The Use of OTC Cough and Cold Products in Children
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Introduction
The cold is one of the most common childhood illnesses and is the second most common
diagnosis made in physician offices. It is a self-limited viral illness that usually lasts ten to
two weeks and can be caused by more than 100 different viruses. Compared to adults;
children experience more colds, averaging six to eight episodes per year. To help children
deal with the nasal congestion, rhinorrhea, cough, and restless nights, many parents turn to
over-the-counter (OTC) cold medications unaware of the risks involved with their use.

The Issue
Cough and cold products are widely used in children and recent reports of adverse events and
fatalities, particularly in young children, have raised safety concerns in this patient population.
The U.S. Food and Drug Administration (FDA) has been investigating the safety of these
products in children closely and product labeling has changed several times in the last two
years in an attempt to make these products safer for children and restrict their use in patients
for whom the risk outweighs the benefit.

Pediatric Utilization
Results of the Slone Survey, a random telephone survey that assessed medication use for
selected individuals in households, indicated that approximately 1 in 10 children in the United
States, or just over seven million individuals, are exposed to at least one cough and cold
medication in a given week. The majority of the products (64%) contained multiple active
ingredients; most commonly decongestant/first-generation antihistamine combinations and
antitussive/decongestant/first-generation antihistamine combinations. Approximately 20% of
cough and cold products also contained an analgesic (primarily acetaminophen). Exposure
to antitussives, decongestants, and first-generation antihistamines was the highest among two
to five year-olds (7.0%-10.1%) followed by children who were younger than two years (5.9%-9.4%).
Concerns
During 2004-2005, the Centers for Disease Control and Prevention estimated that 1,519 children less than two years of age were treated in U.S. emergency departments for adverse effects associated with cough and cold products.\textsuperscript{4} However with such widespread use of these products; it is unknown how many children have actually suffered serious adverse effects from their use. Reported adverse effects have included death, convulsions, tachycardia, agitation, and decreased levels of consciousness.\textsuperscript{5, 6} Many of these adverse effects are the result of dosing errors, unintentional ingestion, and drug-drug or drug-disease state interactions.

Another concern involves the lack of evidence of efficacy with these products when used in children. Although the medications contained in OTC cough and cold preparations have shown efficacy in adolescents and adults, studies conducted in children have shown that they are no more effective than placebo in providing symptom relief.\textsuperscript{6, 9} In addition, cough and cold medication use in young children has the potential for significant dosing errors.\textsuperscript{3-12} First, because of the lack of clinical and pharmacologic studies in children, most pediatric doses are extrapolated from adult data. Many products lack FDA approved dosing recommendations, particularly for children less than two years of age. Concentrations and dosages for young children are not standardized across products. Dosage delivery devices differ from product to product and should not be used interchangeably. Products with different ingredients can have similar names and parents or caregivers may be confused by the various product formulations. Finally, use of multiple ingredient cold products can increase the risk of a child inadvertently receiving products with the same or similar active ingredients leading to an overdose.

In a study that reviewed pediatric fatalities associated with cough and cold medications, 103 cases out of a total of 118 fatalities involved OTC or non-prescription products.\textsuperscript{10} Evidence indicated that 88 of the cases involved an overdose of the cough and cold medication. Most of the fatalities (75\%) were children under the age of two years. Several factors were identified that contributed to the administration of an overdose: use of the cough and cold product for sedation, administration in a daycare setting, use of two medications with the same active ingredient, failure to use a measuring device, product misidentification, and use of an over-the-counter product intended for an adult.

Another study looked at pediatric emergency department (ED) visits and estimated that 7,091 children less than 12 years of age were treated for adverse events from cough and cold products annually.\textsuperscript{11} Most of the visits (64\%) involved children age two to five years. Unsupervised ingestions accounted for 66\% of the emergency department visits, which was significantly higher than ingestions of other medications (47\%). It was also noted that a significantly higher proportion of visits resulting from cough and cold medications involved medication errors (administering an excessive dose, wrong formulation, etc.) compared with ED visits from all other medications combined (8\% vs. 1\%, respectively) and more of these medication errors occurred in children less than two years of age than in any other age group.

Dosing errors may also occur due to misinterpretation of cough and cold product labeling. In a study that assessed parental understanding of OTC cough and cold medication labels for 4 products not indicated for children less than two years of age, nearly all caregivers (98\%) thought that at least one of the four products was appropriate for a child under 24 months of age. The most common features of product labeling that influenced caregiver perceptions of the age indication were: the word “infant” on the package, infant-related graphics, or other language on the package (e.g. the words “pediatrician recommended”). Although each product package specifically recommended consulting a physician before administering the medication to a child less than 24 months of age, 72\% of the caregivers stated they would administer at least 1 of the products to a 13 month-old child with cold symptoms. After reviewing the entire product label, caregivers were influenced by the actual dosing directions less than 50\% of the time.

Regulatory Actions
In October 2007, the FDA’s Nonprescription Drugs Advisory Committee reviewed the safety and efficacy of OTC cough and cold products in children and recommended that they not be marketed for use in
children younger than six(6) years of age. The FDA typically follows the advisory committee recommendations but in this case, it did not. Instead, it issued a public health advisory in January 2008 recommending that parents not use these products in children younger than two years of age. In October 2008, after continued meetings with the FDA, the Consumer Healthcare Products Association (CHPA), a group that represents OTC cough and cold product manufacturers, announced that its members would voluntarily revise the labels of children’s cough and cold medicines to indicate that the products should not be used in children younger than 4 years of age. Products containing antihistamines would also have an additional warning that they should not be used to sedate children. Because these label revisions were voluntary, various pediatric cough and cold products, including products aimed at children less than four years old, remain on the market with no specific FDA ban. The safety of these products in children less than 12 years of age continues to be reviewed by the FDA.8, 9, 13, 14

Tips for Providers

- Ask parents specifically about the use of OTC products during office visits in addition to prescription products.
- Discuss the lack of efficacy and the potential risks that are associated with the use of OTC cough and cold products in children.
- Recommend non-pharmacologic therapies such as saline nasal sprays and drops, cool mist humidifiers, and adequate fluid intake.
- Give specific instructions on how to use OTC products even if the patient is already using them.
- Advice parents to choose products with child-resistant safety caps when available and make sure that medication are stored out of the sight and reach of children. Ingestions of these products are one of the major reasons for pediatric emergency department visits.
- Remind parents to always check the “active ingredients” section of the product label to make sure their child is not receiving two medications with the same or similar active ingredients.
- For liquid preparations, remind parents to use the measuring device that is included with the product instead of a kitchen teaspoon or droppers/measuring cups from other products.
- Inform parents that OTC cough and cold products only treat the child’s symptoms. They do not cure the cough or cold or shorten the duration of the illness.

References
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