



Trends in
Medical Research

ISSN 1819-3587



Academic
Journals Inc.

www.academicjournals.com

Dosing Directions, Measuring Devices Appear Inconsistent for Many Children's Liquid Medications, Study Finds

An examination of 200 of the top-selling cough/cold, allergy, analgesic and gastrointestinal over-the-counter liquid medications for children finds that there have been high levels of variability and inconsistencies regarding medication labeling and measuring devices, according to a study that will appear in the December 15 issue of JAMA. The study is being released early online because of its public health importance.

"In November 2009, the U.S. Food and Drug Administration (FDA) released new voluntary guidelines to industry groups responsible for manufacturing, marketing, or distributing over-the-counter (OTC) liquid medications, particularly those intended for use by children. These guidelines were developed in response to numerous reports of unintentional overdoses that were attributed, in part, to products with inconsistent or confusing labels and measuring devices," according to background information in the article.

H. Shonna Yin, M.D., M.S., of the New York University School of Medicine and Bellevue Hospital Center, New York, and colleagues conducted a study to determine the prevalence of inconsistent dosing directions and measuring devices among 200 top-selling pediatric oral liquid OTC medications at the time the FDA's guidelines were released. The analysis was conducted for a period of one year, ending October 30, 2009. The sample represents 99 percent of the U.S. market of analgesic, cough/cold, allergy, and gastrointestinal OTC oral liquid products with dosing information for children younger than 12 years.

Among the findings of the researchers, a standardized measuring device was provided for 148 products (74.0 percent). Within these 148 products, nearly all examined (98.6 percent) contained 1 or more inconsistencies between the labeled directions and the accompanying device with respect to doses listed or marked on the device, or text used for unit of measurement. Almost a quarter of products (24.3 percent) lacked necessary markings.

"Among the measuring devices, 81.1 percent included 1 or

more superfluous markings. The text used for units of measurement was inconsistent between the product's label and the enclosed device in 89 percent of products. A total of 11 products (5.5 percent) used nonstandard units of measurement, such as drams, cubic centimeters, or fluid ounces, as part of the doses listed," the authors write.

The researchers also found that across all products, milliliter (143, 71.5 percent) and teaspoon (155, 77.5 percent) were the most frequently used units of measurement. Tablespoon was used in 37 products (18.5 percent). A nonstandard abbreviation for milliliter (not mL) was used by 97 products. Of the products that included an abbreviation, 163 did not define at least 1 abbreviation.

This study identifies problems in 3 critical areas, according to the authors: a standardized measuring device should be included with all nonprescription liquid products; within each product, consistency should be ensured between the labeled dosing directions and markings on the associated measuring device; and across products, measurement units, abbreviations, and numeric formats should be standardized.

They add that the risks posed by confusing or inconsistent dosing directions on pediatric OTC medication packaging and measuring devices may vary depending on the nature of the discordant labeling, yet the potential for harm is substantial. More than half of U.S. children are exposed to 1 or more medications in a given week, and more than half of these are OTC medications.

The researchers write that this study provides baseline data for assessing the degree and pace of industry conformity

with the guidelines. "At this time, the FDA's guidelines are voluntary, and companies have no legal obligation to follow them. Subsequent systematic product analyses may therefore be helpful to monitor progress, including assessing whether additional regulatory oversight may be needed to ensure practices that best support safe and effective use of OTC medications." In an accompanying editorial, Darren A. DeWalt, M.D., M.P.H., of the University of North Carolina at Chapel Hill, writes that the findings of this study document a concerning state of affairs.

"Clinicians' education in and familiarity with most of these measuring units may lead them to overlook the tremendous variation within and across products and opportunities for dosing errors. But that is just the point: health care providers, including pharmaceutical companies, frequently forget about transferring responsibility to patients who are not comfortable with several different types of measurements," writes Dr. DeWalt. "The most elegant and efficient medical therapies will fail if patients or caregivers cannot adequately and accurately administer the therapy."