Identifying and Advancing Best Practices for the Labeling and Dosing of Pediatric Liquid Medications: Progress and Challenges

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WHAT'S NEW

The National Institutes of Health–funded Safe Administration for Every Rx for Kids study has identified best practices for the labeling/dosing of pediatric liquid medications. Findings support use of pictographic instructions and optimized dosing tool provision, and careful selection of the unit of measurement used.

PARENTS AND CAREGIVERS frequently make errors when dosing liquid medications for their children. Variable units of measurement (eg, milliliter, teaspoon, tablespoon) used by prescribers and manufacturers, along with lack of standardization of their associated abbreviations, contributes to confusion. For a single prescription, the units presented as part of medication counseling often differ from those printed on the prescription, the bottle's label, or dosing tool. In addition, parents may not realize that kitchen spoons are error prone and may not know how to use standardized tools with markings to guide dosing. Over the past decade, growing attention has been paid to identifying labeling/dosing strategies to reduce medication errors in children. In 2008, the Centers for Disease Control and Prevention launched the PRevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) initiative[1]; standardization of liquid medication dosing has been a key area of focus. The National Institutes of Health–funded SAFE Rx for Kids (Safe Administration for Every Rx for Kids) study sought to identify best practices for the labeling/dosing of pediatric liquid medications to inform the development of evidence-based standards, with results presented annually to stakeholders at PROTECT meetings beginning in 2013.

In February 2016, we submitted findings from the first phase of the SAFE Rx for Kids study to *Academic Pediatrics*. We found that parents had a fourfold increased odds of choosing a kitchen spoon when presented with prescription instructions that used teaspoon units compared with parents who looked at prescription instructions in milliliters only (ie, "mL" only).[2] These findings showed that by including teaspoon units on labels, providers are inadvertently endorsing the use of kitchen spoons. Kitchen spoons have long been recognized to contribute to parent dosing errors because they vary widely in size and shape. In this commentary, we provide readers a progress report on the topic since our original publication in this journal.

In September 2016, we published additional results from a SAFE Rx for Kids experiment that sought to assess the impact of units of measurement and dosing tools on dosing errors. Parents were randomly assigned to 5 groups that varied based on the combination of units included with dosing instructions on the prescription label and the units shown on the accompanying dosing tool. Parents were asked to measure 3 dose amounts with 3 dosing tools (9 total doses). Use of the teaspoon-only label was associated with more dosing errors compared with the use of milliliter-only labels/tools (ie, "mL" only).[3] Oral syringes were associated with fewer errors compared with dosing cups,

especially for the smaller dose amounts tested (2.5 mL, 5 mL); overall, cups were associated with >4 times the odds of error compared with oral syringes.

Another SAFE Rx for Kids experiment investigated additional strategies to reduce dosing errors, with findings published in 2017.[4] Text-plus-pictographic dosing instructions were associated with a twofold reduction in large overdosing errors (>2-fold errors) compared with text-only instructions. Fewer errors were seen when parents measured with tools with a volume capacity more closely matched to the prescribed dose volume; a tool that is much larger than necessary allows room for excess medication, whereas a tool that is smaller than a prescribed dose necessitates the measurement of >1 instrument full.

The SAFE Rx for Kids study, to our knowledge, is the first to apply an experimental design to rigorously examine the effect of specific label/dosing tool attributes on parent liquid medication dosing error rates. Our results support the use of pictographic instructions and optimized provision of dosing tools. In addition, our findings suggest that the unit used as part of instructions should be carefully considered, given that milliliter-only dosing is associated with fewer errors compared with teaspoon units, and teaspoon terms can inadvertently endorse kitchen spoon use. We note, however, that a move to metric-based standards in the United States could be a source of confusion. Our study identified that parents with lower literacy have less experience with and feel less comfortable with milliliter dosing.[5] Addressing the educational needs of this at-risk population will be important in the transition to a metric-based dosing standard.

Findings from the SAFE Rx for Kids experiments (conducted between August 2013 and July 2015) have provided evidence to support initiatives to improve national medication labeling/dosing standards, including a 2015 American Academy of Pediatrics policy statement that endorsed metric-only dosing and dosing tool provision with liquid medicines and 2016 guidance from the American Pharmacists Association.[6–8]

Barriers to implementing the best practices identified in our research exist for providers. A recently published study found that ~40% of pediatricians and ~70% of other primary care providers would not use milliliter-only dosing instructions; provider use of teaspoons was associated with the perception that parents/caregivers prefer spoon-based units.[9] Recent findings from the SAFE Rx for Kids Study suggest that these provider perceptions are likely to be incorrect; >70% of parents in our study preferred to use milliliters, perceived milliliter-only dosing to be easy, and had previous milliliter-dosing experience.[5]

Barriers also exist within the pharmacy setting. In a recent study conducted in New York City, 60% of pharmacies had no policy regarding dispensing dosing tools with liquid prescription medications. Alarmingly, 35% of pharmacists recommended using a household spoon to measure doses.[10]

A systems-level approach will be needed to facilitate adoption of best practices for the labeling/dosing of pediatric liquid medications. This approach will need to include health care and pharmacy systems, manufacturers of prescription and over-the-counter products, as well as dosing tool manufacturers. Technology-based approaches, involving electronic health record companies and vendors of pharmacy labeling software, will be needed; this year, a federal health information technology initiative is incentivizing clinician use of electronic systems that automatically prescribe using milliliter dosing alone.[9] In phase 2 of the SAFE Rx for Kids study, we are examining systems issues as we test our labeling/dosing strategies as part of a randomized controlled trial in a public hospital pediatric emergency department.

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CLINICAL TRIAL REGISTRATION

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