



PATIENT EDUCATION: OTC COLD MEDICINES IN PEDIATRICS

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The medical literature has featured many investigations into the use of over-the-counter (OTC) cough and cold medicines in pediatric patients, discouraging their use in kids less than 6 years of age. Many parents have asked me and other respiratory therapists, "What are the official recommendations of the various agencies regarding OTC medicines in small children?"

Because respiratory therapists are on the front lines working with physicians and providing patient education regarding pediatric breathing problems, I reviewed the literature to check the facts behind statements I found in the popular media and comments that were attributed to the American Academy of Pediatrics, Center for Disease Control and the U.S. Food and Drug Administration. This article should serve to inform your discussions with pediatricians, family practitioners and physician extenders when developing a patient-centered plan of care, especially when questions are asked about OTC medications.

The use of OTC cough and cold medicines is very prevalent in our society. Gunn noted the potential toxicity of OTC cough and cold medications in 2001, and Vernaccio and co-workers found that in a given week, 10.1 percent of U.S. children used OTC cough and cold medication, and about 39 percent of all households had purchased and used OTC cough and cold medicines in children. The highest exposure was in 2 to 5 year-olds, followed by children and babies less than 2 years of age.

The CDC, writing in its weekly morbidity and mortality report (MMWR), noted that in 2004 to 2005, more than 1,519 children were treated in hospitals and emergency rooms for side effects or injury attributed to OTC cough and cold medications. That MMWR reported on three specific deaths in two states that were attributed to OTC cough and cold medicines. The post-mortem findings reflect the present-day rationale as to why we should not give OTC cough and cold medications to babies.

All of these infants had high levels of pseudoephedrine (a decongestant) in the infant's blood samples, with one receiving

both a prescription and an OTC cough/cold medication at the same time. The other two infants had received medications containing pseudoephedrine (one prescription and one OTC). There also was evidence of simultaneous use of antihistamines and medicines used to reduce a fever in two of the three children. The authors concluded with a caution to physicians about adverse effects of OTC medications in children.

FDA safety reviewers reached the same conclusions on the danger of OTC medicines when they found that from 1969 to 2006, at least 54 children died after taking OTC decongestants, and 69 died after taking OTC antihistamines. In two regional studies of children who died suddenly, OTC medications were implicated.

Schaefer's research team looked at the prevalence of accidental injury from OTC cough and cold medicines in reviewing data from a 63-hospital cooperative. They estimated that 7,091 pediatric patients had been treated for adverse events from OTC cough/cold medications and this data accounted for 5.7 percent of all emergency department visits from adverse events for medications in children. Rimsza and Newberry calculated a fatality rate from OTC cough and cold medications of nearly 500 children per year, and that OTC cough and cold medications as a cause of death was underreported.

So, with the evidence clearly contraindicating the use of OTC cough and cold medications in children under 6 years of age, why do I think that respiratory therapists must campaign on this subject? The first reason is that the OTC drugs are still out there. Drug makers, after initial resistance, removed some infant versions of the medications from the market, starting in October of 2007, with changes to labeling were to have gone into effect before October 2008. However, while testifying at FDA public hearings on OTC medications in October, Chamberlain, refuting the notion that substantive labeling changes on OTC cough and cold medications had taken place, testified as follows:

"This past week (mid-September 2008) I went to four separate major pharmacies in two different states and examined the labeling of all of the pediatric cough and cold medicines' boxes that were on the shelf. Of the over 30 different boxes I examined, I only found 3 that mentioned "Do Not Use" for children under 2!"

The other reason is that OTC medications enjoy a high degree of consumer confidence in their safety, despite the fact that there is little to no evidence of their efficacy in any age group. In a recent Kaiser poll, 60 percent of adult parents (80 percent of whom had heard that OTC cough and cold medications were bad for their children) responded that they were not convinced that OTC cold meds were unsafe for their young children.



Douglas Masini will be a featured speaker at the 9th annual Focus Conference May 14-16, 2009 Disney's Coronado Springs Resort Orlando, Florida

So what can respiratory therapists do to make a difference? The FDA has suggested avoiding OTC medications in a pediatric patient with a cold or cough. Here are a few of those recommendations:

- Avoid giving OTC medicines to children under 6; never give cough and cold medicine to children younger than age 2.
- Most OTC medicines have not been well studied in younger age groups, so the safety and dosing of OTC medicines in young children are not known.
- Always check with a pediatrician or pharmacist. Follow their dosing directions carefully. Use the dosing devices and ask the pharmacist for detailed instructions when using a dosing device provided for a prescription medication.
- Don't give medicine more often than recommended or more than one medicine at a time. Ingredients in one medicine may duplicate or not mix with the other.
- Think about using other remedies. Infant nasal congestion can be gently cleared using a rubber suction bulb. Soften the nasal mucus by using saline drops. If you use a high quality room humidifier, clean the humidifier frequently.
- Different medicines could have the same ingredients, making it possible to accidentally overdose a child when giving two medicines at once.
- It is never safe to assume that an adult medicine is right for children, even if they weigh the same as adults. Medicine that is safe for an older child may not be safe for a younger child.
- No evidence exists that shows OTC cold and cough medicines work in children under age 2, or for that matter, in older children. The U.S. government has not approved any dose of OTC medicines as safe for a child under age 2.
- A breastfeeding mother can pass concentrated cough and cold medicines to an infant through breast milk.
- Prevent the spread of infection by good handwashing and home hygiene.

In 2008, Sharfstein testified to the FDA that education and regulations work. After efforts to educate parents and the public and removal of the infant OTC formulations from store shelves in Maryland, he noted the following:

"The best response is data that is right under our noses. In October 2007, companies withdrew, in the middle of much publicity, OTC cough and cold products marketed for use by young infants (under age 2). ... We now have data from Maryland Poison Control to answer this question. These data show that calls for cough-and-cold medications for children under age 2 declined 40 percent, from 99 to 60, in the first six months of 2008 compared to the first six months of 2007. Looking just at calls for what we would call therapeutic misadventures, the drop was even greater, of 54 percent from, 41 to 19. All of these declines were far greater than the modest declines for children ages 2 to 6, where the decline in therapeutic misadventures was 15 percent, from 83 to 70."

With respiratory therapist involvement to provide more parental education, and further tightening of FDA regulations regarding availability and labeling of OTC cough and cold medications, tragic pediatric deaths from these medications may become a thing of the past.

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