

Declining Ingestions of OTC Cough and Cold Medications

Source: Mazer-Amirshahi M, Reid N, van den Anker J, et al. Effect of cough and cold medication restriction and label changes on pediatric ingestions reported to United States Poison Centers [published online ahead of print June 12, 2013]. *J Pediatr*; doi:10.1016/j.jpeds.2013.04.054

Investigators from multiple institutions in Washington, DC conducted a retrospective analysis to determine if changes in the labeling and age recommendations for over-the-counter (OTC) cough and cold medications were associated with a reduction in the occurrence of “unintentional ingestions,” “therapeutic errors,” and serious medical outcomes. The investigators utilized data from the American Association of Poison Control Centers (AAPCC) National Poison Data System (NPDS) and poisonings reported to all US Poison Centers. They analyzed data on pediatric ingestions of OTC cough and cold medications coded as unintentional ingestions and therapeutic errors. Children were categorized into 3 age groups: <2 years, 2 to 5 years, and 6 to 12 years. For each age group, the frequency and severity of unintentional ingestions and therapeutic errors were compared between 2 time periods: 2005 to 2006 (pre-labeling and recommendation changes) and 2009 to 2010 (post-labeling and recommendation changes). Outcome severity was dichotomized as follows: (a) no effect or minor outcome (mild symptoms which rapidly resolve), or (b) moderate outcome (more pronounced or systemic symptoms), major outcome (life-threatening or resulted in permanent sequelae), or death.

In 2009 to 2010, the number of unintentional ingestions of OTC cough and cold medications was 9,170 for children <2 years of age, 42,503 for children 2 to 5 years of age, and 2,495 for children 6 to 12 years of age. Compared to 2005 to 2006, this represented declines of 40%, 33%, and 20%, respectively, in children aged <2 years, 2 to 5 years, and 6 to 12 years ($P < .0001$ for each comparison). Between these time periods, the frequency of therapeutic errors of OTC cough and cold medications also declined significantly by 75%, 46%, and 9% for children aged <2 years, 2 to 5 years, and 6 to 12 years, respectively. Moderate, severe, or fatal outcome after unintentional ingestions decreased 32% for children <2 years of age ($P < .001$) and 21% for children 2 to 5 years of age ($P < .001$). Moderate, severe, or fatal outcome after therapeutic errors did not change significantly between periods for any age group.

The authors conclude that restrictions on the use of OTC cough and cold medications has led to a reduction in unintentional ingestions, therapeutic errors, and adverse medical outcomes in children <6 years of age.

Commentary by

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Dr Frymoyer has disclosed no financial relationship relevant to this commentary. This commentary does not contain a discussion of an unapproved/investigative use of a commercial product/device.

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Question: Among children <6 years of age, have national initiatives to restrict the use of over-the-counter cough and cold medications reduced unintentional ingestions, therapeutic errors, and adverse medical outcomes?

Question type: Occurrence

Study design: Retrospective cohort

Prior to 2007 as many as 1 in 10 children in the United States received OTC cough and cold medications each week. However, OTC cough and cold medications have not been shown to be effective in children,¹ and in young children the potential for harm is clear.² This discordance resulted in several changes to the labeling and new recommendations for OTC cough and cold medications in children. The key changes occurred between the 2 time periods examined in the current study and included a voluntary withdrawal by manufacturers of products directed at children <2 years of age (2007), guidelines by the FDA recommending against their use in children <2 years of age (2008), and a subsequent voluntary label change by manufacturers noting “do not use” in children <4 years of age (2008). In addition, the American Academy of Pediatrics supported the position that OTC cough and cold medications are not effective for children <6 years of age.³

A limitation to the current study is that it does not address trends in the overall use of OTC cough and cold medications in children, but instead only self-reported poisonings. A recent survey of parents found that two thirds were unaware of the FDA guidelines on OTC cough and cold medications in children <2 years of age.⁴ What are parents using as a guide for dosing since no information for children <4 years of age is available on the label? Additionally, direct causation of the decline in poisonings by OTC cough and cold medications cannot be established. Nonetheless, examination of medication misuse is informative. The temporal pattern of the large reduction of poisonings from OTC cough and cold medications in a national reporting system is highly suggestive of the impact that concerted efforts by the FDA, industry, and professional organizations had on improving the safety of medication use in children. Additionally, this study refutes concerns that OTC cough and cold medication poisonings would increase as parents turn to “off-label” use of formulations designed for older children and adults.

Continued guidance and education by pediatricians on the appropriate use (or nonuse) of OTC cough and cold medications in children, therefore, continues to be most important. Recent clinical studies supporting the use of honey for cough in children >1 year of age provide pediatricians a viable therapeutic alternative (see *AAP Grand Rounds*, March 2008;19[3]:28⁵ and *AAP Grand Rounds*, February 2013;29[2]:14⁶).

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Key words: poisonings, cough medications, over-the-counter

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