Avens Publishing Group
J Pediatr Child Care
June 2025 Volume:11, Issue:1

Open Access Research Article

Journal of
Pediatrics & Child Care

Clinicians' Perspectives on the use of Amoxicillin-Clavulanic Acid for Pediatric Respiratory Infections in India Settings

Manjula S* and Krishna Kumar M

Department of Medical Services, Micro Labs Limited, Bangalore, Karnataka, India

***Address for Correspondence:**
Manjula S, Department of Medical Services, Micro Labs Limited, Bangalore, Karnataka, India E-mail Id: drmanjulas@gmail.com

Submission: 20 May, 2025
Accepted: 27 June, 2025
Published: 30 June, 2025

Keywords: Antibiotic; Respiratory Infections; Pneumonia; Otitis media; Amoxicillin-clavulanic acid

Abstract

Objective: To investigate clinicians' perspectives regarding the usage of antibiotics for pediatric respiratory tract infections, with a particular emphasis on amoxicillin and clavulanic acid use in pneumonia and otitis media.

Methodology: The cross-sectional study employed a multi-item questionnaire to collect data from clinicians across India on their antibiotic use for pediatric patients with respiratory infections, preferences for dosage regimens, duration of treatment, and factors affecting patient compliance. Descriptive statistics were used to analyze the survey data. Categorical variables were presented as percentages to provide a clear understanding of response distributions.

Results: The study included 568 clinicians, and 94% of them favored co-amoxiclav for acute otitis media in outpatient settings, while 90% preferred it for treating pediatric pneumonia. Around 36% of respondents prescribed high-dose amoxicillin (600 mg) with clavulanic acid (42.9 mg) for various infections, including respiratory, ear, sinus, urinary tract, and skin infections. Among otitis media cases, 32.75% of experts reported using amoxicillin-clavulanate in 61-80% of patients, and 30.81% prescribed the high-dose formulation to 26-50% of those with recurrent cases. A 7-day course was preferred by 47.89% of experts for recurrent otitis media. Antibiotic resistance was cited by 45.60% of clinicians as the most common complication of incomplete treatment.

Conclusion: This study highlights clinicians' preference for amoxicillin clavulanate in treating pediatric respiratory infections, especially pneumonia and otitis media in Indian settings. The high-dose formulation is commonly used for a 7-day course. Clinicians also recognize antibiotic resistance as the primary risk of incomplete treatment in children.

Introduction

Acute respiratory tract infections (RTIs) are a major cause of childhood illness and mortality worldwide.[1] According to the Global Burden of Disease 2019 study, the highest incidence rate is observed in children under 5 years of age, reaching three hundred thousand cases per 100,000 population. Beyond the typical symptoms, upper RTIs can lead to severe complications such as pneumonia, otitis media, glomerulonephritis, and myocarditis, significantly increasing healthcare costs and posing a financial burden on society.[2]

Recent data indicate that acute RTIs, particularly lower respiratory tract infections, result in nearly 1.9 million childhood deaths annually, with approximately 20% of these deaths occurring in India.[3,4] Acute otitis media (AOM) is the second most common childhood illness and a leading cause of pediatric consultations, accounting for approximately 13.6 million visits worldwide each year. The highest incidence occurs in those aged 1 to 4 years, with 61 new cases per 100 children annually. According to the World Health Organization (WHO), otitis media is the leading cause of hearing impairment, affecting 42 million individuals over the age of three worldwide.[2,5]

Co-amoxiclav is primarily prescribed for the treatment of community-acquired RTIs in routine settings. As a β-lactam antibiotic, it exerts a bactericidal effect by inhibiting bacterial peptidoglycan cell wall synthesis, effectively targeting both Gram-positive and Gram-negative bacteria. The addition of clavulanate, a beta-lactamase inhibitor, enhances its efficacy against resistant strains.[6] With its potent antibacterial activity and favorable pharmacokinetic and pharmacodynamic profile, co-amoxiclav is effective in treating beta-lactamase-producing pathogens. It has demonstrated improved outcomes in persistent or recurrent infections where initial antibiotic therapy has failed. Its well-established safety profile and availability in suspension formulations also make it a suitable choice for pediatric patients.[7]

This study aims to explore current clinical perspectives among Indian clinicians regarding antibiotics usage for pediatric respiratory infections, with a focus on amoxicillin-clavulanate use in pneumonia and otitis media. By examining practitioners' preferences, perceptions, and challenges in antibiotic prescribing, the survey seeks to identify potential areas for improvement in pediatric infectious disease management within Indian healthcare settings.

Methods

We carried out a cross-sectional study among clinicians across various Indian healthcare settings from June 2024 to December 2024. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, the Drug Controller General of India.

An invitation was sent to leading clinicians in managing infections in the month of March 2024 for participation in this Indian survey. About 568 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. The questionnaire booklet titled ENCORE (Experts Opinion on Complication of Incomplete

ISSN: 2380-0534

Therapy in treating respiratory tract infections) was sent to clinicians who were interested to participate. The ENCORE study questionnaire explored the prevalence of pneumonia and otitis media, antibiotic preferences, dosing regimens, treatment duration, and factors influencing antibiotic selection. Challenges related to patient compliance and medication packaging were also evaluated. Clinicians had the option to skip any questions they preferred not to answer. They were instructed to complete the questionnaire independently, without consulting their colleagues. Written informed consent was obtained from all participants before the study commenced.

Statistical Analysis

Descriptive statistics were used to analyze the survey data, with categorical variables presented as percentages to illustrate response distributions. Frequencies and percentages were calculated for each survey item, and all tables were generated using Microsoft Excel (version 2409, build 16.0.18025.20030).

Results

The study included 568 clinicians, with nearly 40% reporting that 11–25% of children with RTIs develop pneumonia in their practice. Approximately 67% indicated they usually prescribe antibiotics for 7–10 days in children with pneumonia. Most clinicians (43.13%) considered multiple factors, including infection severity, site, patient age, allergy history, and treatment cost when selecting an antibiotic regimen. According to 55% of respondents, the most common reason for incomplete antibiotic therapy in children is an insufficient quantity of the drug in the bottle to complete the full course. Nearly 21% identified dosing frequency as the primary reason for missed antibiotic doses in children. Additionally, 48% of experts reported that the most common external factor influencing antibiotic course completion is the bottle running out before the full course is completed.

The majority of clinicians (75.88%) reported that a larger bottle offers multiple benefits, including a lower chance of recurrence, reduced risk of incomplete therapy, decreased antibiotic resistance, and lower overall treatment costs. Approximately 69% of respondents stated that fruit flavor is the most acceptable choice in pediatric practice. Nearly half of the experts (48.59%) reported that school-aged children (5–12 years) are most susceptible to incomplete co-amoxiclav therapy for RTIs. According to 42% of clinicians, taste and palatability are the most important factors influencing antibiotic compliance in children. Most clinicians (60.39%) preferred the higher dose of 45/6.4 mg/kg/day for treating pediatric bacterial infections. A significant majority (90.32%) preferred amoxicillin-clavulanate for treating pediatric pneumonia (Figure 1).

The majority of clinicians (40.49%) reported that 11–20% of children in their daily clinical practice have AOM. According to 55% of respondents, school-aged children (5–12 years) are the most commonly affected age group for resistant otitis media in their practice. Around 83% agreed that approximately 26% of children do not complete their antibiotic course due to one bottle being insufficient. The majority of clinicians (94.01%) preferred amoxicillin-clavulanate for treating AOM in children in the outpatient department (Figure 2).

The majority of clinicians (36.09%) reported prescribing high-dose amoxicillin 600 mg and clavulanic acid 42.9 mg for all listed conditions, including ear infections, sinus infections, RTIs, urinary tract infections, and skin infections. Additionally, 30% of clinicians reported using it specifically for RTIs (Table 1). Nearly 33% reported using amoxicillin-clavulanate in 61–80% of patients with otitis media (Figure 3).

Approximately 31% of experts reported prescribing high-dose amoxicillin 600 mg + clavulanic acid 42.9 mg to 26–50% of patients with recurrent otitis media (Table 2). Most clinicians (47.89%) reported prescribing this high-dose regimen for 7 days in patients with AOM (Table 3). The majority of clinicians (33.28%) identified antibiotic resistance as their primary concern when treating RTIs with incomplete antibiotic therapy in pediatric patients (Table 4). According to 46% of clinicians, antibiotic resistance is the most common complication of incomplete antibiotic treatment in children. About 38.5% of clinicians mentioned the recurrence of infection, and 12.15% of them highlighted the persistence of symptoms (Figure 4).

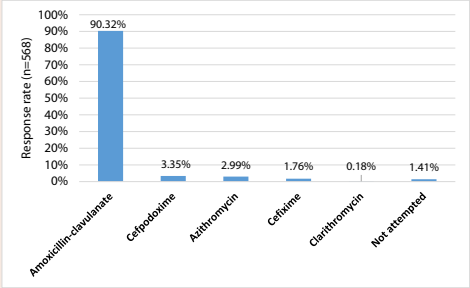

Figure 1: Distribution of responses to preferred drug for pediatric pneumonia in routine settings

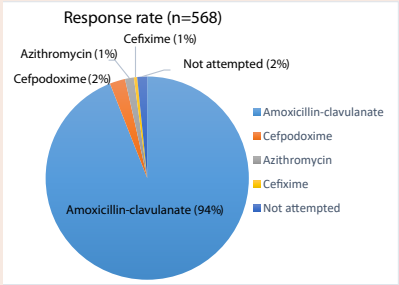

Figure 2: Distribution of responses to preferred antibiotic for pediatric AOM in outpatient practice

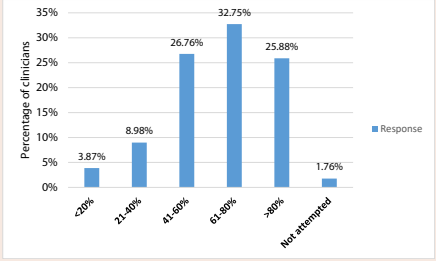

Figure 3: Distribution of responses to the proportion of patients receiving amoxicillin-clavulanate for otitis media management

ISSN: 2380-0534

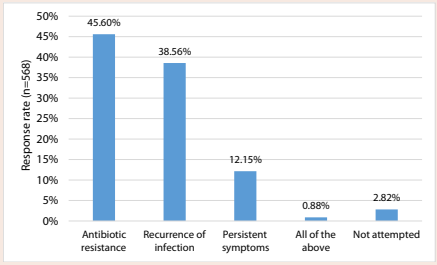

Figure 4: Distribution of responses to the most common complication of incomplete antibiotic treatment in children

Table 1: Distribution of responses to conditions for prescribing high-dose amoxicillin 600 mg and clavulanic acid 42.9 mg in pediatric patients

Conditions	Response rate (=568)
Ear infections	25%
Sinus infections	4.93%
Respiratory tract infections	29.75%
Urinary tract infections	0.70%
Skin infections	1.58%
All of the above	36.09%
Not attempted	1.94%

Table 2: Distribution of responses to the proportion of patients with recurrent otitis media prescribed high-dose amoxicillin 600 mg + clavulanic acid 42.9 mg

Proportion of patients	Response rate (n=568)
<10%	16.73%
11-25%	27.11%
26-50%	30.81%
51-75%	11.97%
>75%	11.27%
Not attempted	2.11%

Table 3: Distribution of responses to duration of high-dose amoxicillin 600 mg + clavulanic acid 42.9 mg in recurrent otitis media

Duration of prescription	Response rate (n=568)
5 days	22.01%
7 days	47.89%
14 days	7.39%
10 days	20.6%
Not attempted	2.11%

Table 4: Distribution of responses to major concerns of incomplete therapy in treating respiratory infections in pediatric patients

Concerns	Response rate (n=568)
Prolonged illness duration	5.641%
Development of antibiotic resistance	33.28%
Increased risk of recurrent infections	26.59%
All of the above	32.57%
Not answered	1.94%

Discussion

The study provides valuable insights into the current practices and perceptions of Indian clinicians regarding antibiotic prescription patterns for pediatric respiratory infections, with particular emphasis on amoxicillin-clavulanate use in pneumonia and otitis media. The findings highlight several key aspects of clinical practice and identify important challenges in ensuring optimal antibiotic therapy for children.

The current study highlighted clinicians' preference for amoxicillin-clavulanate in India for pneumonia treatment, supported by its long-standing use and inclusion in national and international CAP guidelines. Studies report its high efficacy against *Streptococcus pneumoniae* and *Haemophilus influenzae*, with susceptibility rates exceeding 90%.[8] A South India-based study by Moinuddin et al. found amoxicillin-clavulanate to be the most prescribed antibiotic for pediatric pneumonia (43.8%), with 53% of prescriptions in consolidation cases. Indian pediatric guidelines recommend beta-lactams for non-severe pneumonia and beta-lactamase inhibitors (e.g., amoxicillin-clavulanate) for severe cases.[9] Similarly, an Assam-based study reported that amoxicillin-clavulanate was the most frequently prescribed antibiotic overall (35% of total antibiotics). Among pneumonia patients specifically, 17 out of 31 prescriptions (55%) involved amoxicillin-clavulanate, reinforcing its role as the preferred antibiotic for this condition.[10]

In the present study, amoxicillin-clavulanate was the preferred choice for treating AOM in pediatric outpatients (94.01%), with most clinicians reporting its use in 61-80% of their patients. Chu et al. demonstrated that high-dose amoxicillin with clavulanate, as recommended by clinical guidelines, is more effective than conventional doses in children under 20 kg with bilateral disease.[11] Dagan et al. further highlighted that high-dose amoxicillin-clavulanate (90/6.4 mg/kg/day) effectively treats pediatric AOM, particularly in children under 24 months and those with penicillin-resistant *Streptococcus pneumoniae*.[12] Additionally, a randomized controlled trial by Marchant et al. found amoxicillin-clavulanate to be more effective than cefaclor for AOM treatment.[13] Another study demonstrated that amoxicillin-clavulanate showed superior clinical and bacteriological effectiveness compared to azithromycin in children with bacterial AOM, including cases caused by penicillin-resistant *Streptococcus pneumonia* and beta-lactamase-positive *Haemophilus influenzae*.[14]

For recurrent otitis media cases, the majority of the current clinicians prescribed the high-dose formulation amoxicillin-clavulanate to 26-50% of their patients, typically for a 7-day course. Similarly, an Italian intersociety Consensus study recommended amoxicillin-clavulanate for 7–10 days as the preferred treatment option for recurrent otitis media.[15] This duration aligns with evolving evidence suggesting that shorter, appropriate-dose antibiotic courses may be as effective as longer ones while potentially reducing adverse effects and resistance development.[16]

The high-dose formulation (amoxicillin 600 mg with clavulanic acid 42.9 mg) was particularly favored, with the majority of study clinicians reporting its use across multiple conditions, including ear, sinus, respiratory tract, urinary tract, and skin infections. Twice-daily administration of amoxicillin at a dose of 600 mg and clavulanic acid at 42.9 mg per 5 mL appears appropriate for achieving favorable tolerability and efficacy in treating bacterial infections in children under three months of age.[17] Lahiry et al. reported that a high dose of 600 mg amoxicillin plus 42.9 mg clavulanic acid is effective in treating pediatric bacterial infections.[18]

ISSN: 2380-0534

Antibiotic resistance is a major public health concern, contributing to high mortality rates among children and newborns. [19] In the present survey, respondents demonstrated awareness of antibiotic resistance concerns, with the majority identifying it as the most common complication of incomplete antibiotic treatment in children. Furthermore, the majority of them cited the development of antibiotic resistance as their primary concern when treating respiratory infections with incomplete antibiotic therapy. This awareness reflects growing global concern about antimicrobial resistance and its implications for future treatment efficacy.

The study provides valuable insights into current antibiotic prescription patterns among Indian clinicians for pediatric respiratory infections. The findings underscore clinicians' awareness of antibiotic resistance as a critical concern, which is essential for antimicrobial stewardship efforts in India. This research contributes to the understanding of real-world antibiotic use in pediatric practice in India, potentially informing targeted interventions to optimize prescribing patterns. A key strength of this study is the use of a well-structured and validated questionnaire to gather expert insights from a substantial sample of clinicians. However, certain limitations must be considered. The survey-based approach may introduce recall bias and personal preferences that do not always align with evidence-based practice. Additionally, the sample may not fully represent the diversity of Indian healthcare settings, and the study emphasizes clinician preferences rather than objectively measured patient outcomes.

Conclusion

The study underscores clinicians' preference for amoxicillin-clavulanate in treating pediatric respiratory infections, particularly pneumonia and otitis media, in Indian settings. The high-dose formulation is widely favored across multiple conditions, with treatment typically prescribed for a 7-day course. Clinicians demonstrated awareness of antibiotic resistance as a significant concern, emphasizing the need for continued antimicrobial stewardship to balance effective treatment with resistance prevention.

Acknowledgement

We would like to thank all the clinicians who were actively participating in this study.

Author contributions

Both authors have contributed equally to the development of the manuscript.

Conflicts of interest disclosures: None

Disclosure of compliance with ethical principles

The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

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