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CONTRIBUTOR STATEMENT

Dr. Yin and Ms. Patel had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The authors made contributions as delineated below.

Study concept and design: Yin, Wolf, Parker, Sanders, Dreyer, Mendelsohn, Bailey, Pat, Kim.

Acquisition, analysis, or interpretation of data: Yin, Wolf, Parker, Sanders, Dreyer, Mendelsohn, Bailey, Pat, Kim, Jacobson, Landa, Maness, Tailor Raythatha, Hedlund, McFadden.

Critical revision of the manuscript for important intellectual content: Yin, Wolf, Parker, Sanders, Dreyer, Mendelsohn, Bailey, Pat, Kim, Jacobson, Landa, Maness, Tailor Raythatha, Hedlund, McFadden.

Statistical analysis: Pat, Kim, Yin, Wolf, Dreyer, Mendelsohn.

Obtained funding: Yin, Wolf, Parker, Sanders, Dreyer, Mendelsohn, Bailey, Kim.

Administrative, technical, or material support: Yin, Pat, Kim, Jacobson, Landa, Maness, Tailor Raythatha, Hedlund, McFadden.

Study supervision: Yin, Wolf, Parker, Sanders, Dreyer, Mendelsohn, Bailey, Jacobson, Pat. All authors have approved the final manuscript as submitted.

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Abstract

OBJECTIVE—Some experts recommend eliminating “teaspoon” and “tablespoon” terms from pediatric medication dosing instructions, as they may inadvertently encourage use of nonstandard tools (i.e. kitchen spoons), which are associated with dosing errors. We examined whether use of “teaspoon” or “tsp” on prescription labels affects parents’ choice of dosing tools, and the role of health literacy and language.

METHODS—Analysis of data collected as part of a controlled experiment (SAFE Rx for Kids study), which randomized English/Spanish-speaking parents (n=2110) of children ≤8 years old to 1 of 5 groups which varied in unit of measurement pairings on medication labels/dosing tools. Outcome assessed was parent self-reported choice of dosing tool. Parent health literacy measured using the Newest Vital Sign.

RESULTS—77.0% had limited health literacy (36.0% low, 41.0% marginal); 35.0% completed assessments in Spanish. Overall, 27.7% who viewed labels containing either “tsp” or “teaspoon” units (alone or with “mL”) chose nonstandard dosing tools (i.e. kitchen teaspoon, kitchen tablespoon), compared to 8.3% who viewed “mL”-only labels (AOR=4.4[95%CI: 3.3–5.8]). Odds varied based on whether “teaspoon” was spelled out or abbreviated (“teaspoon”-alone: AOR=5.3[3.8–7.3]); “teaspoon” with mL: AOR=4.7[3.3–6.5]; “tsp” with mL (AOR=3.3[2.4–4.7]); p<0.001). Similar findings were noted across health literacy and language groups.

CONCLUSIONS—Use of teaspoon units (“teaspoon” or “tsp”) on prescription labels is associated with increased likelihood of parent choice of nonstandard dosing tools. Future studies may be helpful to examine the real-world impact of eliminating teaspoon units from medication labels, and identify additional strategies to promote the safe use of pediatric liquid medications.

Keywords

medication errors; dosing errors; health literacy; ambulatory care; health communication; injury prevention
INTRODUCTION

Standardizing labels on pediatric liquid medications has been proposed as a way to reduce dosing errors in the United States (US).\(^1\)\(^-\)\(^7\) The Centers for Disease Control and Prevention (CDC), through its PROTECT initiative, along with the American Academy of Pediatrics (AAP), have recently begun to advocate for “milliliter”- or “mL”-only dosing, and the elimination of “teaspoon” and “tablespoon” terms on medication labels.\(^8\)\(^-\)\(^10\) While one study showed that parents are able to dose more accurately using mL instructions, a significant proportion of parents continued to make errors even with mL dosing.\(^10\) Concerns about moving to the metric-only labeling of medications and dosing tools in the US, which has historically relied on a non-metric spoon-based system\(^8\)\(^,\)\(^9\)\(^,\)\(^11\), have led some to call for additional research to better delineate the benefits of a move to an mL-exclusive system.

In this context, some medical providers and public health professionals have suggested that “teaspoon” and “tablespoon” labels may inadvertently cause dosing errors by encouraging parent use of nonstandard dosing tools to measure medications such as kitchen spoons, which vary widely in size and shape.\(^10\)\(^,\)\(^12\)-\(^14\) There is longstanding recognition that kitchen spoons should not be used for dosing pediatric medications.\(^12\)\(^,\)\(^15\)\(^,\)\(^16\) In fact, since 1975, the AAP has recommended the use of standard dosing tools such as oral syringes, droppers, and dosing cups, which have markings to guide parents in the accurate dosing of medications.\(^12\) The US Food and Drug Administration (FDA) recommends inclusion of standard tools with over-the-counter liquid medications.\(^3\)

In this study, we sought to examine the degree to which parents’ choice of medication dosing tools is affected by the unit of measurement present on a medication label, in particular the impact of teaspoon terms (“teaspoon”, “tsp”). We hypothesized that presence of a teaspoon unit on the label, whether spelled out or abbreviated, would increase the likelihood of a parent inappropriately choosing a nonstandard tool (i.e. kitchen spoon) to administer medications. We also sought to examine differences in impact by parent health literacy and language, as those with low health literacy and limited English proficiency have been previously found to be at greater risk for misunderstanding drug labels and subsequent medication errors.\(^10\)\(^,\)\(^13\)\(^,\)\(^17\)-\(^20\)

METHODS

Participants, Recruitment, Randomization

Data for this study were collected as part of a randomized controlled experiment to examine the degree to which specific attributes of medication labels and dosing tools affect parent dosing errors (SAFE Rx for Kids study). Subjects were enrolled from pediatric outpatient clinics affiliated with New York University (Bellevue Hospital Center), Stanford University (Gardner Packard Children’s Health Care Center), and Emory University (Children’s Hospital of Atlanta (CHOA) at Hughes Spalding) Schools of Medicine. These clinics serve predominantly low income families (at least 70% enrolled in Medicaid or the Women Infants and Children (WIC) supplemental nutrition program). Northwestern University served as the data management site; no subjects were enrolled at this site. Institutional review board approval was obtained from each partner site (Emory, New York University, Northwestern, Northwestern, Northwestern, Northwestern, Northwestern, Northwestern, Northwestern,...)
Parents/legal guardians were consecutively approached by trained research assistants to determine eligibility. Those who met inclusion criteria were English or Spanish-speaking parents or legal guardians (≥18 years of age) who had a child ≤8 years of age that was presenting for care in the pediatric clinic. Parents also had to be primarily responsible for administering medications to their child, and could not have participated in a previous medication dosing study. Parents were excluded from participation if they had: 1) visual acuity worse than 20/50 (Rosenbaum Pocket Screener), 2) uncorrectable hearing impairment, or 3) if they or their child were too ill to participate. Written, informed consent was obtained from parents prior to participating in the study.

Once parents were enrolled, they were randomized to one of five groups which varied by the pairing of units of measurement used on the medication bottle label and on the dosing tool (Table 1; Figure 1). Randomization was blocked by site, in sets of 100 (20 per group for each of the 5 groups); a random number generator was used. Unit label/dosing tool combinations were selected to represent commonly seen standard practices. Consistent with pharmacy guidelines, teaspoon units on English language medication labels were translated for Spanish-language parents.\textsuperscript{21,22} For the purposes of this analysis, which only involved what was present on the label, Groups 1 and 4 were collapsed into one group which had “mL-only” labels. Group 2 had both mL and a “tsp” abbreviation. Group 3 had mL and “teaspoon” spelled out, and Group 5 had “teaspoon” units alone.

Parents were also randomized to receive medication labels with 3 different dose amounts (2.5, 5, 7.5 mL) and as part of the larger study, were asked to measure those amounts using 3 different dosing tools (2 types of oral syringes, and 1 dosing cup) (total of 9 trials).

### Assessments

Assessments were performed immediately following subject enrollment. Trained research assistants conducted interviews in English or Spanish, as per caregiver preference. The assessment involving choice of nonstandard dosing tool was conducted first; a structured survey was used subsequently to assess sociodemographic characteristics and health literacy. A gift card ($20) was provided to study subjects as a nominal incentive.

### Choice of Dosing Tool

At the beginning of the dosing assessment, parents were shown the first medication bottle label they were randomized to and asked “If you had all of these dosing tools at home, which of these would let you give your child the correct amount of medicine?” Parents were shown a response card with the following dosing tool names, accompanied by a photograph of the tool (kitchen teaspoon, kitchen tablespoon, dosing spoon, measuring spoon, dosing cup, dropper, oral syringe) (Figure 2); parents were able to select more than one. In addition, parents were asked if they would choose any other tool not shown on the card, with responses recorded verbatim. Parents who selected kitchen teaspoon or kitchen tablespoon were considered to have chosen a “nonstandard” dosing tool.
Health Literacy

Parent health literacy was assessed using the Newest Vital Sign (NVS),\textsuperscript{23} which is validated in English and Spanish. A score of 0 or 1 was considered to be “low” health literacy, reflecting a high likelihood of limited literacy; 2 or 3, “marginal” health literacy, reflecting possible limited literacy; and 4 to 6, adequate health literacy.

Sociodemographic Data and Child Health Status

The following sociodemographic data were collected: child age, gender; parent age, gender, relationship to child, marital status, income, country of birth, race/ethnicity, language, educational attainment. Child’s chronic disease status and associated medication use were assessed using questions from the Children With Special Health Care Needs screener, which were adapted to assess chronic disease and medicine use in any child in the household.\textsuperscript{24}

Statistical Analyses

Statistical analyses were performed using SAS software version (9.4, (SAS Institute, Inc, Cary, North Carolina). Descriptive statistics were calculated for each variable. Chi-square analyses were conducted to compare parent characteristics between randomization groups for categorical variables, while ANOVA and Kruskall-Wallis tests were used to compare differences between groups for continuous measurements. Similar analyses were performed to compare families who did and did not enroll in the study.

Chi-square analyses were used to compare nonstandard dosing tool choice within those groups where a teaspoon unit was present on the label (Groups 2, 3, 5) versus those groups where only mL was present on the label (Groups 1 and 4). Analyses were also used to compare nonstandard dosing tool choice by each group which had a teaspoon unit present on the label individually (Groups 2, 3, 5). Multiple logistic regression was performed, controlling for key study variables of label language and dose amount, which were established \textit{a priori}, and those characteristics found to be statistically different between randomization groups (i.e. health literacy). Stratified analyses and interaction tests were also performed by health literacy and by language.

RESULTS

Between August 26, 2013 and December 18, 2014, a total of 3116 parents were assessed for eligibility (Figure 3). Of these, 816 were not eligible based on one or more criteria, leaving 2300 eligible to complete the study. Ultimately, 2110 parents went on to enroll in the study and underwent randomization (74 parents ran out of time after they were assessed for eligibility and 116 refused to participate). Characteristics did not differ between subjects enrolled in the study and those who were eligible but did not enroll (p>0.05 for all characteristics). Two thousand and ninety-six parents completed the assessment of dosing tool preference and are included in this study analysis.

Characteristics of the study sample are shown in Table 2. Over half of parents were Hispanic, and a third Black, non-Hispanic. Nearly 80% of parents had an annual household
income <$40,000. The majority of parents fell into the lowest 2 levels of health literacy (36.0% low, 41.0% marginal, 23.0% adequate).

**Choice of Dosing Tool**

Parents who received medication labels containing “tsp” or “teaspoon” units (Groups 2, 3, and 5) were more likely to choose a nonstandard dosing tool compared to those parents who received medication labels containing only “mL” units (Groups 1 and 4) (27.7 vs. 8.3%, p<0.001; adjusted odds ratio (AOR)=4.4[95% CI 3.3–5.8]) (see Table 3); the odds of choosing a nonstandard tool varied based on whether “teaspoon” was spelled out or abbreviated on the label (“teaspoon”-alone: AOR=5.3[3.8–7.3]; “teaspoon” with mL: AOR=4.7[3.3–6.5]; “tsp” with mL: AOR=3.4[2.4–4.7]). There was no statistically significant difference between parents who received labels with “teaspoon” spelled out with and without mL present (Group 3 vs. 5). Odds of choosing a kitchen spoon was statistically significantly lower when the “tsp” abbreviation was present compared to when the “teaspoon” was spelled out (Group 2 vs. 3: p=0.04; Group 2 vs. 5: p=0.005). There was no difference by site for group on tool preference.

**Health Literacy and Choice of Nonstandard Dosing Tool**

Parents with low health literacy had a higher odds of choosing a nonstandard dosing tool compared to parents with adequate health literacy (25.0% vs. 18.1%; AOR=1.6 [1.2–2.2]) (see Table 4). There were no significant interactions between label type and health literacy (p=0.2).

**Language and Choice of Nonstandard Dosing Tool**

There was no statistically significant difference in choice of nonstandard dosing tool by language (p=0.1) (see Table 4). In addition, no significant interactions were found between label type and language (p=0.6).

**DISCUSSION**

This study is the first to examine the impact of medication label terms (units of measurement) on parents’ choice of dosing tools. We found that labels with “tsp” or “teaspoon” were associated with an increased likelihood of a parent choosing a nonstandard kitchen spoon, compared to when metric ‘mL’ units were used. Odds of choosing a nonstandard tool were higher when the word “teaspoon” was spelled out, compared to when it was abbreviated (“tsp”). These findings remained consistent across parent health literacy and language groups, as well as across sites.

Among parents who were shown labels with “tsp” or “teaspoon” – nearly a third considered using a kitchen spoon, compared with less than 10% of parents who were shown labels with “milliliter” or “mL.” This 20% decrease in absolute risk is likely to be significant, as it is well-established that use of nonstandard spoons increases the likelihood of parent dosing errors;15,16 use of standard tools, such as oral syringes and droppers, which contain markings to help parents dose accurately, is endorsed by numerous organizations, including the AAP and FDA.3,9,12,25
Some findings may appear intuitive. Choosing a kitchen spoon is an obvious and logical choice when presented with the word “teaspoon” or its abbreviation. Within a traditionally non-metric environment, many US parents may be unaware of the official metric equivalent for one teaspoon (5 mL). A parent’s choice of dosing tool is likely to be driven by a desire to seek concordance between the prescribed or recommended dose and selection of a tool which would allow for measurement of that dose.

Unexpectedly, the precise language on the label had an impact on parent choice of nonstandard tools. When the word “teaspoon” was spelled out rather than abbreviated (“tsp”), parents were more likely to choose a nonstandard kitchen spoon. This may be because the “tsp” abbreviation may be less familiar than words like “tablespoon” or “teaspoon”. The abbreviation might also be more likely to direct parents to think about the “tsp” units on standard dosing tools. IAlso of interest, a label with “mL” alongside “teaspoon” did not reduce parent’s likelihood of choosing a kitchen spoon. This further suggests a parent’s propensity to seek out the familiar.

Interestingly, there was a lack of significant effect modification by parent literacy or language. While those with low health literacy were slightly more likely to choose a nonstandard dosing tool, parents in each health literacy group had similar odds of choosing a kitchen spoon when presented with labels with teaspoon units vs. “mL”-only labels. Still, even with “mL”-only labels, more than 1 in 10 parents with low health literacy chose a kitchen spoon. Interestingly, parents’ English language proficiency was not associated with choice of nonstandard kitchen spoons. Perhaps, parents whose primary language is Spanish may have prior knowledge and orientation to metric measurements, particularly if they immigrated from one of the majority of nations that use metric standards. Nonetheless, parents across language levels benefited from avoidance of teaspoon units on labels.

Notably, our study was conducted in three geographically distinct sites, and there was no difference in the impact of group on tool preference by site. These findings suggest that avoidance of teaspoons on labels is likely to benefit parents across the US.

This study has limitations common for a cross-sectional analysis of data from a controlled experiment. We used a “mock” medication label for a hypothetical child; our findings therefore might not reflect the actual dosing tool choices parents would make at home when medications are prescribed to their own children. Dosing tool choices were purposefully shown as photographs, with markings not clearly identifiable, as we sought to determine whether parents would choose a specific dosing tool type; we did not want parents to be distracted by the individual markings of each tool. Also, images of kitchen spoons were the first ones on the page, followed by a range of standardized dosing tools, which may have affected which choices parents selected. There are also limitations resulting from the study parameters we used. We restricted testing to 4 commonly seen label variations. Other variations (e.g. “tsp” alone, tablespoon units) were not assessed, and only one label design format was used. Furthermore, this study was conducted with parents who speak English and Spanish and who brought their children to university-affiliated pediatric clinics which serve predominantly low income families; results may not be generalizable. We note, however, that our sample included a disproportionate number of lower literate parents, many
of who were from more medically vulnerable communities. We purposefully targeted these patients given their higher risk for misunderstanding medication instructions and unintentionally misusing medications.

**CONCLUSION**

Four decades later, despite recommendations from the AAP that parents not use nonstandard kitchen spoons to dose,\(^{12}\) parents still commonly consider the use of nonstandard spoons to administer medications. Our study findings show that the units of measurement used on prescription medication labels heavily influences parent choice of liquid medication dosing tool; when teaspoon units were present on the label, parents were significantly more likely to choose a nonstandard kitchen spoon. The recently proposed AAP and CDC-endorsed mL-exclusive system seeks to limit the use of terms like “teaspoon” and “tablespoon”\(^{8}\). We found in our study, however, that even with “mL”-only labels, nearly 1 in 10 parents still considered using nonstandard tools, indicating that additional strategies might be needed to further reduce kitchen spoon use and familiarize parents with proper dosing. Health literacy-informed communication strategies such as demonstration and teachback/showback using recommended dosing tools would help providers reinforce the idea that standardized dosing tools are preferable to kitchen spoons.\(^{26–28}\) Developing processes and policies in both clinical settings and pharmacies to support the provision of dosing tools to families would further reinforce this concept.\(^{26,27}\) Because the US has a longstanding reliance on non-metric units, a move to an “mL”-only medication label will likely require a public health campaign to ensure that a move towards eliminating that which is familiar does not drive further disparities, especially among parents with low health literacy.

**Acknowledgments**

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**References**


22. New York State Education Department Office of the Professions. Article 137, Pharmacy. Interpretation and translation requirements for prescription drugs and standardized medication labeling. Vol §68292015


WHAT'S NEW

Parents who received prescription labels with teaspoon units had over 4 times the odds of choosing a nonstandard kitchen spoon. Findings support avoidance of teaspoon terms on labels, with benefits likely to be seen across health literacy and language groups.
FIGURE 1.
Example of Medication Label (Group 3)
FIGURE 2.
Dosing Tool Card Shown to Parents
FIGURE 3.
Study Enrollment Flow Chart

*Ran out of time after signing consent*
**TABLE 1**

Comparison of Randomization Group Characteristics

<table>
<thead>
<tr>
<th>Group</th>
<th>Unit(s) Used on Medication Bottle Label</th>
<th>Example of how 5 mL or 1 tsp amount displayed on Label</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>English</td>
</tr>
<tr>
<td>1&amp;4</td>
<td>mL</td>
<td>5 mL</td>
</tr>
<tr>
<td>2</td>
<td>mL, tsp</td>
<td>5 mL (1 tsp)</td>
</tr>
<tr>
<td>3</td>
<td>mL, teaspoon</td>
<td>5 mL (1 teaspoon)</td>
</tr>
<tr>
<td>5</td>
<td>teaspoon</td>
<td>1 teaspoon</td>
</tr>
</tbody>
</table>

*Full study involves variations in pairing of unit on label and dosing tool. Findings from this study involved only the bottle label; Groups 1 and 4 were exposed to the same label.*

*Acad Pediatr. Author manuscript; available in PMC 2017 November 01.*
TABLE 2

Characteristics of Study Population, by Randomization Group (n=2096)

<table>
<thead>
<tr>
<th>Label unit</th>
<th>Entire Population</th>
<th>Groups 1 &amp; 4</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=834</td>
<td>N=423</td>
<td>N=421</td>
<td>N=418</td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) or n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Child Characteristics**

- **Age, mean (SD), y**
  - Entire Population: 2.1 (2.2)
  - Groups 1 & 4: 2.1 (2.2)
  - Group 2: 2.3 (2.2)
  - Group 3: 2.0 (2.2)
  - Group 5: 1.9 (2.1)
  - p-value: 0.1

- **Gender, n(%)**
  - Female
    - Entire Population: 983 (46.9)
    - Groups 1 & 4: 385 (46.2)
    - Group 2: 209 (49.4)
    - Group 3: 196 (46.6)
    - Group 5: 193 (46.2)
    - p-value: 0.7

- **Chronic medical problem treated with medication, n (%)**
  - Entire Population: 353 (17.3)
    - Groups 1 & 4: 151 (18.6)
    - Group 2: 64 (15.5)
    - Group 3: 64 (15.7)
    - Group 5: 74 (18.2)
    - p-value: 0.4

**Parent Characteristics**

- **Age, mean (SD), y**
  - Entire Population: 29.7 (7.3)
    - Groups 1 & 4: 29.8 (7.3)
    - Group 2: 30.3 (7.5)
    - Group 3: 29.1 (7.1)
    - Group 5: 29.5 (7.5)
    - p-value: 0.2

- **Relationship to Child, n(%)**
  - Mother
    - Entire Population: 1876 (89.5)
      - Groups 1 & 4: 750 (89.9)
      - Group 2: 382 (90.3)
      - Group 3: 377 (89.5)
      - Group 5: 367 (87.8)
      - p-value: 0.6

- **Income, n (%)**
  - <$10,000
    - Entire Population: 497 (23.7)
      - Groups 1 & 4: 217 (26.0)
      - Group 2: 99 (23.4)
      - Group 3: 85 (20.2)
      - Group 5: 96 (23.0)
      - p-value: 0.02
  - $10,000–$19,999
    - Entire Population: 553 (26.4)
      - Groups 1 & 4: 201 (24.1)
      - Group 2: 114 (27.0)
      - Group 3: 143 (34.0)
      - Group 5: 95 (22.7)
  - $20,000–$39,999
    - Entire Population: 584 (27.9)
      - Groups 1 & 4: 221 (26.5)
      - Group 2: 122 (28.8)
      - Group 3: 107 (25.4)
      - Group 5: 134 (32.1)
  - ≥$40,000
    - Entire Population: 255 (12.2)
      - Groups 1 & 4: 111 (13.3)
      - Group 2: 47 (11.1)
      - Group 3: 48 (11.4)
      - Group 5: 49 (11.7)
  - Unknown/Missing
    - Entire Population: 207 (9.9)
      - Groups 1 & 4: 84 (10.1)
      - Group 2: 41 (9.7)
      - Group 3: 38 (9.0)
      - Group 5: 44 (10.5)

- **Country of birth: Non-US Born, n (%)**
  - Entire Population: 1027 (49.4)
    - Groups 1 & 4: 403 (48.6)
    - Group 2: 228 (54.2)
    - Group 3: 200 (48.2)
    - Group 5: 196 (47.3)
    - p-value: 0.2

- **Race/Ethnicity, n (%)**
  - Hispanic
    - Entire Population: 1136 (54.7)
      - Groups 1 & 4: 465 (56.2)
      - Group 2: 225 (53.6)
      - Group 3: 223 (54.0)
      - Group 5: 223 (53.9)
      - p-value: 0.8
<table>
<thead>
<tr>
<th></th>
<th>Entire Population</th>
<th>Groups 1 &amp; 4</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 5</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Label unit</strong></td>
<td></td>
<td>mL</td>
<td>mL/tsp</td>
<td>mL/teaspoon</td>
<td>teaspoon</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=834</td>
<td>N=423</td>
<td>N=421</td>
<td>N=418</td>
<td></td>
</tr>
<tr>
<td><strong>Mean (SD) or n(%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>79 (3.8)</td>
<td>32 (3.9)</td>
<td>14 (3.3)</td>
<td>15 (3.6)</td>
<td>18 (4.3)</td>
<td></td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>605 (33.5)</td>
<td>275 (33.2)</td>
<td>146 (34.8)</td>
<td>134 (32.4)</td>
<td>140 (33.8)</td>
<td></td>
</tr>
<tr>
<td>Other, non-Hispanic</td>
<td>165 (8.0)</td>
<td>56 (6.8)</td>
<td>35 (8.3)</td>
<td>41 (9.9)</td>
<td>33 (8.0)</td>
<td></td>
</tr>
<tr>
<td>Language Spanish, n (%)</td>
<td>733 (35.0)</td>
<td>302 (36.2)</td>
<td>157 (37.1)</td>
<td>133 (31.6)</td>
<td>141 (33.7)</td>
<td>0.3</td>
</tr>
<tr>
<td>Education, n (%)&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than HS Graduate</td>
<td>633 (30.5)</td>
<td>258 (31.2)</td>
<td>136 (32.4)</td>
<td>116 (28.0)</td>
<td>123 (29.7)</td>
<td>0.7</td>
</tr>
<tr>
<td>HS Graduate or Equivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher than HS Graduate</td>
<td>769 (37.0)</td>
<td>303 (36.6)</td>
<td>144 (34.3)</td>
<td>161 (38.8)</td>
<td>161 (38.9)</td>
<td></td>
</tr>
<tr>
<td>Health Literacy, n (%)&lt;sup&gt;f&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inadequate Literacy</td>
<td>741 (36.0)</td>
<td>306 (37.4)</td>
<td>139 (33.4)</td>
<td>142 (34.6)</td>
<td>154 (37.2)</td>
<td>0.02</td>
</tr>
<tr>
<td>Marginal Literacy</td>
<td>843 (41.0)</td>
<td>341 (41.7)</td>
<td>191 (45.9)</td>
<td>167 (40.7)</td>
<td>144 (34.8)</td>
<td></td>
</tr>
<tr>
<td>Adequate Literacy</td>
<td>474 (23.0)</td>
<td>171 (20.9)</td>
<td>86 (20.7)</td>
<td>101 (24.6)</td>
<td>116 (28.0)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Missing for 59 children overall (22 in groups 1 and 4, 11 in group 2, 14 in group 3, and 12 in group 5).

<sup>b</sup> Missing for 17 parents (5 in groups 1 and 4, 2 in group 2, 6 in group 3, and 4 in group 5).

<sup>c</sup> Missing for 21 parents (6 in groups 1 and 4, 3 in group 2, 8 in group 3, and 4 in group 4).

<sup>d</sup> Language of survey administration.

<sup>e</sup> Missing for 20 parents (7 in groups 1 and 4, 3 in group 2, 6 in group 3, 4 in group 5).

<sup>f</sup> Health literacy measured using Newest Vital Sign (NVS). Data missing for 38 subjects who did not complete the NVS (16 in groups 1 and 4, 7 in group 2, 11 in group 3, and 4 in group 5).
### TABLE 3
Parent Choice of Nonstandard Tool by Randomization Group, Health Literacy, and Language (n=2096)

<table>
<thead>
<tr>
<th>Group #</th>
<th>Label Unit(s)</th>
<th>% parents choosing non-standard tool</th>
<th>p-value</th>
<th>AOR c</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 &amp; 4</td>
<td>mL</td>
<td>69 (8.3)</td>
<td>&lt;0.001</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>2</td>
<td>mL/tsp</td>
<td>94 (22.2)</td>
<td>3.4</td>
<td>2.4–4.7</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>mL/teaspoon</td>
<td>122 (29.0)</td>
<td>4.7</td>
<td>3.3–6.5</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>teaspoon</td>
<td>133 (31.8)</td>
<td>5.3</td>
<td>3.8–7.3</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Health Literacy</td>
<td></td>
<td>Low</td>
<td>185 (25.0)</td>
<td>&lt;0.001</td>
<td>1.6</td>
<td>1.2–2.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marginal</td>
<td>138 (16.4)</td>
<td>0.9</td>
<td>0.7–1.3</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adequate</td>
<td>86 (18.1)</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>Language</td>
<td></td>
<td>English</td>
<td>256 (18.8)</td>
<td>0.07</td>
<td>1.0</td>
<td>Ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spanish</td>
<td>162 (22.1)</td>
<td>1.1</td>
<td>0.9–1.5</td>
<td>0.3</td>
</tr>
</tbody>
</table>

*Chi square.

b Full model adjusting for group, dose amount, language, health literacy.

c Statistically significant differences found for Group 2 vs. 3 [AOR (95% CI): 0.7 (0.5–0.99), p=0.04] and Group 2 vs. 5 [AOR (95% CI): 0.6 (0.5–0.9), p=0.005]; No statistically significant difference found between Group 3 vs. 5 [AOR (95% CI): 0.9 (0.7–1.2), p=0.4].

d Health literacy assessed using the Newest Vital Sign (NVS).
### TABLE 4
Parent Choice of Nonstandard Tool by Randomization Group, Stratified by Health Literacy and Language

<table>
<thead>
<tr>
<th>Group #</th>
<th>Label Unit(s)</th>
<th>% parents choosing non-standard tool</th>
<th>AOR(^b)</th>
<th>95% CI</th>
<th>p-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>By Health Literacy(^c,d)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Health Literacy (n=741)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 &amp; 4</td>
<td>mL</td>
<td>41 (13.4)</td>
<td>&lt;0.001</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>2</td>
<td>mL/tsp</td>
<td>38 (27.3)</td>
<td>2.5</td>
<td>1.5–4.1</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>mL/teaspoon</td>
<td>50 (35.2)</td>
<td>3.7</td>
<td>2.3–6.0</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>teaspoon</td>
<td>56 (36.4)</td>
<td>3.8</td>
<td>2.4–6.1</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Marginal Health Literacy (n=843)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 &amp; 4</td>
<td>mL</td>
<td>17 (5.0)</td>
<td>&lt;0.001</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>2</td>
<td>mL/tsp</td>
<td>43 (22.5)</td>
<td>5.5</td>
<td>3.0–10.0</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>mL/teaspoon</td>
<td>40 (24.0)</td>
<td>6.1</td>
<td>3.3–11.1</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>teaspoon</td>
<td>38 (26.4)</td>
<td>6.8</td>
<td>3.7–12.5</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Adequate Health Literacy (n=474)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 &amp; 4</td>
<td>mL</td>
<td>10 (5.9)</td>
<td>&lt;0.001</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>2</td>
<td>mL/tsp</td>
<td>12 (14.0)</td>
<td>2.7</td>
<td>1.1–6.4</td>
<td>0.03</td>
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</tr>
<tr>
<td>3</td>
<td>mL/teaspoon</td>
<td>27 (26.7)</td>
<td>5.7</td>
<td>2.6–12.5</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>teaspoon</td>
<td>37 (31.9)</td>
<td>7.7</td>
<td>3.6–16.3</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td><strong>By Language(^e)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English (n=1363)</td>
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<td></td>
</tr>
<tr>
<td>1 &amp; 4</td>
<td>mL</td>
<td>35 (6.6)</td>
<td>&lt;0.001</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>2</td>
<td>mL/tsp</td>
<td>58 (21.8)</td>
<td>4.1</td>
<td>2.6–6.5</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>mL/teaspoon</td>
<td>81 (28.1)</td>
<td>5.5</td>
<td>3.5–8.5</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Group #</td>
<td>Label Unit(s)</td>
<td>n (%)</td>
<td>p-value</td>
<td>AOR$^b$</td>
<td>95% CI</td>
<td>p-value</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>-------------</td>
<td>---------</td>
<td>---------</td>
<td>------------</td>
<td>---------</td>
</tr>
<tr>
<td>1&amp;4</td>
<td>mL</td>
<td>34 (11.3)</td>
<td>&lt;0.001</td>
<td>1.0</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>2</td>
<td>mL/asp</td>
<td>36 (22.9)</td>
<td>2.5</td>
<td>1.5–4.3</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>mL/teaspoon</td>
<td>41 (30.8)</td>
<td>3.7</td>
<td>2.2–6.2</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>teaspoon</td>
<td>51 (36.2)</td>
<td>4.6</td>
<td>2.7–7.5</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

$^a$Chi square.

$^b$Models by health literacy adjusting for group, dose amount, language; Models for language adjusting for group, dose amount, health literacy.

$^c$Health literacy assessed using the Newest Vital Sign (NVS).

$^d$Group by health literacy interaction non-significant (p=0.2).

$^e$Group by language interaction non-significant (p=0.6)