescribed alone to 9 (10.6%) children. Majority children with LRTI were prescribed paracetamol, N=71 (83.53%), refer (Figure 1). Detailed analysis of drugs prescribed to all children (diagnosed with either URTI or LRTI), either in their brand names or generic

name, their formulation, given in OPD or IPD setting is depicted in (Table 2).

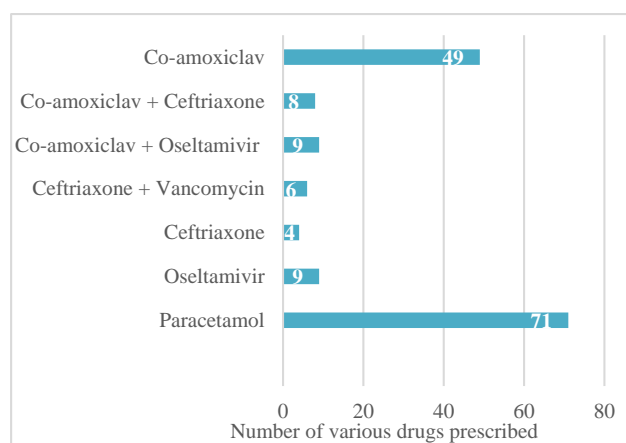
**Table 1: Drugs prescribed to children with URTI (n=145).**

Drugs prescribed	Number of children with URTI	%
Co-amoxiclav	60	41.38
Azithromycin	4	2.76
Paracetamol	112	77.24
Cough syrup	88	60.69

**Table 2: Detailed analysis of various drugs prescribed (in numbers) to all children diagnosed with respiratory tract infection.**

Parameters	Brand	Generic	Injectables	Syrup	Tablet	IPD	OPD
Co-amoxiclav	120	4	40	47	37	51	68
Ceftriaxone	18	0	18	0	0	18	0
Vancomycin	0	6	6	0	0	6	0
Azithromycin	0	4	0	0	4	0	4
Oseltamivir	18	0	0	18	0	18	0
Cough syrup	0	88	0	88	0	0	88
Paracetamol	39	144	56	127	0	56	127
<b>Total</b>	<b>195</b>	<b>246</b>	<b>120</b>	<b>280</b>	<b>41</b>	<b>149</b>	<b>292</b>

Out of 195 drugs prescribed by brand names, 147 (70.8%) were antimicrobials. However, out of 183 prescriptions of paracetamol, 144 (78.7%) were generic and cough syrups were prescribed in generics in all the prescriptions (N=88). Out of 441 drugs prescribed, 280 (63.5%) were in syrup formulations whereas 120 (27.2%) were injectables, and 41 (9.3%) tablet formulations. Co-amoxiclav, paracetamol and cough syrups were available from hospital pharmacy. None of the prescriptions had polypharmacy.



**Figure 1: Drugs prescribed to children with lower respiratory tract infection (LRTI) (n=85).**

## DISCUSSION

In developing countries, due to the high patient-doctor ratio, there is less time available for patient education and meaningful information being communicated to patients, which leads to poor or non-adherence to the treatment as

per the formulated guidelines. Often, broad spectrum antibiotics are prescribed without waiting for definitive diagnosis so as to save precious life. Problem of self-medication in developing countries is another key reason for inappropriate antimicrobial use, resulting in development of antimicrobial resistance<sup>9</sup>. This study was therefore planned to evaluate the prescribing practices being followed at a tertiary care teaching hospital for treating respiratory tract infections in children.

In this study it was found that 40.4% children belonged to the age group of less than 5 years, similar findings were recorded in studies by Kokani et al, Malpani et al, Tiwari et al and Mahapatra et al.<sup>10-13</sup> This large number is perhaps because the children in this age group are more susceptible to infection, mainly due to weaning causing reduction in their immunity and getting exposed to the outside environment more often. In the present study, 2/3<sup>rd</sup> children screened were from the outpatient department whereas 1/3<sup>rd</sup> were from the pediatric ward. This could be due to the fact that the study was carried out during monsoon, and children are more susceptible to infections in this season, both bacterial or viral. Similar finding was reported by Malpani et al.<sup>11</sup>

Majority of drugs prescribed were in the syrup form (63.5%), followed by injectables (27.2%) and tablets (9.3%). In our study most children had URTI for which oral route of delivery in the form of syrup formulation is justified. The studies conducted by Kokani et al, Majhi et al and Baidya et al reported injectables as the major route of drug administration.<sup>7,10,12-15</sup> It could be possibly because these studies had more cases of LRTI and use of injectables was appropriate considering the indication.

Children diagnosed with URTI received antimicrobials, antipyretics and cough syrups containing antiallergics, cough expectorants, mucolytics and antitussives. Most frequently prescribed antimicrobial was Co-amoxiclav (41.38%), followed by azithromycin (2.76%). Studies by Kokani et al, Malpani et al, Adhikary et al, Mohan et al reported similar findings.<sup>10,11,16,17</sup> The use of penicillins was predominant as it is the safest antibiotic in this population and is also recommended by the American academy of pediatrics and National centre for disease control in India pertaining to antimicrobial use in pediatric population. Children diagnosed with LRTI received antimicrobials, anti-pyretics like paracetamol, and antiviral drugs like oseltamivir. Among the various antimicrobials, most commonly prescribed was co-amoxiclav (86.8%) which was given either alone or addition of 3<sup>rd</sup> generation cephalosporin, ceftriaxone, or oseltamivir, an antiviral agent was required. Similar findings were reported by number of such studies.<sup>10,11,16-19</sup> Other studies have reported the use of 1<sup>st</sup> and 3<sup>rd</sup> generation cephalosporin, and aminoglycosides like amikacin for treating LRTI.<sup>7,14-16</sup> Regarding the use FDCs prescribed, co-amoxiclav, FDC of amoxicillin and clavulanic acid which is from the WHO list of approved FDCs was prescribed for treating both URTI and LRTI. However, guidelines regarding appropriate use of antimicrobials for infectious diseases differs as per the difference in the sensitivity of the microorganisms to various antimicrobials and policies related to antimicrobial use. It was observed that antimicrobials were prescribed by brand names whereas paracetamol and antiallergic formulations were prescribed by their generic name. Similar finding was reported by Naik et al. This was in contrast to the study by Baidya et al, Kokani et al and Prajapati et al which reported drugs prescribed mainly by generic name.<sup>7,10,17-21</sup> The most preferred dosage form was syrup as majority patients were diagnosed with URTI and were treated in outpatient department.

## CONCLUSION

The analysis reflected that the prescriptions were in accordance with the national guidelines with the predominant use of  $\beta$  lactam antibiotics for treating both URTI and LRTI. Positive trend toward monotherapy was observed. Regular sensitization program on antibiotic stewardship would inculcate the practice of appropriate antimicrobial prescribing in treating physicians and thereby curb the challenging the threat of antimicrobial resistance.

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