

**Children's Hospital and Health System, Inc.
Patient Care Treatment Guideline
CW Urgent Care**

SUBJECT: Pharmacological Agents for Cough and Cold Symptoms in Children

Purpose: To discuss management of symptoms associated with the common upper respiratory infection (URI) in children using over-the-counter (OTC) cold medications.

Definition: Management of the common cold is intended to provide temporary relief of symptoms until the URI completes its natural history. For infants and young children, relieving nasal obstruction is one of the most important goals because this symptom can impair drinking and dehydration can result. Relieving cough often is an important goal of the family and frequently the reason for seeking care.

The average household possesses 4-8 different OTC medications in an effort to treat the congestion, nasal discharge, cough, sore throat, and other symptoms associated with the common URI. However, there have been few clinical trials in infants and young children testing these products. In the studies that have been done, none have demonstrated any benefit of antihistamines, decongestants, antitussives and expectorants, either singly or in combinations for treatment of the symptoms of the common URI. There are approximately 30,000 concerns for overdose reported to Poison Control centers annually, 55% of which are in children < 6 years. Additionally, in children < 2 years of age, prescription and OTC cough and cold medications have been associated with fatal overdose.

In early October 2007, pharmaceutical companies withdrew OTC cough and cold medicines for infants and children < 2 years from the market, a decision supported by the American Academy of Pediatrics (AAP). On October 19th 2007, an FDA panel affirmed that there is no evidence that these medicines work in children < 6 years and stated that using these medicines in young children cannot be recommended. The panel considered whether multiple symptom OTC pediatric cough and cold medicines should be banned for children < 6 years, and called for more studies about how the drugs affect children. Certain OTC cold medications and combinations of medications have been shown to reduce symptoms of the common cold in adolescents and adults, however.

Guideline

- 1. Symptomatic therapy** (*should be focus of care for patients with uncomplicated URI*)
 - Antipyretics/analgesic

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- Acetaminophen 15mg/kg every 4-6 hours as needed, do not exceed 5 doses within 24 hours.
- Ibuprofen 10 mg/kg every 6-8 hours as needed (≥ 6 months of age)
- Saline irrigation: flushes nasal secretions, increases mucocilliary clearance of secretions, vasoconstricts mucosa. Mix 1 teaspoon of salt in 8 ounces of lukewarm distilled or boiled water. Salt should also be iodide-free like pickling or canning salt.
- Adequate hydration: thins secretions and soothes respiratory mucosa
- Cool mist humidified air: adds moisture to air, which may help thin secretions
- Rest
- Elevation of the head while sleeping
- Honey (over 12 months of age): 2.5-5 mL straight or diluted in liquid beverages as needed
- Warm fluid ingestion: soothes respiratory mucosa, increases flow of nasal mucus, and loosens respiratory secretions
- Consider cough lozenges or hard candy: AAP states may recommend in children ≥ 6 years.

2. **External rubs** (Vaporub, Babyrub)

- **Not recommended**
- Parental report of cough severity improvement has been reported, however parental report is often unreliable compared with objective data.
- Exposure to camphor, an ingredient in many rubs, is a concern. Although the majority of exposures result in minor or no toxicity, refractory seizures can occur due to the high absorption rate of camphor.
- Rubs that do not contain camphor typically contain eucalyptus, lavender, or rosemary, which are known to cause GI or skin irritation.

3. **Antihistamines**

- Antihistamines should only be used in children > 12 months old and with the knowledge that sedation may be the only beneficial effect of treatment in children with the common cold.
- Used to treat the secretions associated with the URI due to their anticholinergic drying effects on mucous membranes. However, in controlled trials, they have been ineffective in relieving cold symptoms in infants and children, whether they were administered in combination with decongestants or as monotherapy.
 - In general, antihistamines are only helpful in reducing congestion when allergy is the underlying cause since that is their mechanism of action.
- Antihistamines alone in adolescents and adults also have not been shown to offer clinically significant benefits, but might be helpful in combination with a decongestant.
- The side-effect of sedation may be helpful to induce sleep in some children with symptoms of the common URI.

- Other possible side-effects of antihistamines to consider include paradoxical excitability, respiratory depression, cardiac arrhythmias, hallucinations, dizziness, blurred vision, urinary retention, or dystonic reactions.
- Use cautiously in children with asthma because they thicken secretions and may make them harder to clear.
- First generation anti-histamines (such as diphenhydramine) have an increased risk of overdose and have higher incidence of side effects due to ability to cross the blood brain barrier.

4. **Decongestants** (Pseudoephedrine, Phenylephrine, Oxymetazoline)

- Topical decongestants should never be used in infants, who are extremely dependent on nasal airflow for respiration. If topical decongestants are used in older patients, they should be administered sparingly for no more than 72 hours. Oral decongestants have not been shown to be effective in children less than 12 years of age. Use of systemic decongestants in adolescents and adults for a few days to treat the congestion caused by the common URI is reasonable and consistent with standard practice.
- **These medications are approved for use in children ≥ 6 years, but the AAP recommends use only for children ≥ 12 years.**
- Sympathomimetic agents that decrease nasal congestion by causing vasoconstriction, reducing blood volume and swelling in the nasal mucosa and paranasal sinuses.
- Side effects of systemic decongestants include irritability, agitation, sleeplessness, anorexia, nausea, vomiting, cardiac arrhythmias, palpitations, seizures, and dystonic reactions.
- Studies of single-ingredient decongestants have not included children younger than 12 years. There have been anecdotal reports of serious toxicity in young children using these products. In adolescents and adults, some clinical trials have shown a moderate short-term benefit in using decongestants to treat the symptoms of the common URI.
- Topical preparations can cause significant rebound congestion. Prolonged use of topical decongestants can cause rhinitis medicamentosa, a chronic inflammatory rhinitis.

5. **Antitussives** (Dextromethorphan, Codeine, Hydrocodone)

- Parents should be educated about the lack of proven antitussive effects and the potential risks of these medications in children and adolescents including respiratory suppression and abuse of controlled substances.
 - Despite some packages labeled for use in children ≥ 4 years, the AAP does not recommend the use of dextromethorphan in children.
 - Per FDA, cough and cold medicine containing codeine is limited to use in only those 18 years and older.
- Narcotic cough medicines act on the medullary cough center in the brainstem. They do not suppress cough completely and have serious adverse effects, especially in overdose.
- Dextromethorphan is a narcotic analog/isomer of codeine, which suppresses cough as effectively as codeine in adults, but can still cause respiratory depression in overdose.

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- Studies in children and adolescents do not show any benefit in cough suppression over placebo for either narcotic or non-narcotic cough medications.
- Cough medications should be used cautiously in children who have asthma because it can make it harder to expel mucous.
- A 2002 Cochrane review concluded that evidence does not exist for or against the effectiveness of OTC medications in acute cough.
- The American College of Chest Physicians guideline does not recommend centrally acting cough suppressants for cough secondary to URI infection.

6. **Expectorants (Guaifenesin)**

- Parents should be educated about the lack of proven effects of OTC expectorants.
- Intended to help thin secretions so they may be better expelled from the respiratory tract.
- Controlled studies in adults have not demonstrated changes in sputum quality or volume or in cough frequency, although patients perceive a decrease in sputum thickness and quantity.
- There are no good studies in children showing any benefit from the use of expectorants.

7. **Combination Products**

- Combinations of an antihistamine and decongestant may aid in relief of some symptoms of the common cold. These combinations may result in better sleep in younger children, although similar findings have resulted when using first generation antihistamines alone. Combination OTC products containing an antihistamine and a decongestant may modestly decrease the nasal symptoms caused by the common URI in adolescents and adults, however benefits must be weighed against potential side-effects.
- Many OTC cold medicines are combinations of an antihistamine and decongestant. Randomized, placebo-controlled, blinded trials have not discovered any difference between the medicine and placebo in terms of symptom relief for small children, except that they are more likely to fall asleep within two hours than those receiving placebo or no medication. In older children and adults, there may be some overall beneficial effect of decreased nasal symptoms.
- Other products contain a combination of an expectorant and cough suppressant. This combination would result in thinned secretions that could not be expelled because of cough suppression. If each product does what it is purported to do, they would be working against each other.
- There is an increased risk of overdose and harmful side effects when using combination products instead of single use products.
- **Again, decongestants are approved for use in children ≥ 6 years, but the AAP recommends use only for children ≥ 12 years.**

8. **Additional Considerations**

- The available scientific data suggest that cough and cold medications are generally not effective in children. If parents strongly desire medication to treat their child's symptoms,

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they should be counseled that medications are unlikely to work and given information on non-pharmacologic therapies as well as safe medications and their correct doses. They should be encouraged to use single-ingredient preparations whenever possible to decrease the risk of both adverse effects and overdose.

- Combination products can be dangerous if a similar medicine is being given to the child inadvertently in another product.
- Many products do not include dosing recommendations for children under the age of 2 years. This may lead to parents “guessing” at the correct dose of medication to give their small children.
- Products deemed to be natural are not well-studied. Therefore, it is unknown how much of the ingredients are absorbed and which side effects they may lead to. They are also known to be expensive.

9. Summary

- The AAP recommends absolutely no use of OTC cold medicine for children < 6 years.
- The AAP suggests no use of OTC cold medicine for children 6-12 years despite some medications being approved for use in this age group.
- The AAP states OTC cold medicine may be used for children \geq 12 years despite studies showing limited benefit.
- The age recommendations on packaging usually do not match AAP recommendations.
- OTC cold medicines do not cure illness but may provide temporary relief of some symptoms.
- All ingredients in the formulation must be taken into consideration.
- Generic products are less expensive than name brands.

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This guideline is designed to serve as a reference for clinical practice and does not represent an exclusive course of treatment nor does it serve as a standard of medical care. Providers should apply their professional judgment to the management of individual patient conditions and circumstances. Children’s Hospital and Health System (CHHS) does not make any representation with respect to any sort of industry recognized standard of care for the particular subject matter of this clinical guideline. Additionally, CHHS form documents are subject to change, revision, alteration, and/or revocation without notice.

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