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NARRATIVE REVIEW

Over-the-counter cough and cold medications in children: bridging the gap between evidence and clinical practice

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ABSTRACT

Over-the-counter cough and cold medications are widely used in children despite insufficient evidence of efficacy and well-documented safety concerns. This narrative review summarizes current evidence on pharmacological and non-pharmacological treatments for both acute and chronic cough in pediatric populations. Most over-the-counter medications, including antitussives, antihistamines, expectorants, and mucolytics, have not demonstrated superiority over placebo. In contrast, selected non-pharmacological interventions, such as honey and vapor rub, may provide modest symptomatic relief in specific age groups.

In chronic wet cough, cough suppression may be inappropriate, as it can delay the diagnosis and treatment of underlying conditions such as protracted bacterial bronchitis and bronchiectasis. Management should therefore prioritize etiological evaluation, caregiver education, and evidence-based interventions.

IMPACT STATEMENT

Over-the-counter cough medications in children lack consistent evidence of efficacy, with most pharmacologic agents performing no better than placebo while exposing children to potentially significant adverse effects. Chronic wet cough should not be suppressed, as it may represent an important clinical marker of underlying airway disease. At present, honey remains the only consistently supported symptomatic therapy for acute cough in children older than one year.

KEY WORDS

Pediatric cough; OTC medicines; antitussives; honey; herbal medications.

INTRODUCTION

Cough remains one of the most common reasons for pediatric consultation and a central challenge in everyday clinical practice. It accounts for approximately 4.7-23.3% of all pediatric primary care visits, particularly in younger children, emphasizing its substantial healthcare burden. A key distinction in pediatric cough is between acute and chronic presentations, as management strategies and clinical implications differ substantially. Acute cough is most commonly associated with upper respiratory tract infections, whereas chronic cough may reflect a broad spectrum of underlying conditions, including asthma, pertussis, and protracted bacterial bronchitis (PBB) (1).

The economic impact of over-the-counter (OTC) cough and cold medications is considerable, with annual revenue in the United States estimated at $10.3 billion despite limited supporting evidence (2). This discrepancy highlights a persistent gap between clinical evidence and real-world practice. Clinicians are frequently pressured to recommend symptomatic treatments, particularly by caregivers seeking rapid relief. Previous studies have shown that such expectations, combined with the lack of effective alternatives, contribute to continued prescribing practices despite guideline recommendations to the contrary (3).

This narrative review is based on a non-systematic literature search conducted using PubMed, Cochrane Library, and guideline databases (*e.g.*, CHEST, GINA). Relevant studies, systematic reviews, and guidelines published in English were selected based on clinical relevance to pediatric cough and over-the-counter treatments. Priority was given to high-quality evidence sources, including randomized controlled trials, meta-analyses, and international guideline recommendations.

ACUTE COUGH IN CHILDREN: EVIDENCE-PRACTICE GAP AND SAFETY CONSIDERATIONS

Available evidence consistently demonstrates a substantial discrepancy between the widespread use of OTC medications and their actual clinical efficacy. Although recent data suggest a modest reduction in acute cough frequency with dextromethorphan (4) these findings are not consistent with earlier pediatric studies. Paul *et al*. demonstrated that neither dextromethorphan nor diphenhydramine improved nocturnal cough frequency, severity, or sleep quality compared with placebo (5). The CHEST Expert Panel further concluded that no pediatric studies have demonstrated clinically relevant superiority of antitussives, antihistamines, decongestants or combination products over placebo (6).

Evidence supporting opioid antitussives is particularly limited. A Cochrane review identified no randomized controlled trials evaluating codeine in children, highlighting the absence of high-quality evidence for its use (7). Overall, systematic reviews consistently show that codeine, dextromethorphan, and hydrocodone do not provide clinically meaningful benefit compared with placebo (6, 8). In line with these findings, the American College of Emergency

Physicians recommends prioritizing caregiver education rather than pharmacologic treatment (2).

Beyond the lack of efficacy, safety concerns are considerable. Dosing errors are common, particularly when household spoons are used, as these vary significantly in volume. The American Academy of Pediatrics reports increased error rates with such practices, compounded by caregiver misunderstanding of medication labels (9). Multi-symptom formulations further increase the risk of unintentional overdose, while dosing cups have been associated with higher error rates compared with oral syringes (9, 10).

Pharmacogenetic variability introduces additional risk, particularly with codeine. As a prodrug metabolized predominantly through CYP2D6, ultra-rapid metabolizers may develop life-threatening respiratory depression. This has led to strict regulatory restrictions, including contraindication in children under 12 years and in adolescents following tonsillectomy or adenoidectomy (11, 12). Dextromethorphan also carries risk, acting on N-Methyl-D-Aspartate (NMDA) receptors and potentially causing neuropsychiatric and neurological toxicity at high doses, including hallucinations, ataxia, and seizures (2, 13). Rare but severe cases of cerebellar toxicity (DANCE syndrome) have also been reported (14).

Other OTC categories, including expectorants, mucolytics, and antihistamines, similarly lack convincing evidence of benefit. The CHEST Expert Panel found no evidence supporting their use in pediatric acute cough (5). A Cochrane review suggests minimal clinical benefit and potential harm, including paradoxical bronchorrhea in infants (15). Antihistamines have consistently failed to demonstrate superiority over placebo in randomized trials (2, 4, 16).

Given the combination of limited efficacy and potential harm, regulatory authorities have imposed restrictions. The FDA advises against use in children under 2 years, extended to under 4 years by manufacturers, while Health Ministry of Canada and the Medicines and Healthcare products Regulatory Agency in United Kingdom recommend avoidance in children under 6 years (2, 9, 17, 18). Professional bodies, including the American Academy of Pediatrics, similarly discourage use in young children (19).

NON-PHARMACOLOGICAL THERAPIES

In contrast to pharmacologic agents, certain non-prescription interventions appear to provide modest symptomatic benefit, likely through non-specific soothing mechanisms. The perceived effectiveness of many syrups may relate to their demulcent properties, as viscous solutions provide a protective coating of the pharyngeal mucosa and reduce cough receptor sensitivity (20). Sensory modulation also plays a role, with menthol activating Transient Receptor Potential Melastatin 8 (TRPM8) receptors to produce a cooling sensation that reduces cough perception (21, 22).

Among available options, honey has the most consistent evidence base. It has been shown to reduce cough frequency and improve sleep quality compared with placebo or no treatment (23, 24). Multiple subsequent studies have supported these findings (25, 26). From a practical

perspective, administration of 2.5-5 mL of honey before bedtime may be beneficial in children older than one year; however, it is contraindicated in infants due to the risk of botulism (23).

Vapor rub preparations represent another intervention with evidence of benefit. In a randomized trial. Paul *et al*. demonstrated significant improvements in cough frequency, nasal congestion, and sleep quality compared with placebo and no treatment (27). However, the evidence is based on a single study with methodological limitations, including incomplete blinding (6). The proposed mechanism involves sensory counter-irritation, altering the perception of airflow and cough (2, 28).

CHRONIC WET COUGH

The clinical implications of cough extend beyond symptom control in chronic presentations, particularly in children with chronic wet cough. This condition, defined as a daily productive cough lasting more than 4 weeks, is a key clinical marker of underlying airway disease rather than a benign, self-limiting symptom. It is most commonly associated with protracted bacterial bronchitis and bronchiectasis and reflects ongoing lower airway infection (29). Importantly, wet cough serves a physiological role in airway clearance. SSuppression with antitussive agents may therefore be harmful, leading to retention of infected secretions and perpetuation of inflammation (18). CHEST guidelines explicitly advise against the use of cough suppressants in this context (30).

Increasing evidence supports a continuum from PBB to chronic suppurative lung disease and bronchiectasis when appropriate treatment is delayed (32). Prospective studies show that a proportion of children with PBB progress to bronchiectasis, particularly in the presence of recurrent episodes or persistent infection (33). The duration of wet cough correlates with disease severity, including radiological and inflammatory markers (31, 33).

A critical but often overlooked concept is the “opportunity cost” of symptomatic treatment. The use of OTC medications may create false reassurance, delaying appropriate investigation and treatment while the underlying disease progresses (18). Given that a significant proportion of children with chronic cough have serious underlying conditions, such delays may have long-term consequences (34).

Current guidelines emphasize an etiology-based approach. Initial antibiotic therapy is recommended, with escalation to further investigation if symptoms persist (29, 31). This approach is supported by randomized evidence demonstrating significant treatment benefit (35).

CHRONIC DRY COUGH

Chronic dry cough represents a heterogeneous clinical entity. Asthma and asthma-like conditions are among the most common causes (36). The Global Initiative for Asthma (GINA) 2025 guidelines highlight that cough-variant asthma may present with isolated cough, often with normal spirometry (37). However, asthma is also frequently overdiagnosed in this context, particularly in the absence of typical symptoms (38).

Somatic cough syndrome is another important consideration, characterized by suppressibility and variability. Management is primarily behavioral, and pharmacologic therapy is generally ineffective (39). The use of cough syrups in this setting may reinforce illness behavior and hinder effective treatment (26, 36).

Across chronic dry cough, OTC medications have consistently failed to demonstrate meaningful benefit (6). Current guidelines therefore recommend against their routine use, emphasizing instead a structured, diagnostic approach (29, 30).

CONCLUSIONS

The continued use of OTC cough medications in children reflects a persistent disconnect between clinical practice and evidence-based medicine. While certain non-pharmacological interventions may provide modest symptomatic relief, most pharmacologic treatments offer no meaningful benefit and carry potential risks (**Table 1**).

More importantly, in chronic cough – particularly wet cough – symptom suppression may delay diagnosis and contribute to disease progression. Effective management requires a shift in focus from symptom control to identification and treatment of the underlying cause. Clinicians must balance caregiver expectations with evidence-based practice, adopting a strategy that validates concerns while redirecting care toward appropriate evaluation.

Ultimately, pediatric cough should not be viewed as a symptom to be suppressed, but as a clinical signal to be interpreted. Aligning clinical practice with this principle is essential to prevent avoidable long-term respiratory morbidity.

Future research should focus on age-specific, mechanism-based therapies targeting specific cough pathways, rather than non-specific symptomatic suppression.

COMPLIANCE WITH ETHICAL STANDARDS

Conflicts of interest

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Table 1. *Over-the-Counter cough medications in children: efficacy, risks, and recommendations.*

Category	Examples	Efficacy	Risks	Recommendation
Antitussives	Dextromethorphan, Codeine	No clinically meaningful benefit compared with placebo	CNS toxicity, respiratory depression (especially with codeine)	Not recommended
Antihistamines	Diphenhydramine	No benefit compared with placebo	Sedation, paradoxical excitation, dosing errors	Not recommended
Mucolytics / Expectorants	Acetylcysteine, Guaifenesin	Minimal or uncertain benefit	Worsening airway secretions in infants	Not recommended
Combination OTC products	Multi-symptom cough and cold syrups	No proven efficacy	Increased risk of overdose (acetaminophen toxicity), polypharmacy	Avoid
Honey	Natural product	Moderate evidence of symptom relief (nocturnal cough)	Risk of botulism in infants <1 year	Recommended in children >1 year

Topical vapor rubs	Menthol, camphor, eucalyptus	Symptomatic relief (improved sleep)	Skin irritation, accidental ingestion toxicity	May be considered with caution
Chronic wet cough	-	Cough suppression may be detrimental	Risk of disease progression (*e.g.* PBB, bronchiectasis)	Treat underlying cause (*e.g.* antibiotics)
Chronic dry cough	-	OTC medications ineffective	May reinforce cough hypersensitivity	Etiology-based diagnostic and therapeutic approach

OTC: over the counter; CNS: central nervous system; PBB: protracted bacterial bronchitis.