A Critical Review of:

"Pediatric fatalities associated with over the counter (nonprescription) cough and cold medications"

Dart RC, Paul IM, Bond GR, Winston DC, Manoguerra AS, Palmer RB, Kauffman RE, Banner W, Green JL, Rumack BH

Ann Emerg Med. 2009;53(4):411-7.

SUMMARY OF FINDINGS

Millions of children around the world use over the counter (OTC) cough and cold preparations every year. Previous reports associated some of the preparations with severe toxicity and even death, especially in very young children (under 2 years old). While some expert groups recommended restrictions for the use of these medications, and actions of the Food and Drug Administration in the US upon these recommendations, the use of such cough and cold preparations is widespread.

In this study a group of pediatricians and toxicologists from several centers in the US sit on an expert panel to look at reported incidents of death and to determine - what was the potential relationship between the use of cough and cold preparations and the child's death.

All cases of death among children under 12 years old, documented in five different sources of information, including the medical literature, FDA databases and manufacturers' reports that mentioned a cough and cold ingredient were abstracted.

The experts found that of 189 cases, 118 were judged possibly, likely, or definitely related to a cough and cold ingredient. Of the latter, 103 involved a nonprescription drug and of these 88 involved an overdose. The authors identified that age younger than 2 years, use of the medication for sedation, use in a daycare setting, combining two or more medications with the same ingredient, failure to use a measuring device, product misidentification, and use of products intended for adults were associated with the fatalities. Finally, the review of the information showed that six of the children died after an attempt to sedate them; three were cases of abuse; and in 10 cases homicide was suspected.

COMMENTS

What is unique about this paper is the significant effort done by a group of inter-professionals in combing separate sources of information in order to identify as many of the fatalities associated with OTC cough and cold medications. Beyond just sorting out cases reported in the literature, they went through cases reported by parents and manufacturers alike. Yet, it is clear that the findings reported are an underestimate of the true incidence of death due the commonly used preparations. As readers, we are compelled to ask ourselves how many more children will die each year due to exposure to what seems to parents and many health care providers as an innocent non-prescription group of medications.

What was found in this study and was previously reported, is that some of these pediatric deaths were associated with preventable errors in administration of OTCs. Efforts to eliminate administration of two drugs containing the same components, providing measuring devices to ensure correct dosage administration and clear differentiation between adult and pediatric regimens are some of the possible solution that can prevent future therapeutic errors.

What is maybe most astounding here is the fact that some of the fatalities were associated with a non-therapeutic intent of parents and day care workers, and included efforts to sedate the children, abuse and homicide. These findings must alert parents and the medical community to immediate regulatory and educational efforts, in order to eliminate these stoppable losses.

It was reassuring to learn just before the publication of the article from the group that the FDA[1] endorsed the Consumer Healthcare Products Association in the US recommendation to use OTC for cough and cold from age 4 years, and

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Health Canada[2] that requested manufacturers re-label the products to be used by children age 6 and older.

Ran D. Goldman, MD
Division of Pediatric Emergency Medicine,
BC Children's Hospital, Vancouver, BC

REFERENCES

1. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01899.html
2. http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2008/2008_184-eng.php

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