

This lesson is supported by an educational grant from Hyland's.

Treatment Options for Managing Cough and Colds in Children

INTRODUCTION

Few medical issues are as contentious as determining the most effective and the safest treatment of cough and colds in children. Parents and caregivers know that antibiotics are not useful in treating viruses that are often the cause of these ailments. [1] They have turned, therefore, to over-the-counter (OTC) medications to relieve their children's symptoms and have found more than 800 cough and cold medications, many of which are different drug combinations for the same symptoms. These drugs include antihistamines, decongestants, antitussives, expectorants, cough suppressants and antipyretics/analgesics. Manufacturers spend more than \$50 million annually in marketing these products and more than 95 million packages are sold each year for use in children. [2] Still, the question remains — are children's colds and cough helped by these agents?

The most recent action on the use of OTC cough and cold medications in children was taken Oct. 7 by the Consumer Healthcare Products Association (CHPA). The trade organization ordered revised labeling of oral OTC pediatric cough and cold medicines to state "do not use" in children under 4 years of age. Additionally, for products containing certain antihistamines,

manufacturers will add new language that warns parents not to use antihistamine products to sedate a child. [3] The Food and Drug Administration (FDA) indicated support for the changes but will continue its re-evaluation of the safety and efficacy of OTC cold and cough medications in children, regardless of their age. [4]

PREVALENCE OF OTC COUGH/COLD MEDICATION USE IN CHILDREN

In a national study that used periodic telephone surveys to assess medication use from 1999-2006, 10.1 percent of ~4200 US children under anticipating the age of 18 were found to be medicated weekly with OTC cough and cold medications; of this percentage, almost two-thirds were taking multi-ingredient agents. [5] The greatest usage was among 2- to 5-year-olds; the next highest was in children less than 2 years old. Exposure to antitussives, decongestants and first-generation antihistamines was highest among 2- to 5-year-olds (7.0 percent, 9.9 percent and 10.1 percent, respectively) followed by children who were younger than 2 years (5.9 percent, 9.4 percent and 7.6 percent, respectively); expectorant use was low in all age groups. For the 489 products used, the stated reason for use was cough in 116 children (23.7 percent);

cold in 106 (21.7 percent); allergy in 96 (19.6 percent); and not related to cough, cold or allergy or unclear in 171 (35.0 percent). The investigators concluded: "The especially high prevalence of use among children of young age is noteworthy, given concerns about potential adverse effects and the lack of data on the efficacy of cough and cold medications in this age group." [5]

CDC, FDA AND MEDICAL ASSOCIATION POSITIONS REGARDING OTC MEDICATIONS

According to a 2005 Centers for Disease Control and Prevention (CDC) report on infant deaths from cough and cold medications, 1,519 children less than 2 years old were treated in emergency departments (EDs) for adverse events associated with OTC cough and cold preparations. Of these, three infants 6 months of age or younger died. [6] Postmortem blood levels of pseudoephedrine were extremely high. One infant had received a prescription and an OTC cough and cold combination preparation at the same time; both contained pseudoephedrine. The other infants received either a prescription or OTC pseudoephedrine.

In an FDA report covering the years between 1969 and 2006, the deaths of 54 children were associated with deconges-

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Program Goal: To increase awareness of the recent recommendations related to safety concerns associated with the use of over-the-counter pediatric cough and cold products; as well as safe options for parents seeking to manage cough and cold symptoms in their children.

Learning Objectives:

Upon completion of this program, the clinician should be able to:

1. Describe issues that have been raised regarding the effectiveness of OTC cough/cold products in infants and young children.
2. Describe adverse effects that have been associated with the use of OTC cough/cold products in infants and young children.
3. Relate FDA recommendations and possible future action.
4. Counsel parents regarding the importance of selecting safe options for management of their child's cough/cold symptoms.
5. Counsel parents regarding safety and effectiveness of OTC homeopathic products for cough and cold symptoms in children.

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PATIENT CASE 1

Jennifer Rodriguez, age 4 years, is brought into the clinic by her mother. Ms. Rodriguez reports Jennifer started with a “cold” two weeks ago, and her nasal discharge and cough have persisted. The nasal discharge is “often yellow or green, especially in the morning,” and “the preschool teacher asked to have Jennifer seen to make sure she didn’t need medication.” Ms. Rodriguez reports Jennifer has been essentially healthy, receiving regular well-child care from a private community practice, and is up-to-date on her immunizations “because the preschool requires she have all her shots.” Ms. Rodriguez denies any prior history for Jennifer of asthma, recurrent ear infections, allergies, hospitalizations or emergency department visits. Ms. Rodriguez does report Jennifer “gets frequent colds, but this one seems to be lasting longer.” When questioned, Ms. Rodriguez reports both she and her husband smoke “outside the house.”

After examining Jennifer, the clinician makes the following notes:

T: 98.6 F, oral

P: 100, regular

R: 30, unlabored, regular

General: Cooperative child in no acute distress

Skin: Warm, pink, free of lesions

Eyes: PERLA, conjunctiva clear, sclera white, no discharge

Ears: External canal partially obstructed by soft dark orange cerumen, tympanic membranes concave, translucent with normal movement on insufflation

Nose: Moderate amount clear to white bilateral discharge, turbinates pink and moderately swollen

Mouth: Teeth in good condition, no oral lesions, posterior pharynx slightly erythematous

Nodes: Bilateral shotty, nontender, cervical lymphnodes palpable

Lungs: Normal respiratory effort and rate, lungs clear to auscultation with good air exchange in all lobes, occasional cough during evaluation

Heart: Regular rate and rhythm, split S2, no murmurs

Abdomen: Bowel sounds present, soft, no masses, liver percussed at right costal margin

Neuro: Responds to questions and directions appropriately, able to climb on and off exam table with out difficulty or apparent pain, no tremors or fine motor disturbance noted

CASE DISCUSSION

As a patient with diabetes, TG considers it normal to test blood glucose levels. When patients with diabetes visit, there is no indication of illness other than common symptoms of viral URI. It is not unusual for Jennifer’s symptoms of nasal discharge and cough to linger for three weeks. The clinician does not recommend medications for current symptoms. The clinician reviews with Ms. Rodriguez the symptoms and the duration of symptoms associated with viral URIs, the frequency of URIs in children of Jennifer’s age (especially in preschool children) and increased respiratory effort that will indicate a need for Jennifer to be seen. Also, it is important for Ms. Rodriguez to know that exposure to secondhand smoke increases the frequency of URI illnesses in children.

The clinician should write a note to the day care staff assuring them that Jennifer’s lingering symptoms secondary to mild viral URI illness are normal. There is no need for Jennifer to be excluded from daycare, but frequent hand washing and assisted blowing of nose would be beneficial for infection control.

Wait, watch, review: If Jennifer is not better in seven to 10 days, she should return for further evaluation. If symptoms of respiratory distress or fever occur, Ms. Rodriguez should seek medical evaluation for Jennifer.

tants, and 69 deaths were linked to antihistamines. Most deaths were in children younger than 2 years of age; overdose and drug toxicity were commonly given as the causes of death. [6]

Because of the unproven efficacy of the cough suppressants codeine and dextromethorphan in young children and the potential for adverse events, the American Academy of Pediatrics (AAP) issued a policy statement in 1997 recommending that parents should be educated regarding the lack of antitussive effects, risk for adverse events and potential for overdose in children. [7] The AAP suggested that suppression of cough may be hazardous and contraindicated in many pulmonary airway diseases and recommended the use of fluids and humidity to reduce cough.

In 2006, the American College of Chest Physicians (ACCP) released clinical practice guidelines for management of cough, advising healthcare providers to refrain from recommending cough suppressants and other OTC cough medications for young children because of associated morbidity and mortality. According to the ACCP, "the literature regarding over-the-counter cough medications does not support the efficacy of such products in the pediatric age group." [8]

The availability of pseudoephedrine-containing medications has been affected by the federal Combat Methamphetamine Epidemic Act, which was signed into law March 9, 2006. [9] This act bans OTC sales (but permits behind-the-counter sales in limited amounts) of cold medications that contain pseudoephedrine, which can be used to make methamphetamine. Because of this act, pseudoephedrine has been removed as an ingredient in many cough and cold medications and replaced with other decongestants.

On June 8, 2006, the FDA took enforcement action to stop the manufacture of carbinoxamine-containing medications that had not been approved by the agency; FDA noted that many of the medications were inappropriately labeled for use in infants and young children despite safety concerns about use of carbinoxamine in children less

than 2 years of age. [10] Manufacturers of 120 such products were required to cease production by Sept. 6, 2006. Two approved carbinoxamine-containing products can continue to be sold legally.

RECENT FDA ACTIONS CONCERNING OTC COUGH AND COLD MEDICATIONS FOR CHILDREN

On March 1, 2007, the FDA received a citizen's petition filed by 15 pediatric and public health experts with the agency, asking the FDA to order a halt to marketing OTC cough and cold remedies for children under the age of 6 years, citing a lack of evidence of efficacy and concerns about safety. [10] The petition requested a revision of the labeling for OTC products containing any of 38 active ingredients that are in the following classes: antitussive, expectorant, nasal decongestant, antihistamine and bronchodilators. In addition, the petition asked that the agency notify manufacturers of products whose labeling either uses such terms as "infant" or "baby," or uses images of children under the age of 6, that such marketing is not supported by scientific evidence and that manufacturers will be subject to enforcement action at any time. (The petition and additional information can be found at the following web site: <http://www.fda.gov/ohrms/dockets/dockets/07p0074/07p0074.htm>.)

At an October 2007 meeting, the FDA's Pediatric Advisory Committee and Nonprescription Drug Advisory Committee examined the use of OTC cough and cold products in children younger than 2 years of age, 2 to 5 years of age, and 6 to 11 years of age. [2] They looked, too, at the extent of use of these products in children less than 2 years of age; the potential for misuse, unintentional overdose and excessive dosing; and the ability of parents or caregivers to correctly dose and administer cough and cold products to their children. There was strong consensus that more data are needed regarding efficacy of these products in children under 2 years

of age. A majority of the members also voted to recommend that the products not be used in children under 6 years of age while the rulemaking that would be necessary for revised OTC monographs proceeded. With regard to products intended for children ages 6 to 12, a majority recommended the continued availability of these products during the rulemaking process, expressing concern that, if these products were not available, parents or caretakers would use adult preparations instead, possibly resulting in higher incidents of drug overdoses and adverse drug effects.

In January 2008, the FDA issued a public health advisory, which recommended that OTC cough and cold products not be used in infants and children less than 2 years of age. [11] The FDA also said that the review of these products' safety in children ages 2 through 11 years of age was incomplete and provided the following precautions and recommendations for use by the public: the directions on the "drug facts" label should be followed carefully, products with safety caps should be chosen, appropriate measuring spoons should be used, concurrent use of multiple OTC cough and cold products should be avoided, and OTC cough and cold products should not be used to sedate children. In anticipation of the release of the FDA's public health advisory, most manufacturers voluntarily withdrew their cough and cold products for children younger than 2 years of age in October 2007.

On Aug. 20, 2008, the FDA announced a special public meeting to be held Oct. 2, 2008, to gather information, including scientific, regulatory and product use issues, as it proceeds with the rulemaking process to revise pediatric labeling for certain OTC cough and cold preparations. [10] The FDA noted its support for the voluntary action taken by many pharmaceutical manufacturers to withdraw cough and cold products intended for use in children under 2 years of age. Also noted was information from the FDA's Adverse Event Reporting data-

TABLE 1
Nonpharmacologic Treatment of Children with Cough and Colds

| | |
|-----------------------------------|--|
| Congestion | To aid decongestion, saline nasal drops or sprays can be used to ease irritated mucosal membranes and to loosen encrusted mucus. (Continuous nose wiping can make the skin raw; this can be alleviated by applying petroleum jelly below the nose.) Because saline has few side effects, it is safe for use in small children. The recommended dosage for saline drops is one to two drops in each nostril 15 to 20 minutes before feeding and bedtime with a repeated dose 10 minutes later. Older children may prefer a saline nasal spray. In infants, use a rubber suction bulb; secretions can be softened with saline nose drops or a cool-mist humidifier. Less than 7 percent of total calories (16 grams/2000 calorie diet) |
| Fever | A sponge bath may reduce fever. The water evaporates on the skin and results in a cool feeling, drawing the heat to the skin's surface. The water should be lukewarm, not cold. |
| Sore throat | Gargling with salt water may be effective, but few children like the taste. Liquids, honey and/or hard candies may soothe a scratchy throat. Sipping warm fruit juice, warm water or herbal tea with lemon, as well as sucking on a Popsicle, may be beneficial. |
| Cough | Hydration is important, and, other than gargling, the advice for "sore throat" above, applies here. Note that children younger than 12 months of age should not consume drinks to which honey has been added because of the risk for bacterial growth in honey. |
| Rest and diet | Sufficient rest is essential: this means an early bedtime, daytime naps and a break from strenuous activities. Also important is a diet that includes nutritious foods — or, at least, as many as a picky eater will consume. It is equally important that sick children remain well hydrated; children experience dehydration more quickly than adults. |
| Humidifiers and vaporizers | <p>More humid air can clear secretions, soothe airways, and reduce cough. Because cold viruses tend to thrive in dry air, colds are more common in winter. The types of humidifiers and vaporizers include cool-mist, steam, warm-mist, evaporative and ultrasonic.</p> <p>Cool-mist humidifiers create water vapor. Although cool-mist humidifiers cannot be used with medicated inhalants because there is no heat produced, their use reduces the risk of a burn if a child puts his or her face over the machine or if the water is spilled. Distilled water should be used in cool-mist humidifiers to prevent dispersion of minerals and organisms found in tap water. This type of humidifier, however, can provide a breeding ground for bacteria regardless of the type of water that is used. It is particularly important, therefore, to clean the machine daily with soap and hot water.</p> <p>In evaporative humidifiers, a wick system draws water from the reservoir, and a fan blows over the wick to allow the air to absorb the moisture. As the humidity level in the room increases, the humidifier's water vapor output decreases because the air cannot evaporate from the filter, thus allowing the machine to self-regulate. Many of these machines offer wicks treated with an antimicrobial agent or antimicrobial water additives to inhibit bacterial growth.</p> <p>Ultrasonic humidifiers release vapor by creating ultrasonic vibrations in the water. These machines are quiet, compared to cool-mist which are often noisy. Similar to cool-mist machines, ultrasonic humidifiers allow for the growth of bacteria, which is dispersed into the room, although high-end ultrasonic units include antibacterial features, among others. Many machines also feature a demineralization cartridge to filter minerals out of the water, eliminating the need for distilled water.</p> <p>Steam and warm-mist vaporizers boil water and release the steam into the air. The steam allows for the use of medicated inhalants. Because the water is boiled, these vaporizers do not release organisms into the air, and distilled water is not needed. Steam vaporizers are usually the least expensive humidifiers. If medicated inhalants are used with the vaporizer, camphor- or menthol-containing products may be added to the machine to temporarily relieve cough associated with a cold.</p> |

TABLE 1 (CONT)
Nonpharmacologic Treatment of Children with Cough and Colds

Safety precautions: Humidifiers should always be placed on a firm, flat, level surface and in an area that is out of reach of children. They should be at least five inches from walls and heat sources. Humidifiers should always be unplugged and emptied when not in operation. Most humidifiers require daily cleaning, as well as weekly disinfection, and routine filter replacement. It is possible that more humid air may cause increases in mold and dust mites, which can aggravate asthma and some allergies.

base that, although many adverse events were due to overdoses and allergic reactions, children under 4 years of age who received the labeled dose were more likely to experience nonallergic adverse events than were older children.

As noted, on Oct. 7, the FDA indicated its support for the voluntary actions of CHPA, which announced that it will revise labeling on OTC cough and cold medications to read that they should not be used in children younger than 4 years of age and that antihistamines should not be given to children for sedation purposes. The FDA will continue to work with the CDC to study the use of OTC medications in children and to develop educational materials for parents/caregivers and consumers.

RESULTS OF STUDIES ABOUT SAFETY AND EFFICACY OF OTC COUGH AND COLD MEDICATIONS

The safety of OTC cough and cold medications in children has been questioned in several studies. In ~28,000 cases of exposure to diphenhydramine reported to Poison Control Centers in 2003, 43 percent were in children younger than 6 years of age. [12, 13] There were six deaths from use of diphenhydramine, resulting from seizures or cardiac arrhythmias; the lowest dose that resulted in death was 11.6 mg/kg in a 9-week-old. There was severe toxicity at 10 to 15 mg/kg in a 13-month-old.

A study published in 2008 reported that an estimated 7091 children younger than 12 years of age were treated annually in EDs for adverse drug events

from cough and cold medications. [14] Emergency department visits were tabulated from a nationally representative stratified probability sample of 63 US EDs from Jan. 1, 2004, through Dec. 31, 2005. The 7,091 patients comprised 5.7 percent of ED visits for all medication concerns in this age group. Most visits (64 percent) were for children ages 2 to 5 years. Unsupervised ingestions accounted for 66 percent of estimated ED visits, which was significantly higher than unsupervised ingestions of other medications (47 percent). Most of these

ingestions involved children aged 2 to 5 years (77 percent), and most did not require admission or extended observation (93 percent).

In a study of infant deaths (ranging in age from 17 days to 10 months) in 2006 in Arizona, 10 were associated with cold-medication use. [15] Only four infants had received medical care for their current illness, and the OTC cough and cold medication had been prescribed by a clinician for only one infant. The families who used these medications were poor and publicly insured; half were not

FIGURE 1

Chronic cough without specific cough pointers in children with normal spirometry and chest X-rays

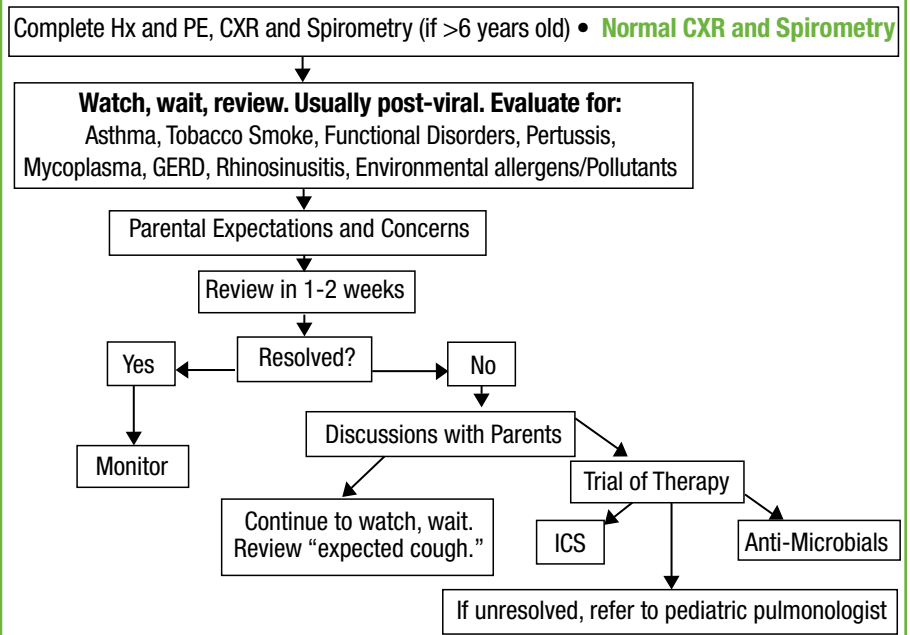


TABLE 2
Homeopathic combination products for cough and colds

| Brand | Product | Ingredients | Purpose |
|---------------------|------------------|--|---|
| COUGH SYRUPS | | | |
| Boiron | Chestal honey®*† | Antimonium tartaricum 6C | Helps loosen thick mucus |
| | | Bryonia alba 3C | Relieves dry and painful cough |
| | | Coccus cacti 3C | Relieves cough associated with a tickling in the throat |
| | | Drosera rotundifolia 3C | Barking cough worse at night |
| | | Ipecacuanha 3C | Relieves cough associated with nausea |
| | | Pulsatilla 6C | Relieves wet cough during the day that becomes dry at night |
| | | Rumex crispus 6C | Relieves dry cough triggered by cold air |
| | | Spongia tosta 3C | Relieves dry, croupy and barking cough |
| | | Sticta pulmonaria 3C | Relieves nighttime hacking cough |
| | | Honey, sucrose, citric acid, sodium benzoate | Inactive ingredients |

*NOT FOR USE IN CHILDREN YOUNGER THAN 2 YEARS; †HONEY SHOULD NOT BE USED IN CHILDREN YOUNGER THAN 1 YEAR

| | | | |
|----------|---------------------------|--|--|
| Hyland's | Cough Syrup with Honey®*† | Ipecacuanha 6X | Spasmodic, gagging cough; Dry, barking cough |
| | | Aconitum nappelus 6X | Hoarse, dry, croupy cough with sudden onset |
| | | Spongia tosta 6X | Dry, barking, croupy coughs that are nonproductive |
| | | Antimonium tartaricum 6X | Rattling cough |
| | | Honey syrup base, orange honey, purified water, cane sugar, vegetable glycerine, sodium benzoate | Inactive ingredients |

*NOT FOR USE IN CHILDREN YOUNGER THAN 1 YEAR; †HONEY SHOULD NOT BE USED IN CHILDREN YOUNGER THAN 1 YEAR

| | | | |
|----------|------------------------|----------------------|--|
| Hyland's | Cold 'n Cough 4 Kids®* | Allium cepa 6X | Watery, runny nose, cold, hacking cough, painful throat |
| | | Hepar sulph calc 12X | Cold, sneezing |
| | | Natrum mur 6X | Dry cough, sore throat |
| | | Phosphorus 12X | Hoarse dry cough, nasal congestion, chest congestion |
| | | Pulsatilla 6X | Spasmodic cough, cold, nasal congestion |
| | | Sulphur 12X | Chest congestion, nasal congestion, sneezing, burning runny nose |
| | | Hydrastis 6X | Rattling/tickling cough, sinus congestion, dry/raw/sore throat |

*NOT FOR USE IN CHILDREN YOUNGER THAN 2 YEARS

proficient in English.

Randomized, placebo-controlled studies in children have not shown that OTC cough and cold preparations are effective. [16-18] In an examination of trials and articles (including the Cochrane Central Register of Controlled Trials),

Schroeder and Fahey did not find good evidence for or against the effectiveness of OTC medicines in acute cough. These medications included antitussives, expectorants, mucolytics, antihistamine-decongestants and antihistamine. [16] Diphenhydramine and dextrometho-

rphan were not superior to placebo in providing nighttime symptom relief for children with cough and sleep difficulty that are caused by URIs, nor did the medications taken by children result in improved quality of sleep for their parents when compared with placebo. [17]

TABLE 2 (CONT.)
Homeopathic combination products for cough and colds

| Brand | Product | Ingredients | Purpose |
|--|--------------------------------|--|--|
| COLD | | | |
| Boiron | Coldcalm Tablets®* | Allium cepa 3C | Relieves sneezing and runny nose |
| | | Apis mellifica 6C | Relieves nasal congestion |
| | | Belladonna 6C | Relieves colds with a sudden onset |
| | | Eupatorium perfoliatum 3C | Relieves sinus pain |
| | | Gelsemium sempervirens 6C | Relieves headache associated with cold |
| | | Kali bichromicum 6C | Relieves nasal discharge |
| | | Nux vomica 3C | Relieves sneezing attacks |
| | | Phytolacca decandra 6C | Relieves sore throat associated with colds |
| | | Pulsatilla 6C | Relieves colds with a loss of taste and smell |
| | | Lactose, croscarmellose sodium, magnesium stearate | Inactive ingredients |
| MAY BE RECOMMENDED IN CHILDREN YOUNGER THAN 3 YEARS BY A HEALTHCARE PROVIDER | | | |
| Hyland's | Hyland's C-Plus Cold Tablets®* | Eupatorium perfoliatum 3X | Headache, vomiting cough, sneezing |
| | | Euphrasia officinalis 2X | Runny eyes and nose |
| | | Gelsemium sempervirens 3X | Sneezing with stuffy nose, difficulty swallowing, swallowing causes pain in ear |
| | | Kali iodatum 3X | Headache, runny eyes and nose |
| Lactose | | | |
| Inactive ingredient | | | |
| *NOT FOR USE IN CHILDREN YOUNGER THAN 1 YEAR | | | |
| Zicam* | Cold Remedy RapidMelts®* | Zincum aceticum 2X Zincum gluconicum 1X FD&C red 40, glycerin, HPMC, lecithin, maltitol syrup, maltodextrin mono- and di-glycerides, natural and artificial strawberry flavor, partially hydrogenated cotton seed and soy oil, sugar | Reduces duration and severity of cold Reduces duration and severity of cold Inactive ingredients |
| *NOT FOR USE IN CHILDREN YOUNGER THAN 3 YEARS | | | |

Lack of evidence to support the use of OTC medications in young children is well documented in the literature. [18]

DIAGNOSING COUGH IN CHILDREN

Cough is a normal defensive process; healthy children may cough 1 to 34 times daily. [19]

Preschool- and school-age children average six to eight colds annually. Cold symptoms last 10 to 14 days and include rhinorrhea, nasal congestion and cough

(normal up to two to three weeks post-viral URI). Fever, if present, generally lasts only 24 to 48 hours. Consequently, healthy children may exhibit cold symptoms from viral URIs for 60 to 112 days annually.

Specific vs nonspecific cough

It is important to reach an accurate diagnosis. A cough may be "specific" or "nonspecific." [8] A specific cough is one that is secondary to an underlying

condition (e.g., cardiac condition, airway anomaly [including asthma], suppurative lung disease, gastroesophageal reflux disease, environmental toxins and drug reaction) other than the common respiratory tract infection. A nonspecific cough lacks "pointers" on examination and history that would suggest an underlying etiology. Generally, a nonspecific cough is associated with upper and lower respiratory tract infections and an increased cough receptor sensitivity (the

latter may occur after a viral illness).

Cough is most often associated with respiratory tract infection; it is usually a self-limiting viral condition. If symptoms recur or are prolonged, allergies should be considered. It is important to keep in mind the ACCP's statement regarding the reliability of cough history: "Neither the characteristic of the cough (e.g., wet, dry, paroxysmal, barking and honking) nor the timing of cough (e.g., nocturnal, and with or without meals) is helpful in predicting its cause." [8]

Cough usually gets better with time — a therapeutic trial of medication is not conclusive for therapeutic value (i.e., use of a medication does not demonstrate conclusively that it was curative). [8] Symptoms improve with time; the therapeutic benefit of placebo is as high as 85 percent, and placebo-controlled studies often show no effect. It remains difficult, however, to convince families that time is the most effective healer for nonspecific cough. Cough is a common source of worry for parents — cough interferes

with sleep (in the child and, probably, in the parent[s]) and provokes concern about choking/breathing, spread of infection and dismissal from day care or school. [20]

An acute cough is one of less than two to three weeks' duration. A viral respiratory tract infection is the most common cause — 70 percent of children with this infection will have a cough; 50 percent will have a cough for one week, 20 percent to 30 percent for up to two to three weeks, and 5 percent for up to four weeks. In a review of evidence about the natural history of acute cough and respiratory tract infection in children younger than 4 years of age who were treated by primary care practitioners, Hay and Wilson found that illness improved in two days in 66 percent of the children, and nasal discharge and cough were present in 50 percent of children at one week and 20 percent at three weeks. [21] Other causes include exacerbation of preexisting condition (i.e., asthma), upper airway cough syndrome (formerly

known as postnasal drip syndrome) and acute environmental irritant or allergic exposure. If onset is abrupt, rule out aspiration.

Evaluating acute, nonspecific cough in children

In considering asthma and asthma-like conditions, most children with nonspecific cough do NOT have asthma; nocturnal cough without a history of wheezing is not highly correlated with asthma. [8] Approximately 80 percent of asthma exacerbations are caused by respiratory tract infections. Clinicians should determine if the associated cough is due to respiratory tract infection or asthma; if the child is started on asthma therapy, re-evaluate in two to four weeks. It should be noted that abatement of symptoms may be due to resolving URI and is not a therapeutic response.

Upper airway disorders may be a cause of cough. Sinusitis is diagnosed but rarely proved in children; abnormal sinus films have been seen in 8 percent to 82 percent of asymptomatic children. Cough and nasal discharge are common symptoms. Studies have indicated that sinusitis is not associated with cough once children are controlled for atopy and allergic rhinitis. There have been no RCTs on therapies for upper airway disorders with cough in children.

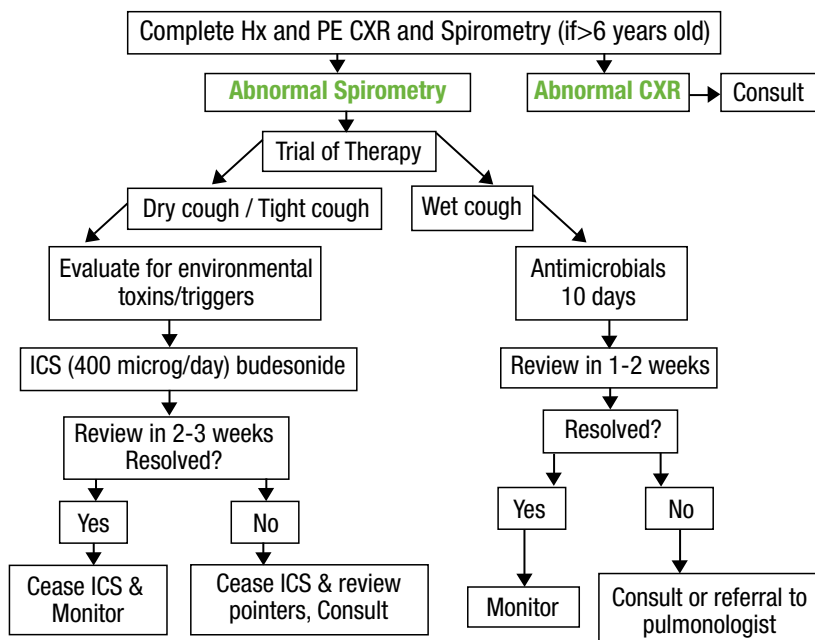
Environmental pulmonary toxicants may be a factor in the development of cough. Environmental tobacco smoke increases the incidence of respiratory illnesses and may cause cough/nasal discharge in children. Ambient pollutants can increase cough.

Evaluating specific pointers for cough in children

In children with specific indications for cough, further investigation is needed, except when asthma is the etiology. If chest X-rays and spirometry are abnormal, refer to a pulmonologist.

In children with chronic cough lasting longer than four weeks and no specific pointers, chest X-rays and spirom-

FIGURE 2
Chronic cough without specific cough pointers with abnormal spirometry and chest X-rays



etry are recommended. If the test results are normal, watch, wait, follow and continue to try and determine diagnosis (Figure 1). If they are abnormal, a consultation is needed to follow up on asthma/allergic etiology or infectious etiology (Figure 2).

TREATMENT OF COUGH AND COLDS IN CHILDREN

Over-the-counter medications with the active ingredients of concern have little or no benefit in controlling cough and colds in children. They have caused significant morbidity and mortality, especially in young infants and children. [6] Although the Consumer Healthcare Product Association asserts that an "educational campaign could solve the safety problems," [22] an educational campaign will not alter the ineffectiveness of OTC products and their potential for adverse effects.

Evidence-based management of cough and colds in children should follow these recommendations [8]:

- Recognize the normalcy, frequency and duration of cough and cold symptoms — most will resolve without treatment; have a follow-up plan for those that do not
 - Use nasal saline, bulb syringe and/or a cool humidifier
 - Do not prescribe or recommend OTC cough medications
 - Educate regarding effectiveness and hazards of OTC medications
 - Diagnose the cause carefully: specific cough in infants due to congenital defects should have a screening chest x-ray; do not overdiagnose "cough-variant asthma;" prescribe antibiotics cautiously; and refer to a specialist for unresolved cough.
- "Treatment" for parent and caregiver expectations should be

PATIENT CASE 2

A young mother, Ms. Winslow, comes in with her 3-year-old daughter, Alice, who was fine until last night when she suddenly woke up coughing. According to her mother, Alice's cough was like a seal barking. Ms. Winslow thinks that Alice seems to cough less when she is outside. Today, Alice also has had clear nasal congestion and a low-grade fever. The child seems restless, even a little anxious and fearful, and wants to stay close to her mother, which is very unlike her, according to Ms. Winslow. Alice does not want to eat her usual foods, but she is drinking well, and has normal urination. There is no vomiting or diarrhea, and the child has not had any new rashes. Alice's grandmother, who also is present, states that Alice had been playing outside, when it was very windy, the day that the cough started. Although Alice is being held by her mom and is fussy, she is consolable. She is well-hydrated, breathing comfortably and in no respiratory distress.

After examining Alice, the clinician notes the following:

T: 99.0 F, oral

P: 100, regular

R: 30, unlabored

Skin: Pink, warm, dry; no rashes, no pallor

Eyes: Conjunctiva without injection or discharge. Sclera white, nonicteric. PER RLA

Ears: Canals- no erythema or discharge. TMs- clear, no erythema, with good bony landmarks. No bulging and no perforation. Good mobility of both TMs with insufflations

Nose: Mucosa with slight erythema. + clear nasal discharge from both nostrils

Mouth: Moist mucous membranes, no tonsillar hypertrophy or erythema

Neck: Supple with FROM; no enlarged lymph nodes

Lungs: Clear to auscultation bilaterally; no stridor, no wheezing, no rales and no rhochi; no retractions; no use of any accessory muscles of breathing.

Heart: S1, S2, RRR, no murmurs

Abdomen: +Bowel sounds, soft, non-tender, non-distended, no rebound and no guarding

Neuro: Alert and awake; nonfocal neurologic exam.

CASE DISCUSSION

Alice is a 3-year-old with URI and a mild, croupy cough. Supportive care is advised — her mother should continue to encourage hydration, fluids and rest. Ms. Winslow can also use normal saline drops to help with nasal discharge. Steam treatment may help; turn on hot shower and sit with Alice in bathroom, allowing her to inhale steam. This can be done several times a day, if needed. Warm tea with honey may soothe Alice's throat.

Homeopathic treatments can include the following preparations. Aconitum Napellus (monkshood) – or aconite, as it is commonly called — is indicated in the early stages of onset of a cold, especially during the first 24 hours. Usually, the child has been exposed to dry, cold windy weather, and onset is usually sudden. The child is generally anxious and restless, and can also have a croupy cough. Spongia tosta is used in a similar situation in the later part of the illness. Hepar sulphuris also can be used in a child with symptoms similar to Alice's and who is also very irritable and has pronounced, often foul-smelling discharge (i.e., either from nose or ear).

considered, also. Ask about their concerns, and address them. Explain the duration of cough and cold symptoms, and how they should be treated without OTC medications or antibiotics (Table 1). Establish a follow-up plan for unresolved cough and colds. If the parents/provider are anxious to determine a diagnosis, tests can be done earlier in the child older than 6 years old to rule out possible diagnoses and make everyone feel more comfortable during the period of watching, waiting and reviewing.

Another form of treatment, homeopathy, is explained in the next section. Homeopathic formulations are indicated for common ailments and may be used safely in children with colds and cough.

WHAT IS HOMEOPATHIC MEDICINE?

This system of medicine was developed by Samuel Hahnemann in Germany more than 200 years ago. "Homeopathy" is derived from the Greek "homeo," meaning similar, and "pathos," meaning suffering. Homeopathic practitioners use highly diluted preparations of different plant, mineral and animal substances to heal and cure illness.

Hahnemann practiced in a medical era that was characterized by treatments such as bloodletting, purging and leeches. Very large doses of toxic metals, including mercury, arsenic, cadmium and lead, were used to treat patients — and these treatments were often administered simultaneously. Discontented with the practice of medicine, Hahnemann became a writer and a translator of scientific works.

In 1790, Hahnemann was translating "A Treatise on the Materia Medica," by William Cullen, a well-known contemporary physician. Quinine, made from cinchona bark, was considered effective in the treatment of malaria secondary to its bitter and astringent properties. Hahnemann questioned the accuracy of this belief and began ingesting doses of cinchona over a short period of time until he developed malaria symptoms (e.g.,

fever, chills, sweating and weakness).

Hahnemann reasoned that the efficacy of cinchona was related to the fact that the substance caused symptoms similar to that of malaria. In other words, "like cures like," or *similia similibus curantur*: this is the cornerstone of homeopathic medicine. A medicinal substance that can create a set of symptoms in a healthy individual can treat a sick individual who is manifesting similar symptoms. Indeed, the law of similars is an ancient concept; it was found in the writings of Hippocrates (c 460 BC to c 377 BC), as well as in 4000-year-old Indian and Chinese texts.

Hahnemann conducted experiments, or provings, in which common herbal and medicinal substances were administered to healthy people to see what symptoms they produced. He noted their reactions in meticulous detail. Together, the provings and his notes created a "drug picture" of the substance being tested.

In applying these principles clinically, Hahnemann would begin by conducting a thorough history and physical examination of the patient's symptoms, general health, way of life and attitudes. Next, he would assess temperature, sleep, energy level, digestion, thirst, appetite; traumatic events, stressors, personality and anxieties/fears. As a result, Hahnemann developed a "symptom picture" from each interview. Then and today, treatment depends, not only on disease symptoms, but on the total picture of the patient's symptoms. The treatment, therefore, is the substance whose drug picture most closely matches each patient's symptom picture — the closer the match, the more successful the treatment outcome.

REGULATION OF HOMEOPATHY

The Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. § 201 et seq., Section 01(g)(1) of the FD&C Act, 21 U.S.C. § 321(g)(1) regulates homeopathic drugs, defining the term drug as an article rec-

ognized in official compendiums or pharmacopoeias of the United States.

The official guidelines for homeopathic preparations are found in the Homeopathic Pharmacopoeia of the United States, which is authored by a nongovernmental, nonprofit organization of industry representatives and homeopathic experts. [23] The Pharmacopoeia also specifies how new remedies are to be tested and how their clinical effectiveness should be verified. Remedies on the market before 1962 have been accepted into the Homeopathic Pharmacopoeia of the United States based on historical use, rather than scientific evidence from clinical trials. Homeopathic Pharmacopoeia of the United States works with the FDA to set standards for preparations of homeopathic medication and to assure quality and consistency among different homeopathic manufacturers.

Homeopathic preparations are required to meet certain legal standards for strength, quality, purity and packaging. In 1988, the Food and Drug Administration required that all homeopathic remedies list the indications for their use on the label. [24] The FDA also requires the label to list ingredients, dilutions and instructions for safe use. As with all products, whether nutritional or medicinal, consumers are advised to read product labels carefully.

SCIENTIFIC RESEARCH AND HOMEOPATHY

The medical literature with respect to homeopathy is mixed. In some trials, homeopathy appeared to be no more helpful than a placebo; in other studies, some benefits were seen that the researchers believed were greater than one would expect from a placebo. [25]

Four of five major comprehensive reviews of randomized controlled trials (RCTs) in homeopathy have reached broadly positive conclusions. [26-29] Positive conclusions have been reported in nine of 21 reviews of RCTs in the following medical conditions — allergies and upper respiratory tract (URI) infections, child-

hood diarrhea, influenza and seasonal allergic rhinitis. [30-35]

Up to the end of 2006, 127 RCTs had been published: 57 positive; 6 negative; 64 not statistically conclusive. There is positive evidence from two or more RCTs in the area of sinusitis. [36, 37] There is evidence from single RCTs (not refuted elsewhere) in favour of homeopathy for a number of other conditions, including acute otitis media. [38].

Integration of homeopathy with conventional treatment is associated with better clinical outcomes for similar or lower costs. [39-41] In a British study, many patients attending the Royal London Homoeopathic Hospital were able to reduce or stop conventional medication following homeopathic treatment. [42]

In a prospective, observational study, 30 researchers with traditional medical licenses at six clinical sites in four countries enrolled 500 consecutive patients with at least one of the following complaints: upper respiratory tract (including allergies); lower respiratory tract (including allergies); or ear. [43] The primary outcomes criterion was the response to treatment, defined as cured or major improvement in symptoms after treatment for 14 days. Of the 456 patient visits that were studied, 281 received homeopathy, 175 received conventional medicine. The response to treatment as measured by the primary outcomes cri-

PATIENT CASE 3

Mrs. Roberts brings her 15-month-old granddaughter, Tina, for evaluation of a cold and fever. Tina is a healthy toddler who has had regular medical care and is up-to-date with her immunizations. She stays at home with her grandmother while her parents are at work, and she has been generally healthy, and growing and developing well. She has had a couple of colds but has not needed treatment with any medication. Mrs. Roberts states that Tina has had a cold for a few days and a low-grade fever. She has a runny nose, which has mostly been clear, and has not really had any coughing. Her appetite is slightly decreased, but she is drinking well and has "plenty of wet diapers." She has no vomiting or diarrhea and no new rashes. Mrs. Roberts has been using normal saline drops with a bulb syringe, which seems to help, but she wants to know if she can use anything else. She heard something about not using cold medications for children younger than 2 years of age so she is not sure what else she can do.

Tina is an active, playful toddler who is walking well and is well-developed and well-nourished. She is happy and smiling and also babbling. She is breathing comfortably and in no respiratory distress.

After examining Tina, the clinician notes the following:

T: 99.0 F, oral

P: 120, regular

RR: 30, unlabored

Skin: Pink, warm, dry; no rashes, no pallor

Eyes: Conjunctiva without injection or discharge. Sclera white, nonicteric. PERRLA

Ears: Canals- no erythema or discharge. TMs- clear, no erythema, with good bony landmarks. No bulging and no perforation. Good mobility of both TMs with insufflations

Nose: Mucosa with slight erythema. + clear nasal discharge from both nostrils

Mouth: Moist mucous membranes, no tonsillar hypertrophy or erythema

Neck: Supple with FROM; no enlarged lymph nodes

Lungs: Clear to auscultation bilaterally; no stridor, no wheezing, no rales and no rhochi; no retractions; no use of any accessory muscles of breathing.

Heart: S1, S2, RRR, no murmurs

Abdomen: +Bowel sounds, soft, non-tender, non-distended, no rebound and no guarding

Neuro: Alert and awake; nonfocal neurologic exam.

CASE DISCUSSION

Tina is a 15-month old with a URI. Supportive care is advised; her grandmother should continue to encourage hydration with adequate fluids, and use normal saline nasal drops and nasal bulb syringe. She can also use a cool-mist humidifier at night.

The clinician should reassure the grandmother of how well Tina is doing in terms of her overall appearance and activity level and that her body will clear this infection on her own with time. The grandmother can also be advised about an age-appropriate combination homeopathic product specifically for cold symptoms that can also assist Tina in her healing process. (Table 2) The grandmother should also be instructed to stop the homeopathic medications as the symptoms abate.

The clinician should also praise the grandmother for not using OTC cough and cold preparations; the clinician can emphasize that OTC cough and cold medications are not recommended for use in Tina's age group (i.e., younger than 4 years of age). The grandmother should be advised that if Tina is not better in another week or so, she should be seen again. If Tina has any worsening of symptoms (i.e., she is not drinking well or seems to be less active), she should be evaluated sooner.

terion for patients receiving homeopathy was 82.6 percent; for conventional medicine, it was 68 percent. Improvement in less than one day and in one to three days was noted in 67.3 percent of the group receiving homeopathy and in 56.6 percent of those receiving conventional medicine. The rate of adverse events for those treated with conventional medicine was 22.3 percent versus 7.8 percent for those treated with homeopathy. Homeopathy appeared to be at least as effective as conventional medical care in the treatment of patients with the three conditions studied.

A multi-center, comparative cohort study was conducted in six different European countries among more than 1,500 adults and children presenting to 57 primary care practices with acute respiratory and ear complaints (i.e., runny nose, sore throat, ear pain, sinus pain and cough). [44] Six-hundred fifty-nine children older than 1 month and up to 18 years of age were enrolled; 407 children were enrolled in the homeopathy group and 252 were enrolled in the conventional group. The homeopathy group received homeopathic medications prescribed on an individual basis; 62 different remedies were prescribed. The conventional group received antibiotics, analgesics, nasal preparations and cough/cold preparations. The primary outcome criterion was response rate after 14 days of therapy. Recovery rates were similar in both groups of children, but onset of improvement within the first seven days after treatment was significantly faster among the homeopathic treatment group. The authors concluded that homeopathic medications are not inferior to conventional treatment for management of acute respiratory and ear complaints.

In an open, pragmatic, randomized parallel group trial conducted in Norway with a waiting-list group as control, 169 children younger than 10 years of age, who had been diagnosed with an URI, were recruited into study. [45] The children were randomly assigned to receive either pragmatic homeopathic care from one of five homeopaths for 12 weeks or to a waiting-list control using self-selected, conventional health care. Par-

PATIENT CASE 1 REVISITED

In the case of Jennifer Rodriguez, supportive care was recommended, and the child's mother was advised to return for re-evaluation if symptoms did not improve in seven to 10 days. Over-the-counter cough and cold products are not indicated because data do not support their safety or effectiveness, especially in children younger than age 4; OTC products are being re-labeled to state this restriction for children in this age group.

It is often difficult for parents of young children to wait for a few days for their children's symptoms to abate. In Jennifer's case, the clinician can recommend homeopathic cough and cold combination products to use along with standard measures of rest, hydration, cool-mist humidifier and saline with bulb syringe. If cold symptoms predominate, a combination product designed for colds can be used; if cough is the predominant symptom, combination homeopathic cough syrups are available. If a child seems to have both cough and cold symptoms, an appropriate product can be recommended (Table 2). The clinician should instruct the parent to follow age-appropriate directions and gradually stop the medications as the symptoms abate. The clinician can also advise parents/caregivers to seek medical care if symptoms do not lessen over the subsequent seven to 10 days. If symptoms worsen, the parent should be advised to have child re-evaluated sooner.

ents in both groups were instructed to keep symptom diaries for 12 weeks. Both groups were allowed use of conventional medication or care. Results showed a statistical significantly greater symptom score in the waiting-list control group (44) versus that of homeopathic care group (24). The median number of days that the parents judged their child to be sick with URI symptoms was eight days in the homeopathic care group versus 13 days in the control group (also statistically significant). There was no statistically significant difference in use of conventional medication or care between the two groups. The strength of the study is that it is pragmatic, mirroring real life for parents of children with URI; the sample size was adequate. The authors concluded that there was a clinically relevant effect of individualized homeopathic care in the prevention of URI in children.

A group of researchers in France conducted a statistical analysis of data obtained from a population of 499 patients included in a previous six-month prospective, pragmatic study. [41] The researchers selected 431 cases based on the following inclu-

sion criteria: children between the ages of 18 months and 4 years of age diagnosed with rhinopharyngitis (rhinorrhea and/or cough; temperature greater than 100.4° within 24 hours of inclusion); and who had at least at least five bouts of acute rhinopharyngitis in 1999, and had consulted a general practitioner in 2000 for preventive treatment or for treatment of a current episode. Data were reorganized according to the type of drug prescribed: in Group H, patients received at least one homeopathic drug and no antibiotic (n=241); in Group A, patients received at least one antibiotic and no homeopathic drug (n=190).

The investigators determined that 'homeopathic strategy' yielded significantly better results than the 'antibiotic strategy' in terms of medical effectiveness (number of episodes of rhinopharyngitis: 2.71 versus 3.97, P<.001; number of complications: 1.25 versus 1.95, P<.001), and quality of life (global score: 21.38 versus 30.43, P<.001), with lower direct medical costs covered by Social Security (88 Euros versus 99 Euros, P<.05) and significantly less sick-leave (9.5 percent of parents versus 31.6 percent

of parents, $P < .001$). Homeopathy is a cost-effective alternative to antibiotics in the treatment of recurrent infantile rhinopharyngitis.

GENERAL RECOMMENDATIONS FOR TREATING COUGH AND COLDS IN CHILDREN

Six million Americans used homeopathic products in 1999. [46] Most homeopathy in the United States is practiced within another healthcare practice for which the practitioner is licensed, such as conventional medicine, naturopathy, chiropractic, dentistry, or acupuncture. The course of traditional homeopathic treatment involves a lengthy first patient visit, during which the provider performs an in-depth assessment to develop a symptom picture to determine the most effective homeopathic remedy (or remedies). During follow-up visits, the practitioner assesses patient response and decides upon further treatment. As interest in homeopathy has expanded, an increasing number of consumers who may not have access to a traditional homeopathic practitioner have sought out information and products for their personal use.

In a real-world practice that includes children's colds and URIs, the approach of all clinicians should begin with reassurance — most colds and cough are self-limited and will improve on their own with time. Next, patients should be encouraged to look at URIs and colds as opportunities for their bodies to build up immunities. It is helpful, also, if patients see a cough as a protective mechanism that helps clear the airway of inhaled material, such as pathogens, secretions, accumulated mucus and foreign bodies.

Children need adequate rest and sleep. Too many children are overscheduled with school, athletic and extracurricular activities. Similar to adults, there is an association between psychological stress and susceptibility to URI in children. [47] Helping children find ways to cope effectively with daily stressors and encouraging them to rest and relax both

have been shown to decrease duration of URI symptoms in children. [47]

Treatment, then, of URIs and cough may include — in addition to adequate rest and sleep — normal saline drops, use of a humidifier, fluids and analgesics (at age-appropriate dosing for fever/pain). Honey can be added to fluids except in children younger than 12 months. Table 1 provides general nonpharmacologic recommendations about the care of children with cough and colds.

HOMEOPATHIC TREATMENTS FOR CHILDREN WITH COLDS AND COUGH

Many parents, in seeking medicinal help other than OTC agents, look for complementary and alternative medicines, mistakenly thinking that these are all “natural” preparations that do not carry any risk. However, some products, such as herbal remedies, have the potential for adverse effects and are not regulated by the FDA. Their contents and concentrations cannot be guaranteed; there is a risk of contamination with pesticides, heavy metals and pharmaceuticals; and they may interact with other medications.

Homeopathic preparations, which are regulated by the FDA, are a safe and effective option for treatment of children with cough and colds. They are available in drugstores, health food stores and mass merchandise stores. Homeopathic products are available individually and as combination agents.

Regarding potential side effects resulting from use of homeopathic remedies, the National Center for Complementary and Alternative Medicine, a division of the National Institutes of Health, has observed the following: [25]:

- Homeopathic medicines in high dilutions, taken as directed by healthcare professionals, are considered safe and unlikely to cause severe adverse reactions. [48]
- Some patients report feeling worse for a brief time after starting a homeopathic regimen. Homeopathic

practitioners consider this reaction to be the body's temporary stimulation of symptoms while the body makes an effort to restore health.

- Liquid homeopathic remedies can contain alcohol and are allowed to contain higher levels of alcohol than conventional drugs for adults. This may concern some consumers. However, no adverse effects from the alcohol levels have been reported either to the FDA or in the scientific literature. [49]
- Homeopathic remedies are not known to interfere with conventional drugs; however, healthcare provider(s) should know all drugs — homeopathic or conventional — that their patients are taking.

HOMEOPATHIC COMBINATION PRODUCTS

Selecting single-ingredient products requires time and knowledge of many homeopathic remedies. However, homeopathic treatments also come in combination products. Some of the most common preparations for cough and colds in children are described in Table 2. Combination products include several homeopathic preparations in a single agent and can be useful in treating one condition, because they address several symptoms that characterize the condition or ailment. For example, combination homeopathic products are available for treatment of cold (as described in the patient cases) and earache.

Consumers should note that the composition of homeopathic ingredients in a combination product for a specific illness may vary from one manufacturer to another. It is important, therefore, to read each product's drug facts label carefully — as carefully as consumers should scrutinize all labels.

CONCLUSION

Over-the-counter cough and cold medications should not be used in children younger than 4 years of age. It is important for all healthcare practitioners

to make this age restriction clear to parents and other caregivers because it will take time for product labels to be revised to reflect this change. For products with certain antihistamines, new language will be added to their labels warning against their use to sedate children. Use of these products may worsen sickness-induced breathing difficulties in some children.

It is important, also, to make clear that OTC cough and cold medications are being restricted because their use has not been proved safe or effective in young children with cough and colds. The FDA is continuing to study the use of these agents in children older than age 4.

Most children with cough and cold will improve with time and supportive care — this needs to be made clear to

parents and caregivers. They need reassurance that, in following this medical advice, they are giving their children the best care possible for treatment of cough and colds. At the same time, they may want to consider combination homeopathic preparations for children's coughs and colds, which have been shown to be effective and safe when taken as directed.

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Treatment Options in Managing Cough and Colds in Children

Learning Assessment

Successful completion of "Treatment options in managing cough and colds in children" is accredited for 2.0 (two) hours of continuing education credit of which 1.0(one) hour is considered pharmacology credit. To obtain credit, answer the following questions and complete the evaluation online at www.retailclinician.com.

- 1. According to a national study, during the period 1999-2006, the greatest users of over-the-counter (OTC) cold and cough medications among children were ages:**

 - <2 years old
 - 2-5 years old
 - 6-12 years old
 - >12 years old
- 2. In this same survey, the most frequently stated reason for OTC cold and cough use was:**

 - Colds
 - Cough
 - Allergy
 - Cough associated with allergy and asthma
- 3. In an Oct. 7, 2008, announcement, manufacturers of children's cold and cough medicines announced that they would change their products' labels to recommend that the medicines not be used in children younger than age:**

 - 2
 - 4
 - 6
 - 12
- 4. Following a series of meetings in 2006 and 2007 about the use of OTC cough and cold medications in children, the FDA recommended that**

consumers:

 - Follow carefully the directions on all drug facts labels.
 - Avoid concurrent use of multiple cough and cold products.
 - Not use OTC cough and cold medications to sedate children.
 - All of the above.
- 5. In evaluating acute nonspecific cough in children:**

 - Nocturnal cough with a history of wheezing is correlated with asthma.
 - Most children with nonspecific cough do not have asthma.
 - Most asthma exacerbations result from a cause other than respiratory tract infections.
 - Environmental pulmonary toxicants are a factor in cough only in children with asthma.
- 6. In applying homeopathic principles, homeopathic practitioners:**

 - Use highly concentrated preparations of different plant, mineral and animal substances.
 - Depend on the total picture of the patient's symptoms, not only on disease symptoms.
 - Select treatments by identifying substances that create symptoms that are the opposite of those being experienced by the patient.
 - None of the above.
- 7. In homeopathy, a medicinal substance that can create a set of symptoms in a healthy individual can treat a sick individual who is manifesting similar symptoms.**

 - True
 - False
- 8. In a study conducted by Haidvogel, et al:**

 - Patients showed greater improvement from conventional treatment after 14 days than did homeopathic patients.
 - Homeopathic treatment for acute respiratory and ear complaints was not inferior to conventional treatment.
 - The conventional treatment group did not receive antibiotics.
 - Adverse drug reactions were greater in children in the conventional treatment group.
- 9. The FDA requires that homeopathic preparations:**

 - Meet certain legal standards for strength, quality, purity and packaging.
 - List the indications for their use on the package label.
 - List ingredients, dilutions and instructions for safe use.
 - All of the above.
- 10. Homeopathic medicines, in high dilutions, taken as directed by healthcare professionals, are considered safe and unlikely to cause severe adverse reactions.**

 - True
 - False