Instructions on over-the-counter medications for children are found to be confusing

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Instructions on boxes and bottles of over-the-counter (OTC) medicines for children in the United States are confusing and hard for parents to understand and follow, according to a study in the December 1 issue of *JAMA*.

"There is an unacceptable amount of inconsistency in labels and measuring devices of OTC liquid medications for children," said H. Shonna Yin, MD, assistant professor of pediatrics at NYU School of Medicine who co-led the study. "These types of inconsistencies are likely to be a source of confusion for parents and can lead to errors in dosing, placing children at risk."

The study was undertaken after the U.S. Food and Drug Administration issued voluntary guidelines last year recommending greater consistency in dosing directions and accompanying measuring devices, following numerous reports of accidental overdosing in children attributed in part to these issues.

The researchers reviewed 200 top-selling pediatric oral liquid OTC medications categorized as analgesics, cough/cold, allergy, or gastrointestinal medicines – representing 99 percent of the U.S. market of these products. They found that 25 percent of these products did not include dosing devices, such as a cup or dropper for giving the medicine, and that 99 percent had directions on the bottle's label and dose markings on the device that do not match. In addition, more than half the products did not use standard abbreviations for terms such as teaspoon

or milliliter.

"This is an issue of patient safety and needs urgent attention," said Ruth Parker, MD, professor of medicine at Emory University School of Medicine, who co-led the study. "Given how many products are affected, it seems unlikely that the voluntary guidelines alone set by the FDA and industry will fix this problem. The current guidance does not contain a timeline for compliance or specify consequences for non-compliance. Standards and regulatory oversight will likely be needed to ensure that all products contain label information and dosing device markings that match and are understandable and useful."

The study authors believe that when dosing instructions and devices match, and standard abbreviations are used, parents will be less confused and better able to give the proper dose of medication to their child. "Devices often have extra markings on them that are not listed on the label, which can be distracting and lead to confusion," says Dr. Yin. "Furthermore, some devices are missing doses that are recommended on the label, making the task of dosing more difficult.

The authors recommend that terms such as "cc" and "drams", which are not commonly understood, not be used in labeling. Tablespoon instructions, they note, should also not be used because they are often confused with teaspoon instructions which can lead to a 3-fold underdose or overdose.

"There are very straightforward things that can be done to help parents dose OTC medications correctly," said co-author Benard P. Dreyer, MD, professor of pediatrics at NYU School of Medicine, and president-elect of the Academic Pediatric Association. "Making sure that all products follow these guidelines will help parents use OTC medicines more safely and effectively."