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Irrational Prescribing of Antibiotics in Pediatric Outpatients: A Need for Change

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Abstract:

Background and Aims: Antibiotics play a major role in the treatment of infectious diseases and are among the drugs most commonly prescribed for children. Respiratory tract infections in pediatric patients are a common cause of antibiotic prescribing which increases morbidity, mortality, patient cost and the likelihood for emergence of antibiotics-resistant microorganisms. This study was undertaken to determine the proportion of common respiratory tract infections and to generate data on the extent of rational/irrational prescribing of antibiotics in patients attending the pediatric out-patient department. Material and Methods: retrospective study carried out during one year (January to December, 2013) in the pediatric out-patient department of the Clinical Center in Tetovo. Patients of either sex at age group between 1 week and 14 years who attended the pediatric out-patient department and were prescribed antibiotics for respiratory tract infections were included in the study. The data was compared against national guideline-based medicine, major antibiotic guidelines recommended by World Health Organization (WHO) and American Academy of Pediatrics (AAP), and cross-referenced against Cochrane studies. Results: Children aged >1 - ≤3 years received 49.6% of antibiotics. The most common prescribed antibiotics were penicillins (62.2%), followed by cephalosporins (32.5%). Sore throat (61.5%) was identified as the most common diagnosis. There was a significant relationship ($r=0.234$, $p<0.05$) between diagnosis and antibiotic prescribing. Ninety two percent of pediatric patients with common cold, laryngitis, viral sore throat, acute otitis media and bronchitis were prescribed antibiotics irrationally, that represents a major deviation from the recommendations from the guidelines. High levels (90%) of antibiotic irrational prescribing were revealed in pediatric outpatients diagnosed with pneumonia. Conclusion: This study reinforces the need to implement strategies that promote rational use of antibiotics in respiratory tract infections in children and close monitoring of antibacterial use at national, regional and local level.

Keywords: Antibiotics, irrational prescribing, pediatric outpatients

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Introduction

Infants and children are among the most vulnerable population groups to contract illnesses and because of this the use of antimicrobial agents, especially antibiotics has become a routine practice for the treatment of pediatric illness [1]. Acute upper respiratory tract infection, acute watery diarrhea and viral fever are the most common childhood illnesses accounting for the major proportion of pediatric outpatient visits [2]. Different studies across the globe have shown inappropriate prescribing of antibiotics to treat common pediatric illnesses which were not caused by bacteria, especially the broad-spectrum antibiotics, which have contributed largely to the development of antibiotic resistance. Inappropriate or irrational use of drugs is described by James Trostle as consumption of drugs in a way that reduces or negates their efficacy or in a situation where they are unlikely to have the desired effect” [3]. Guidelines have been propagated for decades and yet they frequently are not followed [4] thus it is very important to study the use of antibiotics and introduce interventions depending upon the local requirements and this process should involve the physicians/prescribes and the pharmacists in order to achieve judicious use of antibiotic drugs. Judicious use of antibiotics includes provider adherence to prescribing guidelines, not using antibiotics for probable viral infections, and using the narrowest spectrum agent that is active against the targeted pathogens [5, 6]. Prompted by this problem, this study was undertaken to determine the proportion of common respiratory tract infections and to generate data on the extent of rational/irrational prescribing of antibiotics in patients attending the pediatric out-patient department.

Material and Methods

This retrospective study was carried out during one year (January to December, 2013) in the pediatric out-patient department of the Clinical Center in Tetovo, an urban city in the north-

western part of the Republic of Macedonia. Patients of either sex at age group between 1 week and 14 years who attended the pediatric out-patient department and were prescribed antibiotics for respiratory tract infections were included in the study. Data regarding demographics such as age, sex, diagnosis, drug details which included name of the drug, generic/brand name, dosage form, dose frequency and duration were recorded in specially designed data entry form. Permission to conduct the study was taken from the Committee of the Directorate of Clinical Hospital, Tetovo and the Head of the Department of Pediatrics.

Wherever possible, acquired data was compared against national guideline-based medicine, major antibiotic guidelines recommended by World Health Organization (WHO) and American Academy of Pediatrics (AAP), and cross-referenced against Cochrane studies. Further information was gathered from reference sources such as the British National Formulary for children 2011-2012 and the NELSON textbook of pediatrics.

Statistical analysis: Descriptive statistics was used to summarize the data about demographic characteristics. Chi-square and Fisher exact tests were used to test the significance of the study parameters on a categorical scale between multiple groups. Analyzing and measuring the strength of the relationship between interval variables is done by calculating the Pearson coefficient of correlation. In all statistical analyses, a p-value of <0.05 was considered statistically significant. The data collected were analyzed using Statistical Package for Social Sciences program (SPSS), version 19.0 and Microsoft word and Excel were used to generate tables.

Results

Socio-Demographic Data

A total of 8594 visits were made during 2013 calendar year in pediatric out-patient department, of whom 3452 were prescribed antibiotics, which resulted in an 84.2% rate of antibiotic prescribing in patients with respiratory tract infections.

The population consists of 55.3% male and 44.7% female patients. The group receiving most antibiotics was toddlers aged $> 1 - \leq 3$ years (49.6%). The age group less involved in the study was neonates up to 4 weeks (1.6%) (Table 1).

Pediatric diagnosis with respect to age and sex

The most common diagnosis of antibiotic prescribing in pediatric outpatients was sore throat (61.5%), followed by acute bronchitis (20.2%) and the common cold (12.9%) (Table 2).

Type and dosage forms of antibiotics prescribed for various diagnoses

The penicillin class of antibiotics, including amoxicillin, clavulanic acid (29.5%), remains the most frequently prescribed, followed by benzathine phenoxymethylpenicillin (16.8%), amoxicillin (15.6%) and ampicillin (0.3%). Cephalosporins, such as cephalexin prescribed in 12%, cefaclor in 10.5% and cefuroxime in 1.2% of pediatric patients, are recommended in penicillin-allergic individuals. Cefadroxil (7.4%) which is a first generation cephalosporins and cefixime (1.3%) which is a third generation

cephalosporin were also prescribed. The macrolides, azithromycin (3.3%), midecamycin (1.3%) and clarithromycin (0.5%) were also antibiotics of choice in the treatment of respiratory tract infections in pediatric outpatients. Sulfamethoxazole, trimethoprim was also prescribed in 0.1% of cases (Table 3).

Table 1: Pediatric out patients socio-demographic data

Parameters	Number of patients	Percentage
Age		
Neonates (up to 4 weeks)	46	1.6
Infants (> 4 weeks - ≤ 1 year)	675	23.2
Toddler ($> 1 - \leq 3$ years)	1443	49.6
Pre-school ($> 4 - \leq 6$ years)	484	16.6
School age ($> 6 - \leq 14$ years)	259	8.9
Sex		
Male	1608	55.3
Female	1299	44.7

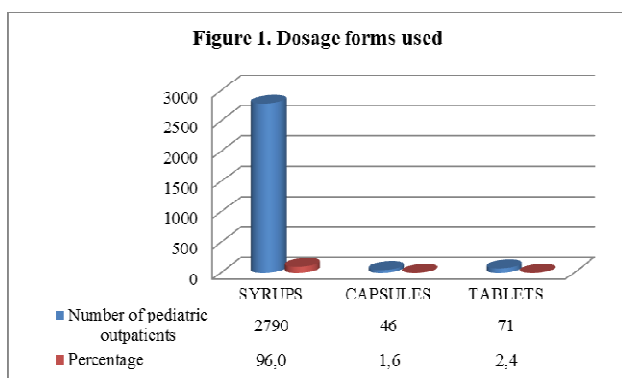
Table 2. Diagnosis of antibiotic prescribing in pediatric outpatients with respect to age and sex

	Neonates		Infants		Toddler		Pre-school		School age		Total	%
	M	F	M	F	M	F	M	F	M	F		
Common Cold	13	16	107	94	68	54	7	9	5	2	375	12.9
Sore Throat	3	8	168	129	525	439	198	151	86	82	1789	61.5
Laryngitis	0	2	6	9	12	8	8	0	2	2	49	1.7
Acute Otitis Media	0	0	11	10	5	6	0	3	0	1	36	1.2
Acute Bronchitis	0	3	81	53	174	118	51	42	42	24	588	20.2
Pneumonia	1	0	2	5	18	16	7	8	8	5	70	2.4

Table 3. Antibiotics prescribed for various diagnoses

Class of antibiotics	Total No	%	Type of antibiotics	No	% of total
Cephalosporins	944	32.5	Cefaclor	305	10.5
			Cefalexin	349	12.0
			Cefadroxil	215	7.4
			Cefixime	39	1.3
			Cefuroxime	36	1.2
Penicillins	1809	62.2	Amoxicillin, clavulanic acid	855	29.4
			Benzathine phenoxymethyl penicillin	491	16.9
			Amoxicillin	455	15.7
			Ampicillin	8	0.3
Macrolide	153	5.3	Midecamycin	37	1.3
			Azithromycin	100	3.5
			Clarithromycin	16	0.5
Sulfonamide	1	0	Sulfamethoxazole, trimethoprim	1	0.0

Syrups were the common dosage forms prescribed for all outpatients in the pediatric age group (Figure 1).

**Figure 1. Dosage forms used.**

Pediatric diagnosis and antibiotics prescribed

Common cold

The common cold is generally regarded as a self limiting viral infection of the upper respiratory tract. Usually bacteria do not cause the common cold, which make antibiotics useless against

them. Therefore, according to the guideline recommended by the World Health Organization [7] and American Academy of Pediatrics [8], antibacterial therapy is not recommended in the treatment of common cold. However, in our study, the prescription rate of antibiotics for this diagnosis is 12.9%, that confirms the irrational use of antibiotics in these cases (Table 4).

Sore throat

Acute sore throat is a symptom often caused by an inflammatory process in the pharynx, tonsils or nasopharynx. Most of these cases are of viral origin and occur as a part of the common cold [9]. In addition to viral pathogens, bacterial pathogens, mainly group A β -haemolytic streptococcus may also cause pharyngeal infections. There is broad overlap between the signs and symptoms of streptococcal and nonstreptococcal (usually viral) pharyngitis and the ability to identify streptococcal pharyngitis accurately on the basis of clinical grounds alone

is generally poor [10-13]. Presence of swollen and tender anterior cervical nodes, fever $>38^{\circ}\text{C}$, tonsillar exudates or swelling, absence of cough are signs that have a low positive-predictive value (35-50%) for streptococcal pharyngitis. Throat culture if performed correctly is 90-95% sensitive for detection of streptococcal pharyngitis. This illness is relatively uncommon before 2-3 years of age, has a peak incidence in the early school years [14]. Antimicrobial therapy is of no proven benefit as a treatment for acute pharyngitis due to organisms other than group A β -haemolytic streptococcus. Patients with acute streptococcal pharyngitis should be treated with an appropriate antibiotic at an appropriate dose for duration likely to eradicate the organism from the pharynx (usually 10 days) [15]. According to the national guideline-based medicine for streptococcal tonsillitis and pharyngitis in children and the national guideline-based medicine for using the antimicrobial therapy, Penicillin V is the

recommended drug of choice for those non-allergic to these agents. Treatment of GAS pharyngitis in penicillin-allergic individuals should include cephalexin (for those not anaphylactically sensitive) for 10 days. Clindamycin or clarithromycin for 10 days, or azithromycin for 5 days. Amoxicillin and penicillin are also drugs of choice, according to the guideline recommended by the American Academy of Pediatrics [8]. In our study, sore throat was the dominant diagnosis observed, with an antibiotic prescription rate of 61.5%, with a higher prevalence in the age group between 1-3 years. Streptococcal pharyngitis is diagnosed in 369 (20.6%) cases. Among them, 193 (52.3%) are treated with the recommended antibiotics and at an appropriate dose and duration. The rest of pediatric outpatients (89.2%) diagnosed with sore throat are treated irrationally (Table 4).

Table 4. Pediatric diagnosis and antibiotics prescribed

Prescribed antibiotics	Common Cold		Sore throat		Laryngitis		Acute Otitis Media		Bronchitis		Pneumonia		Total		p
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	
Benzathine phenoxymethyl penicillin	9	2.1	468	26.2	1	2.0	3	8.3	9	1.5	1	1.4	491	16.9	<0.05
Amoxicillin	74	19.7	259	14.5	14	28.6	15	41.7	81	13.8	12	17.1	455	15.7	
Amoxicillin, clavulanic acid	46	12.2	571	31.9	20	40.8	6	16.7	197	33.5	15	21.4	855	29.4	
Ampicillin	2	0.5	4	0.2	1	2.0				0.0	1	1.4	8	0.3	
Cefaclor	79	21.1	147	8.2	3	6.1	1	2.8	73	12.4	2	2.9	305	10.5	
Cefalexin	142	37.9	145	8.1	7	14.3	4	11.1	45	7.7	6	8.6	349	12.0	
Cefadroxil	9	2.4	129	7.2	2	4.1	3	8.3	70	11.9	2	2.9	215	7.4	
Cefixime	4	1.1	4	0.2		0.0			12	2.1	19	27.1	39	1.3	
Cefuroxime	3	0.8	16	0.9		0.0	2	5.6	15	2.5			36	1.2	
Midecamycin	3	0.8	16	0.9	1	2.0			17	2.9			37	1.3	
Azithromycin	4	1.1	24	1.3			2	5.6	59	10.0	12	17.1	101	3.5	
Clarithromycin			5	0.3					10	1.7			15	0.5	
Sulfamethoxazole, trimethoprim			1	0.1									1	0.0	

Laryngitis

Laryngitis is considered as a predominantly upper respiratory tract infection almost exclusively due to common respiratory viruses and usually associated with the common cold syndrome [16]. Even though, according to the national guideline-based medicine for laryngitis in children and the guideline recommended World Health Organization [7] antibiotics have limited usage in the treatment of laryngitis, in our study they are prescribed in 49 (1.7%) of pediatric outpatients. Prescribing antibiotics for laryngitis shows the irrational usage for this diagnosis (Table 4).

Acute Otitis Media

Acute Otitis Media is defined as the rapid onset of signs and symptoms of inflammation in the middle ear [8]. Although the pathogenesis of AOM is multifactorial, both viruses and bacteria are implicated [17]. Individual episodes of AOM have customarily been treated with antimicrobial drugs. Concern about increasing bacterial resistance has prompted some clinicians to recommend withholding antimicrobial treatment in some or most cases, unless symptoms persist for 2 or 3 days, or worsen [18]. According to the national guideline-based medicine for otitis media in children and the national guideline-based medicine for using the antimicrobial therapy, antibiotics such as Amoxicillin and Amoxicillin/clavulanic acid are the first and second line recommended treatment while Cefuroxime, Cefaclor and Sulfamethoxazole/Trimethoprim are alternatives in case of penicillin allergy. The recommended duration of treatment is 7 days. Amoxicillin with or without clavulanate and cefuroxime in case of penicillin allergy are recommended by the American Academy of Pediatrics guideline [8], while, Amoxicillin or Sulfamethoxazole/Trimethoprim (co-trimoxazole) are drugs of choice recommended by the World Health Organization guideline [7]. Among the 36 (1.2%) of pediatric patients diagnosed with acute otitis media, antibiotics are rationally prescribed in 14 (38.9%) cases, while in two cases azithromycin is prescribed, which according to

the American Academy of Pediatrics [8] is generally not recommended attributable to *Streptococcus pneumoniae* resistance. The rest of the prescriptions (61.1%) contain irrationally prescribed antibiotics (Table 4).

Acute bronchitis

Acute bronchitis is a syndrome, usually viral in origin, with cough as a prominent feature. The disease is self-limited, and antibiotics, although often prescribed, do not hasten improvement [19]. Even so, the use of antibiotics in acute bronchitis may be indicated when pertussis or *Mycoplasma pneumoniae* infection are detected. In our study, acute bronchitis is the second most prevalent diagnosis with prescription rate of 20.2%. Among 588 cases, only 42 (7.1%) of them show signs of pneumonia, where prescribing of antibiotics is recommended. Even though, in cases where pneumonia is suspected, an antibiotic such as Amoxicillin is recommended by the World Health Organization guideline [7], in our study only 7 (10.0%) prescriptions are rational. Other prescriptions for acute bronchitis in our study present irrational treatment (Table 4).

Pneumonia

Pneumonia, inflammation of the parenchyma of the lungs, is a substantial cause of morbidity and mortality in childhood throughout the world [20]. Viruses, atypical and typical bacteria cause the vast majority of childhood pneumonia [21, 22]. For infants from 3–6 months of age [23] hospitalization is recommended, while, as recommended by the national guideline-based medicine for pneumonia in children, amoxicillin for 7 days plays a significant role for children from 6 months up to 14 years. Amoxicillin is also the recommended antibiotic, according to the guidelines of the World Health Organization [7] and American Academy of Pediatrics [8]. However, among 70 (2.4%) of antibiotic prescribing for pneumonia, rationality was observed in only 12 (17.1%) of pediatric outpatients (Table 4).

Discussion

Taking into consideration, the key factors in the development of antimicrobial resistance such as the total amount of antimicrobial usage, class or groups of antibiotics, dosage and frequency as well as public behavior all indicates that outpatient prescribing is playing a major role in the development of antimicrobial resistance. [24]

According to Murphy et al., most common causes of antibiotic prescribing are due to respiratory complaints [25]. This consists with the results of our study where the most frequent diagnoses for which antibiotic drugs are prescribed, are respiratory tract infections (84.2%). This study also showed a significant relationship ($r=0.234$, $p< 0.05$) between diagnosis and antibiotic prescribing.

In this study, antibiotics were prescribed in 61.5 % of pediatric patients diagnosed with sore throat. This result shows a practice of irrational prescribing since the diagnosis of streptococcal pharyngitis or tonsillitis may reflect difficulty by pediatrician to precisely identify the diagnosis and etiology. Wang et al., [26] in her study reported a higher rate (76%) of antibiotic prescribing for acute pharyngitis and tonsillitis in children aged <5 years, while a much lower rate (8.4%) of antibiotic prescribing for acute tonsillitis, acute otitis media and acute pharyngitis for all children studied was reported by Mungrue et al., [27]. Streptococcal pharyngitis or tonsillitis was diagnosed in only 20.6% and among them 52.3 % were treated with the recommended antibiotics at an appropriate dose and duration. Antibiotic use in streptococcal pharyngitis or tonsillitis is beneficial and whenever indicated, it is important that patients are treated in dose and for a duration that is likely to eradicate the infecting organisms from the pharynx [28]. This needs further pediatrician and parent education on the epidemiology of streptococcal pharyngitis or tonsillitis as well as for its adequate management. About 20.2% of pediatric patients with bronchitis were prescribed an antibiotic. The result of this study is lower than that of Fossum et al., (40%) [29] and much lower than

the result reported by Wang et al., [26], where the rate of antibiotic prescribing for bronchitis and bronchiolitis was 65%. It is well known that the common cold is caused by viruses and prescribing antibiotics do not benefit patients. Even so, in this study, antibiotics are prescribed in almost 13% of pediatric patients diagnosed with common cold. A study by Mungrue et al., [27], reported a higher rate of antibiotic prescribing for common cold in pediatric patients (32.7%). Only 36 patients diagnosed with acute otitis media were prescribed antibiotics. While antimicrobials are indicated for treatment of acute otitis media, diagnosis requires documented middle ear effusion and symptoms and signs of acute local or systemic illness [30]. The choice of antibiotic for this diagnosis was compliant with guidelines in almost 39% of the cases. If antibiotic treatment is indicated for acute otitis media compliance to guidelines is very important because inadequate management can lead to complications which include chronic suppurative otitis media, mastoiditis, labyrinthitis, facial palsy, meningitis, intracranial abscess and lateral sinus thrombosis [31]. In 2010, the National Institute for Health and Clinical Excellence (NICE) guidelines recommended either delayed or no prescribing for five common diagnoses; acute otitis media, acute sore throat, acute cough/bronchitis, acute sinusitis and common cold [32], while the Cochrane database Meta-analysis of randomized controlled trials demonstrated that antibiotic use to treat acute otitis media, rhinitis and acute sore throat has no or minimal benefit on the outcome [33-35]. However, in our study, 92 % of pediatric patients are prescribed antibiotics irrationally for these diagnoses that represent a major deviation from the recommendations from the guidelines.

High levels (90%) of irrational prescribing in pediatric outpatients diagnosed with pneumonia, mainly in the inappropriate drug selection, were identified when compared to the guidelines of World Health Organization and American Academy of Pediatrics. This is similar to the result revealed by Dorj et al., [36], where 84% of drugs for community -acquired pneumonia were

inappropriately prescribed. When children with pneumonia are treated promptly and effectively with antibiotics their chance of survival increases significantly [37].

These results show that penicillin's are the most prescribed class of antibiotics, that according to the national guideline-based medicine, major antibiotic guidelines recommended by the World Health Organization and American Academy of Pediatrics are the recommended first line antibiotics of choice in the treatment of bacterial respiratory tract infections. Unfortunately, the results of this study could not determine whether macrolides and cephalosporins were really prescribed for pediatric patients sensitive to penicillins.

There was no statistically significant difference by sex in the prescribing of antibiotics for respiratory tract infections in pediatric outpatients. A statistically significant difference was found in the use of antibiotics by pediatric age ($p < 0.05$), similar with the study by Mishra et al. [38].

There are several factors other than the clinical condition that could have influenced antibiotic prescribing. Such factors include lack of certainty of diagnosis [39], fear for not treating a bacterial infection, heavy workload and inadequate time for each patient [40], pressure from parents to prescribe; pediatrician may not be familiar with or may not agree with the guidelines or reject the idea of using these standards, believing that guidelines restrict their autonomy of practicing medicine. The focus of this study was not on analyzing the influence of these factors on antibiotic prescribing for pediatric outpatients diagnosed with respiratory tract infections. Therefore, future research should be conducted to determine if these or other factors could be associated with antibiotic prescribing for respiratory tract infections in Tetovo, Republic of Macedonia.

There were limitations to our study. The results are gained from the only pediatric hospital in the city of Tetovo, which prevents their generalization to the larger population of the Republic of Macedonia. The diagnosis was

assumed to be correctly written by the pediatricians' and represents an indication for the prescribing of antibiotics. Physicians may diagnose certain conditions as bronchitis, sinusitis, or otitis media to justify antibiotic prescriptions [41, 42].

Antibiotics are frequently and irrationally prescribed for children for viral conditions such as common colds, laryngitis, bronchitis, sore throat despite their non-recommendations according to the standardized guidelines. This study confirms the overuse of antimicrobials for these common conditions among pediatric patients and concludes that the antibiotic treatment prescribed in most of the cases is without doing much culture sensitivity test which may lead to irrational prescription. Efforts to improve the rational antibiotic prescribing practices are needed for all pediatricians and parents who care for their children. Using the national guideline-based medicine and standardized guidelines for pediatric antibiotic prescription in respiratory tract infections can reduce prescribing rates of antibiotics for these diagnoses. The manner in which the antibiotics are prescribed by the pediatricians' needs further studies about decision making on more appropriate and cost effective prescribing and patient health-seeking behavior. Therefore, implementing strategies that promote rational use of antibiotics in respiratory tract infections in children and close monitoring of antibacterial use at national, regional and local level are important public-health priorities in order to find problematic areas and trends of antibiotic prescribing and to preserve the efficacy of these vital drugs.

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