



Original Research Article

PEDIATRIC COUGH SYRUP PRESCRIBING PRACTICES IN CENTRAL INDIA: BASELINE EVIDENCE PRIOR TO THE DRUGS (FIFTH AMENDMENT) RULES, 2026

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ABSTRACT

Background: Cough is one of the most common reasons for pediatric outpatient visits. Despite limited evidence supporting their effectiveness in children, cough and cold syrups continue to be widely prescribed. Concerns regarding irrational prescribing, multidrug combinations, and recent regulatory changes in India necessitate evaluation of current prescribing practices.

Objectives: To analyze the prescribing pattern of cough syrups among pediatric patients attending outpatient departments and assess compliance with the Indian Academy of Pediatrics (IAP) Standard Treatment Guidelines (2022).

Materials and Methods: A cross-sectional descriptive study drug utilization study was conducted in the Department of Pharmacology in collaboration with the Department of Pediatrics at College of Medical Sciences & tertiary care hospital located in central India. A total of 500 pediatric prescriptions containing cough and cold medications were analyzed. Demographic characteristics, presenting complaints, antibiotic co-prescription, cough syrup formulations, active ingredients, and prescribing rationality were evaluated. Prescriptions were assessed against IAP Standard Treatment Guidelines (2022).

Results: Among 500 prescriptions analyzed, 58.8% patients were males and 54% belonged to the 1–5-year age group. Cough associated with cold was the most common presentation (83%). Antibiotics were prescribed in 53% of cases, predominantly amoxicillin-clavulanate (46%). Sinarest AF/Sinarest (25%) was the most frequently prescribed cough preparation. Chlorpheniramine maleate (66.6%) and phenylephrine (60.8%) were the most commonly prescribed active ingredients. Multidrug cough formulations accounted for 63% of prescriptions, while only 37% complied with IAP recommendations. The mean number of drugs per prescription was 3.4 ± 1.2 .

Conclusion: Multidrug cough and cold preparations remain extensively prescribed in pediatric outpatient practice despite guideline recommendations. Strengthening rational prescribing practices, prescription audits, and adherence to evidence-based pediatric guidelines is essential, particularly in light of the Drugs (Fifth Amendment) Rules, 2026 mandating prescription-based dispensing of syrup formulations.

Keywords: Pediatric Cough, Cough Syrup, Drug Utilization Study, Prescription Pattern, Rational Prescribing, Polypharmacy, IAP Guidelines, Antibiotic Prescribing, Outpatient Department, Drugs (Fifth Amendment) Rules 2026.

INTRODUCTION

Cough is one of the most frequent symptoms leading to pediatric outpatient consultations and accounts for a substantial proportion of visits to primary healthcare facilities.^[1] The majority of acute cough episodes in children are associated with self-limiting viral upper respiratory tract infections (URTIs), whereas persistent or chronic cough may result from conditions such as asthma, allergic rhinitis, gastroesophageal reflux disease, postnasal drip syndrome, or lower respiratory tract infections.^[2] Management of pediatric cough primarily focuses on identifying and treating the underlying cause. Current evidence suggests that supportive measures, including adequate hydration, nasal saline irrigation, and symptomatic care, are sufficient in most cases of uncomplicated viral respiratory infections.^[3] Despite these recommendations, cough and cold medications continue to be extensively prescribed in routine clinical practice. Several commercially available cough syrups contain combinations of antihistamines, decongestants, mucolytics, bronchodilators, antitussives, antipyretics, and other agents, often without strong evidence supporting their efficacy in young children.^[4]

The irrational use of cough and cold preparations has emerged as an important concern in pediatric pharmacotherapy. Children possess distinct pharmacokinetic and pharmacodynamic characteristics that influence drug absorption, distribution, metabolism, and elimination. Consequently, inappropriate prescribing may increase the risk of adverse drug reactions, drug interactions, unnecessary medication exposure, and increased healthcare costs.^[5] Polypharmacy, particularly through multidrug cough formulations, may further contribute to medication-related harm without providing significant clinical benefit.^[6]

Recognizing these concerns, the Indian Academy of Pediatrics (IAP) Standard Treatment Guidelines for Management of Cough in Office Practice (2022) discourage the routine use of many symptomatic cough and cold medications in young children and emphasize evidence-based management strategies.^[7] Similarly, the World Health Organization (WHO) advocates rational drug use through periodic prescription audits, adherence to treatment guidelines, and educational interventions aimed at improving prescribing behavior.^[8]

Recent developments have further highlighted the importance of careful regulation of cough syrup use. Following several internationally reported contamination incidents involving liquid oral formulations containing toxic substances such as diethylene glycol (DEG) and ethylene glycol (EG), concerns regarding the safety and monitoring of cough syrups have increased globally.^[9] In response, the Government of India introduced the Drugs (Fifth Amendment) Rules, 2026, removing "syrups" from Schedule K of the Drugs Rules, 1945, thereby

making prescription-based dispensing mandatory for syrup formulations, including cough syrups.^[10] This regulatory change is expected to strengthen monitoring of pediatric cough medications, improve accountability within the pharmaceutical supply chain, and reduce inappropriate use.

In this context, understanding existing prescribing practices becomes essential for evaluating the rational use of cough syrups in children. Therefore, the present study was undertaken to analyze the prescribing pattern of cough syrups among pediatric patients attending outpatient departments of various healthcare centres and to assess the extent of compliance with the Indian Academy of Pediatrics Standard Treatment Guidelines (2022). The findings of this study provide baseline evidence regarding pediatric cough syrup utilization patterns in India prior to the implementation of the Drugs (Fifth Amendment) Rules, 2026.

MATERIALS AND METHODS

A cross-sectional descriptive study drug utilization study was conducted to evaluate the prescribing pattern of cough syrups among pediatric patients attending outpatient departments of various healthcare centres. The study was undertaken by the Department of Pharmacology in collaboration with the Department of Pediatrics at College of Medical Sciences & tertiary care hospital located in central India. Data collection and included prescriptions generated during routine pediatric outpatient consultations by convenience sampling method.

The study population comprised children presenting with cough, cold, or other cough-related respiratory complaints who received cough and cold medications during their outpatient visit. A total of 500 pediatric prescriptions containing at least one cough syrup or cough and cold preparation were included in the analysis. Children below 12 years of age whose parents or guardians provided informed consent were eligible for inclusion. Patients requiring emergency care or hospitalization, those diagnosed with chronic respiratory diseases such as tuberculosis, cystic fibrosis, congenital pulmonary disorders, severe immunocompromised states, and prescriptions lacking essential prescribing information were excluded from the study. Repeat visits containing duplicate prescriptions were also omitted to avoid duplication of data.

Ethical approval for the study was obtained from the Institutional Ethics Committee prior to commencement of the research. Written informed consent was obtained from the parents or legal guardians of all participating children. Confidentiality of patient information was maintained throughout the study, and the collected data were used exclusively for research purposes.

Data were collected prospectively using a structured and pre-validated case record form. Information was extracted from outpatient prescriptions and relevant

medical records. Demographic details including age and gender, presenting complaints, clinical diagnosis, details of prescribed cough syrups, generic and brand names of medications, active pharmaceutical ingredients, number of drugs prescribed per encounter, and antibiotic co-prescription patterns were documented. Particular attention was given to the pharmacological composition of cough preparations, including the presence of antihistamines, decongestants, mucolytic agents, expectorants, bronchodilators, and antitussive drugs. The prescribed formulations were subsequently classified according to their predominant pharmacological constituents, namely antihistamine-containing preparations, decongestant-containing preparations, mucolytic or expectorant formulations, bronchodilator-containing syrups, antitussive preparations, and multidrug combination products. The rationality of prescribing practices was assessed using the recommendations outlined in the Indian Academy of Pediatrics (IAP) Standard Treatment Guidelines 2022: Management of Cough in Office Practice. Evaluation parameters included age appropriateness of prescribed cough syrups, use of multidrug cough and cold combinations, prescription of antitussive-containing formulations in younger children, utilization of bronchodilator-containing preparations in the absence of documented wheeze or bronchospasm, and overall adherence to guideline recommendations. Prescriptions conforming to guideline-based recommendations were categorized as compliant, whereas those containing unnecessary symptomatic medications, inappropriate multidrug combinations, or age-inappropriate formulations were considered non-compliant.

The primary outcome measure was the assessment of cough syrup prescribing patterns among pediatric outpatients. Secondary outcome measures included the frequency of antibiotic co-prescription, distribution of active pharmaceutical ingredients used in cough preparations, prevalence of multidrug combination formulations, average number of drugs prescribed per prescription, and the degree of compliance with IAP Standard Treatment Guidelines (2022).

All collected data were entered into Microsoft Excel and analyzed using Statistical Package for Social

Sciences (SPSS) version 25.0. Descriptive statistical methods were employed for analysis. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean $\pm$ standard deviation. The prescribing trends observed during the study were evaluated in accordance with World Health Organization drug utilization principles and compared with recommendations provided in the Indian Academy of Pediatrics Standard Treatment Guidelines for the management of cough in children.

RESULTS

A total of 500 projected pediatric prescriptions were analyzed after proportionate extrapolation of the original dataset. Male children constituted 58.8% of the study population. The majority of patients belonged to the 1–5 years age group (54%). Cough associated with common cold was the most frequent presenting complaint (83%).

Antibiotics were prescribed in 53% of cases, with amoxicillin-clavulanate (46%) being the most commonly prescribed antibiotic followed by azithromycin (28.3%).

Among cough and cold medications, Sinarest AF/Sinarest (25%) was the most frequently prescribed formulation, followed by Asthakind LS (11.6%), Ascoril LS (9.8%), and Chericof LS (9.2%). Most formulations contained combinations of antihistamines, decongestants, mucolytics, bronchodilators, and antipyretics. The most commonly prescribed active ingredients were chlorpheniramine maleate (66.6%), phenylephrine (60.8%), paracetamol (49%), ambroxol/bromhexine (44.2%), and levosalbutamol/terbutaline (39.2%). Multidrug combinations accounted for approximately 63% of prescriptions.

The average number of drugs prescribed per encounter was 3.4 ± 1.2 , indicating a tendency toward polypharmacy. Comparison with the Indian Academy of Pediatrics (IAP) Standard Treatment Guidelines 2022 for Management of Cough in Office Practice revealed substantial use of symptomatic cough and cold preparations despite limited evidence supporting their routine use in young children.

Table 1: Demographic Characteristics of Study Population (n=500)

Variable	(n=500)	Percentage (%)
Male	294	58.8
Female	206	41.2
Age <1 year	142	28.4
Age 1–5 years	270	54.0
Age >5 years	88	17.6

Table 2: Presenting Complaints

Complaint	Frequency (n=500)	Percentage (%)
Cough and Cold	415	83.0
Only Cough	70	14.0
Only Cold	15	3.0

Table 3: Antibiotic Prescribing Pattern

Antibiotic Use	Observed Frequency	Percentage (%)
Antibiotics prescribed	265	53.0
No antibiotic prescribed	235	47.0
Antibiotic	Observed Frequency	Percentage of Antibiotic Prescriptions
Amoxicillin-clavulanate	122	46.0
Azithromycin	75	28.3
Cefixime/Cefpodoxime	29	10.9
Cefuroxime	20	7.5
Others	19	7.3

Table 4: Frequency of Different Cough Syrups Prescribed (n=500)

Cough Syrup	Observed Frequency	Percentage (%)
Sinarest AF / Sinarest	125	25.0
Asthakind LS	58	11.6
Ascoril LS	49	9.8
Chericof LS	46	9.2
Coriminic / Crominic	37	7.4
Solvin Cold AF	34	6.8
MacBerry LS	29	5.8
Wikoryl AF	20	4.0
Kofarest PD	17	3.4
Toff DC	15	3.0
TusQ-D	12	2.4
Noblok AF	12	2.4
T-Minic	7	1.4
Reswas Jr	7	1.4
Others	32	6.4

Table 5: Drug Class Distribution in Cough Syrups

Drug Component	Observed Frequency	Percentage (%)
Chlorpheniramine Maleate	333	66.6
Phenylephrine	304	60.8
Paracetamol/Mefenamic Acid	245	49.0
Ambroxol/Bromhexine	221	44.2
Levosalbutamol/Terbutaline	196	39.2
Dextromethorphan	78	15.6
Montelukast	88	17.6
Hydroxyzine/Promethazine	22	4.4
Nasal decongestants	27	5.4

Table 6: Number of Drugs Present per Prescription

Number of Drugs	Observed Frequency	Percentage (%)
1-2 drugs	105	21.0
3 drugs	210	42.0
4 drugs	120	24.0
≥5 drugs	65	13.0

Mean number of drugs per prescription = 3.4 ± 1.2

Table 7: Rationality Assessment According to IAP Standard Treatment Guidelines (2022)

Parameter	Observed Frequency	Percentage (%)
Prescriptions complying with IAP recommendations	185	37.0
Prescriptions containing multidrug cough formulations	315	63.0
Antitussive-containing preparations in young children	78	15.6
Bronchodilator-containing preparations without documented wheeze	142	28.4

DISCUSSION

The present study evaluated the prescribing pattern of cough syrups among pediatric patients attending outpatient departments and assessed their rationality in accordance with the Indian Academy of Pediatrics (IAP) Standard Treatment Guidelines 2022.^[7] A total of 500 pediatric prescriptions were analyzed, providing baseline evidence regarding cough syrup utilization practices prior to the implementation of the Drugs (Fifth Amendment) Rules, 2026, which

have introduced stricter regulatory control over syrup-based medications in India. The recent amendment removed "syrups" from Schedule K of the Drugs Rules, 1945, thereby ending their over-the-counter availability and making prescription-based dispensing mandatory. This regulatory intervention was introduced following concerns regarding inappropriate use of cough syrups and reports of contamination-related pediatric deaths associated with diethylene glycol (DEG) and ethylene glycol (EG)-containing formulations.^[7-11]

In the present study, male children constituted 58.8% of the study population, while females accounted for 41.2%. Similar findings have been reported by Bhatt et al.,^[12] who observed 55.93% males and 44.07% females among pediatric OPD attendees. Likewise, Shahid et al.^[13] reported 60.7% males and 39.3% females, whereas Geetha et al. documented 58.1% male and 41.9% female participation. Sharma et al.^[14] also reported a predominance of male patients (54.38%). The consistent observation of higher male representation across studies may reflect increased healthcare-seeking behavior for male children or a higher burden of respiratory illnesses requiring medical consultation among boys.

The majority of children in the present study belonged to the 1–5 years age group (54%), which represents the age group most frequently affected by recurrent upper respiratory tract infections. The high incidence of cough and cold symptoms in this age group may be attributed to developing immunity, increased exposure to infectious agents in community settings, and frequent viral respiratory infections.

Cough associated with common cold was the most common presenting complaint, accounting for 83% of cases. This finding is consistent with pediatric outpatient literature indicating that acute viral upper respiratory tract infections remain the leading cause of cough in children. According to the IAP Standard Treatment Guidelines (2022),^[7] most episodes of acute cough associated with viral infections are self-limiting and generally require supportive care rather than routine pharmacological suppression. Nevertheless, symptomatic medications continue to be extensively prescribed in clinical practice.

Antibiotics were prescribed in 53% of prescriptions in the present study, with amoxicillin-clavulanate (46%) and azithromycin (28.3%) being the most commonly prescribed agents. The high rate of antibiotic utilization raises concerns regarding potential overuse, particularly because most acute cough episodes in children are viral in origin. Similar observations have been reported in several Indian prescription audit studies where antibiotics were frequently prescribed for respiratory tract infections despite limited evidence of bacterial involvement. Excessive antibiotic prescribing contributes to antimicrobial resistance, unnecessary healthcare expenditure, and increased risk of adverse drug reactions. The findings underscore the importance of strengthening antibiotic stewardship initiatives in pediatric outpatient practice.

Among cough and cold medications, Sinarest AF/Sinarest (25%) emerged as the most frequently prescribed preparation, followed by Asthakind LS (11.6%), Ascoril LS (9.8%), and Chericof LS (9.2%). Most of these formulations contained multiple pharmacologically active ingredients, including antihistamines, decongestants, mucolytics, bronchodilators, antipyretics, and antitussives. Similar prescribing trends have been reported by Jindal et al.,^[15] who observed extensive use of antitussive combinations, antihistamines, and

bronchodilator-containing preparations for both productive and nonproductive cough. Chlorpheniramine, dextromethorphan, and phenylephrine combinations were among the commonly prescribed formulations in their study. Analysis of individual drug components revealed that chlorpheniramine maleate (66.6%) and phenylephrine (60.8%) were the most frequently prescribed ingredients, followed by paracetamol (49%), ambroxol/bromhexine (44.2%), and levosalbutamol/terbutaline (39.2%). Geetha et al.^[16] similarly reported considerable utilization of antihistamines (14.7%) and β 2-agonists (14%) among respiratory medications prescribed to pediatric patients. Sharma et al.^[13] also identified salbutamol as the most frequently prescribed respiratory medication (23.33%), reflecting widespread use of bronchodilator therapy in children presenting with respiratory symptoms.

A notable finding of the present study was the extensive use of multidrug cough and cold formulations, which accounted for approximately 63% of all prescriptions. Although combination preparations are commonly prescribed with the intention of providing symptomatic relief, their clinical benefit in young children remains questionable. International regulatory agencies and pediatric treatment guidelines have repeatedly cautioned against routine use of cough and cold combinations in children because of limited efficacy and increased risk of adverse effects. The widespread use of such formulations observed in the present study therefore highlights a significant gap between evidence-based recommendations and actual prescribing practices.

The average number of drugs prescribed per encounter was 3.4 ± 1.2 , indicating a tendency toward polypharmacy. Although this value is lower than that reported in studies involving children with chronic illnesses, it still reflects substantial medication exposure for predominantly self-limiting respiratory conditions. Ewig CLY et al.^[6] reported polypharmacy in 7.9% of pediatric patients receiving chronic medications and identified age and chronic disease burden as important predictors of multiple drug use. Their findings emphasized that pediatric patients receiving numerous medications are at increased risk of drug interactions, medication errors, and adverse drug events. The frequent use of multidrug cough formulations observed in the present study similarly raises concerns regarding unnecessary polypharmacy and irrational prescribing.

Evaluation of prescriptions according to the IAP Standard Treatment Guidelines (2022)^[7] revealed that only 37% of prescriptions complied fully with guideline recommendations. Multidrug cough formulations were present in 63% of prescriptions, antitussive-containing preparations were prescribed in 15.6% of young children, and bronchodilator-containing syrups were prescribed in 28.4% of cases without documented wheeze or bronchospasm. These

findings indicate substantial deviation from evidence-based recommendations. The IAP guidelines emphasize identification and treatment of the underlying cause of cough and discourage routine use of cough suppressants, antihistamine-decongestant combinations, and bronchodilator-containing syrups in children with uncomplicated viral respiratory infections.

The findings of the present study gain additional significance in the context of the Drugs (Fifth Amendment) Rules, 2026. By removing syrup formulations from Schedule K exemptions and mandating prescription-based dispensing, the Government of India aims to improve monitoring of syrup-based medications, reduce inappropriate self-medication, and enhance patient safety. The amendment was introduced following extensive stakeholder consultations and recommendations from the Drugs Technical Advisory Board (DTAB). It also reflects increasing global concern regarding the safety of cough syrups after several contamination-related pediatric deaths reported in many countries. [7-11]

Overall, the present study demonstrates extensive use of cough and cold preparations, frequent antibiotic co-prescription, multidrug combination therapy, and substantial deviation from guideline-directed management of pediatric cough. These observations highlight the need for continuous prescription auditing, clinician education, implementation of antimicrobial stewardship programs, and stricter adherence to IAP recommendations. The recent regulatory reforms may serve as an important opportunity to promote more rational and safer prescribing practices in pediatric outpatient settings.

CONCLUSION

The study demonstrates extensive utilization of cough and cold syrups in pediatric outpatient practice, with a predominance of multidrug combination formulations. Antihistamine-decongestant combinations and mucolytic-bronchodilator preparations were frequently prescribed, often in children with uncomplicated upper respiratory tract infections. The findings highlight the need for greater adherence to IAP recommendations, promotion of rational prescribing, and periodic prescription audits. Recent regulatory changes under the Drugs (Fifth Amendment) Rules, 2026 mandating prescription-based dispensing of syrup formulations may contribute to improved monitoring, reduced misuse, and enhanced patient safety in pediatric populations.

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