Evaluation of Consistency in Dosing Directions and Measuring Devices for Pediatric Nonprescription Liquid Medications

H. Shonna Yin, MD, MS
Michael S. Wolf, PhD, MPH, MA
Benard P. Dreyer, MD
Lee M. Sanders, MD, MPH
Ruth M. Parker, MD

Context  In response to reports of unintentional drug overdoses among children given over-the-counter (OTC) liquid medications, in November 2009 the US Food and Drug Administration (FDA) released new voluntary industry guidelines that recommend greater consistency and clarity in OTC medication dosing directions and their accompanying measuring devices.

Objective  To determine the prevalence of inconsistent dosing directions and measuring devices among popular pediatric OTC medications at the time the FDA’s guidance was released.

Design and Setting  Descriptive study of 200 top-selling pediatric oral liquid OTC medications during the 52 weeks ending October 30, 2009. Sample represents 99% of the US market of analgesic, cough/cold, allergy, and gastrointestinal OTC oral liquid products with dosing information for children younger than 12 years.

Main Outcome Measures  Inclusion of measuring device, within-product inconsistency between dosing directions on the bottle’s label and dose markings on enclosed measuring device, across-product use of nonstandard units and abbreviations, and presence of abbreviation definitions.

Results  Measuring devices were packaged with 148 of 200 products (74.0%). Within this subset of 148 products, inconsistencies between the medication’s dosing directions and markings on the device were found in 146 cases (98.6%). These included missing markings (n=36, 24.3%) and superfluous markings (n=120, 81.1%). Across all products, 11 (5.5%) used atypical units of measurement (eg, drams, cc) for doses listed. Milliliter, teaspoon, and tablespoon units were used for doses in 143 (71.5%), 155 (77.5%), and 37 (18.5%) products, respectively. 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.

Conclusion  At the time the FDA released its new guidance, top-selling pediatric OTC liquid medications contained highly variable and inconsistent dosing directions and measuring devices.

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For editorial comment see p 2641.
Box. Food and Drug Administration Recommendations to Industry for Over-the-Counter Liquid Medications

Presence and Type of Measuring Device

- Measuring devices should be included for all over-the-counter liquid medications.

Within-Product Inconsistency Between Labeled Dosing Directions and Measuring Device

- Devices should be marked with calibrated units of measure that are the same as those specified in the labeled dosage directions.
- Abbreviations used on devices should be the same as those used in directions.
- Devices should not bear extraneous or unnecessary markings.
- Devices should not be significantly larger than the largest dose described.

Across-Product Variability

- Abbreviations should conform to international or national standards.
- Abbreviations should be defined on devices and/or label directions.
- Decimals and fractions should be used with care and conform to recommendations, including use of leading zeros before decimal points to avoid 10-fold errors and use of small font size for numerals in fractions (eg, ½ rather than 1/2).

Consumer Guidance on Appropriate Use

- Consumers should be encouraged to use measuring devices only with the products with which they are included.
- Consumers should be directed to consult a health care provider when a physician-recommended dose is not marked on the enclosed measuring device.
- Usability studies should be done to confirm understandability and accurate use.

METHODS
Selection of Pediatric Nonprescription Liquid Medication Products

The inclusion criteria were as follows: medication was a liquid to be taken orally; dosing directions were provided for a child younger than 12 years; and the product was categorized as analgesic, cough/cold, allergy, or gastrointestinal. Data for US retail stores, excluding Internet and phone orders, for the top-selling nonprescription medications categorized as analgesic, cough/cold, allergy, or gastrointestinal products for the 52 weeks ending October 30, 2009, were obtained from the IMS Health Medicine Cabinet database. IMS Health is a provider of market intelligence to pharmaceutical and health care industries; the FDA and other professional health care associations do not collect or provide this type of information. The list of medications provided by IMS Health was ordered from highest to lowest market share (based on number of products sold). Products not meeting inclusion criteria, or which were discontinued, were excluded, and the top medications that made up 99% of US market share for these products were chosen for the final sample.

The list included products classified as “private label,” which did not identify a specific manufacturer and represent a number of store-brand nonprescription medications of the same type sold by chain and retail pharmacies. Because no specific identifying information was provided (eg, “Private label Cough/Cold; Cold relief/analges”), a representative product was selected from 1 of 4 top US retail pharmacy chains for each of the private-label products listed (ie, Walgreens, CVS, Rite Aid, Walmart).3,4

Identification of Variables for Analysis

Product packaging was independently assessed by 2 investigators (H.S.Y. and Jennifer King) following the FDA’s criteria (Box). A third investigator (B.P.D.) reviewed any instances in which there was not agreement between raters, and final results reflected the agreement of 2 of the 3 investigators.

The following data were abstracted by the 2 investigators from the product label and any enclosed measuring device: presence and type of device, numeric dose amounts (eg, 0.5 mL, 1½ tsp), exact text and abbreviations used to specify units of measurement (eg, mL, teaspoonful, cc) associated with doses, presence of definitions for abbreviations of units of measurement (eg, tsp=teaspoon, tablespoons [TBSP]), and format of decimals and fractions. For all products listing a numeric dose amount less than 1 in decimal format, doses were assessed for use or nonuse of a leading zero before the decimal point (ie, 0.₅ or .₅). For products using fractions, doses were categorized as using small numeral font size offset text (eg, ½) or horizontally displayed regular-size text (eg, 1/2).

Products were also examined for the presence of elements designed to guide consumers on appropriate use, including (1) a strategy to ensure that the measuring device is used only with the associated product (eg, inclusion of written statement or presence of a mechanism to secure the device to its product, such as a dropper that also serves as a cap for the bottle), and (2) a statement warning about appropriate use of the measuring device if the physician’s recommended dose does not match doses marked on the device.

Outcome Measurement and Analysis Plan

Data were analyzed using SPSS version 17.0 statistical software (SPSS Inc, Chicago, Illinois). A 2-tailed P value ≤.05 was considered to be statistically significant.

Analyses were performed to document conformity with the draft FDA guidance.1 For each product packaged with a device, descriptive analyses were performed to document within-product inconsistency between the dosing directions on the bottle label and enclosed measuring device. For all
products, descriptive analyses were performed to document across-product variability in units of measurement, abbreviations, and formats of numeric text as well as whether the product provided consumer guidance on appropriate use.

**Within-Product Inconsistency.** For each product packaged with a measuring device, evidence of inconsistency was defined as any of the following: device missing necessary markings (ie, dose specified in directions not marked on device), superfluous markings on device (ie, dose marked on device but not specified in directions), or inconsistent use of units of measurement (ie, text used for unit of measurement on device different from that used in label directions).

**Across-Product Variability.** Across all products in the sample, variability was assessed for each of the following: atypical unit of measurement (ie, other than milliliter, teaspoon, or tablespoon), nonstandard abbreviations of the unit of measurement (mL is the standard abbreviation for milliliter used by the Joint Commission and the US Pharmacopoeia; tsp is the FDA-recommended standard abbreviation for teaspoon; no standard abbreviation for tablespoon exists but TBSP is most commonly used), no definition for an abbreviated unit of measurement, and nonstandard use of numeric text (ie, leading zero before a decimal point is the Joint Commission standard to avoid 10-fold errors, use of small numeral font size offset text format [eg, ½2] is the FDA-recommended standard).

The degree of interrater agreement for each outcome of interest was determined by calculation of the κ statistic. Subgroup comparisons were preplanned. χ² or Fisher exact tests (2-tailed) were performed to examine associations between inclusion of measuring device and manufacturer type, medication category, and targeted age group, and to quantify the strength of associations between the presence of inconsistency and manufacturer type, medication category, and targeted age group.

Manufacturers were categorized as large (>2.5% market share each), small (<1% of market share each), or private label (store brand). Medications were categorized as analgesic, cough/cold, allergy, gastrointestinal, or combination products (ie, products containing analgesic and cough/cold ingredients). Targeted age group was characterized by whether dosage directions were provided for infants and/or children only or included adults.

No adjustment was made for multiple comparisons. Using the Bonferroni adjustment, the corrected level of significance would have been .008. Because all of the significant results were significant at P < .001, no adjustment was necessary.

**RESULTS**

The process for product selection began with a preliminary list of 732 OTC products generated by IMS Health (Figure 1). The final sample consisted of 200 pediatric OTC analgesic, cough/cold, allergy, and gastrointestinal products, including 58 private-label products, that represented 99% of the US market share for these products.

Product characteristics are described in Table 1. Baseline conformity with the recommendations outlined in the FDA's voluntary guidelines is summarized in Table 2. Across outcomes of interest, interrater agreement was high (κ = 0.91-1.00). Six outcomes without a κ of 1 (involving a total of 9 products) required assessment by the third rater.

A standardized measuring device was provided for 148 products (74.0%). Dosing cups were provided for 83.1%, droppers were provided for 13.5%, and 2.7% had oral syringes. Small manufacturers were less likely to include a dosing device (37/80, 46.3%) compared with large manufacturers (59/62, 95.2%) or private-label companies (52/58, 89.7%) (χ² = 53.8, P < .001). Gastrointestinal products were least likely to include a measuring device (21/42, 50.0%) compared with analgesics (22/23, 95.5%), cough/cold products (64/90, 71.1%), allergy medications (18/20, 90.0%), and combination products (23/25, 92.0%) (χ² = 25.4, P < .001).

Products with a target age range that included only infants and children were more likely to include a measuring device (74/78, 94.9%) compared with products with dosing instructions for adults (74/122, 60.7%) (χ² = 29.0, P < .001).

**Figure 1. Product Selection**

[Diagram showing product selection process]

We requested from IMS Health a list of over-the-counter analgesic, cough/cold, allergy, and gastrointestinal products. IMS Health performed the initial review to remove some known adult-only and nonliquid medications, resulting in the first list of 732 products.

**Table 1. Product Characteristics (N = 200)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Products, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer typeᵃ</td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>80 (40.0)</td>
</tr>
<tr>
<td>Large</td>
<td>62 (31.0)</td>
</tr>
<tr>
<td>Private label</td>
<td>58 (29.0)</td>
</tr>
<tr>
<td>Medication type</td>
<td></td>
</tr>
<tr>
<td>Analgesic</td>
<td>23 (11.5)</td>
</tr>
<tr>
<td>Cough/cold</td>
<td>90 (45.0)</td>
</tr>
<tr>
<td>Allergy</td>
<td>20 (10.0)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>42 (21.0)</td>
</tr>
<tr>
<td>Combination productᵇ</td>
<td></td>
</tr>
<tr>
<td>Infants only</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>Infants and children only</td>
<td>27 (13.5)</td>
</tr>
<tr>
<td>Infants, children, and adultsᶜ</td>
<td>41 (20.5)</td>
</tr>
<tr>
<td>Children only</td>
<td>49 (24.5)</td>
</tr>
<tr>
<td>Children and adults onlyᶜ</td>
<td>81 (40.5)</td>
</tr>
</tbody>
</table>

ᵃManufacturers categorized as large (>2.5% market share each), small (<1% of market share each), or private label (store brand); includes 32 small manufacturers (total combined market share, 3.0%), 6 large manufacturers (total combined market share, 55.7%), and 4 private-label store brands (combined market share, 40.7%).

ᵇRefers to products containing both analgesic and cough/cold ingredients.

ᶜAny “adult” dosing category refers to combination of “infants, children, and adults” and “children and adults only.”
Nearly all products examined (98.6%) 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. Figures 2, 3, and 4 are examples selected to highlight inconsistencies between instructions and devices that may contribute to dosing errors. These problems were evident across manufacturers, medication types, and targeted age groups without significant differences.

Almost a quarter of products (24.3%) lacked necessary markings. Among the measuring devices, 81.1% included 1 or more superfluous markings. The text used

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### Table 2. Level of Industry Adherence in Study Sample With FDA Recommendations

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Relevant Product Sample</th>
<th>Rate Among Surveyed Products</th>
<th>( \chi^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>No standardized measuring device</td>
<td>All</td>
<td>52/200</td>
<td>26.0 (20.1-32.7)</td>
</tr>
<tr>
<td>Within-product inconsistency between directions and measuring device</td>
<td>Measuring device included</td>
<td>146/148</td>
<td>98.6 (95.2-99.8)</td>
</tr>
<tr>
<td>Inconsistent doses listed or marked</td>
<td>Measuring device included</td>
<td>122/148</td>
<td>82.4 (75.3-88.2)</td>
</tr>
<tr>
<td>Missing necessary markings on device</td>
<td>Measuring device included</td>
<td>36/148</td>
<td>24.3 (17.7-32.1)</td>
</tr>
<tr>
<td>Superfluous markings on device</td>
<td>Measuring device included</td>
<td>120/148</td>
<td>81.1 (73.8-87.0)</td>
</tr>
<tr>
<td>Inconsistent text used for unit of measurement</td>
<td>Milliliter, teaspoon, or tablespoon</td>
<td>121/136</td>
<td>90.0 (82.5-93.7)</td>
</tr>
<tr>
<td>Inconsistent text for milliliter</td>
<td>Milliliter on both label and device</td>
<td>40/78</td>
<td>51.3 (39.7-62.8)</td>
</tr>
<tr>
<td>Inconsistent text for teaspoon</td>
<td>Teaspoon on both label and device</td>
<td>91/105</td>
<td>86.7 (78.6-92.5)</td>
</tr>
<tr>
<td>Inconsistent text for tablespoon</td>
<td>Tablespoon on both label and device</td>
<td>6/7</td>
<td>85.7 (42.1-199.6)</td>
</tr>
<tr>
<td>Across-product variability</td>
<td>All</td>
<td>172/200</td>
<td>86.0 (80.4-90.5)</td>
</tr>
<tr>
<td>Atypical units of measurement (other than milliliter, teaspoon, or tablespoon)</td>
<td>All</td>
<td>11/200</td>
<td>5.5 (2.8-9.8)</td>
</tr>
<tr>
<td>“Nonstandard” abbreviations for unit of measurement</td>
<td>Abbreviation used for milliliter, teaspoon, or tablespoon</td>
<td>120/165</td>
<td>72.7 (65.3-79.4)</td>
</tr>
<tr>
<td>Any nonstandard abbreviation for milliliter (not mL)</td>
<td>Abbreviation used for milliliter</td>
<td>97/143</td>
<td>67.8 (59.5-75.4)</td>
</tr>
<tr>
<td>Any nonstandard abbreviation for teaspoon (not tsp)</td>
<td>Abbreviation used for teaspoon</td>
<td>69/110</td>
<td>62.7 (53.0-71.8)</td>
</tr>
<tr>
<td>Abbreviation used for tablespoon other than most common (not TBSP)</td>
<td>Abbreviation used for tablespoon</td>
<td>7/22</td>
<td>31.8 (13.9-54.9)</td>
</tr>
<tr>
<td>Missing ( \geq 1 ) definitions of abbreviations for unit of measurement (eg, tsp = teaspoon)</td>
<td>( \geq 1 ) Abbreviations used</td>
<td>163/165</td>
<td>98.8 (95.7-99.9)</td>
</tr>
<tr>
<td>Definitions present for abbreviation for unit of measurement</td>
<td>( \geq 1 ) Abbreviations used</td>
<td>152/165</td>
<td>92.1 (86.9-95.7)</td>
</tr>
<tr>
<td>Unclear use of numeric text (decimals/fractions)</td>
<td>Decimal dose ( \leq 1 ) or fraction used</td>
<td>78/147</td>
<td>51.7 (43.3-60.0)</td>
</tr>
<tr>
<td>No use of leading zeros before decimal for dose ( &lt; 1 )</td>
<td>Decimal dose ( &lt; 1 ) used</td>
<td>5/40</td>
<td>12.5 (4.2-26.8)</td>
</tr>
<tr>
<td>Use of large font size for numerals in fractions (eg, 1/2 instead of 1/2)</td>
<td>Fraction used</td>
<td>71/110</td>
<td>64.5 (54.9-73.4)</td>
</tr>
<tr>
<td>Lack of consumer guidance on appropriate use [a]</td>
<td>Measuring device included</td>
<td>148/148</td>
<td>100.0 (97.5-100.0)</td>
</tr>
<tr>
<td>No strategy to ensure measuring device used only with its product</td>
<td>Measuring device included</td>
<td>91/148</td>
<td>61.5 (53.1-69.4)</td>
</tr>
<tr>
<td>No statement that only enclosed device be used with its product</td>
<td>Measuring device included</td>
<td>92/148</td>
<td>62.2 (53.8-70.0)</td>
</tr>
<tr>
<td>No mechanism securing measuring device to product</td>
<td>Measuring device included</td>
<td>143/148</td>
<td>96.6 (92.3-98.9)</td>
</tr>
<tr>
<td>No warning about use of appropriate delivery device when physician-recommended doses do not match a dose amount marked on enclosed device</td>
<td>Measuring device included</td>
<td>148/148</td>
<td>100 (97.5-100.0)</td>
</tr>
</tbody>
</table>

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Abbreviations: CI, confidence interval; FDA, Food and Drug Administration.

\[a\] No. represents the number of products that do not adhere to the FDA recommendation; Total No. represents the total number of products relevant to the area of concern.

\[b\] Degree of interrater agreement for each outcome of interest determined by calculation of the \( \chi^2 \) statistic; product packaging was independently assessed by 2 investigators. No \( \chi^2 \) was calculated when No. Total No. = 1; however, there was 100% agreement between investigators in these instances.

\[c\] Any inconsistency between directions and measuring device with respect to doses listed or marked, or text used for unit of measurement.

\[d\] For milliliter, teaspoon, and tablespoon units of measurement. Inconsistency was defined as different forms of the abbreviation used in the labeled dosing directions compared with that used on the measuring device, as well as when full text was used in one location and an abbreviation used in the other location.

\[e\] Across-product variability involving use of atypical units of measurement, use of nonstandard abbreviations for unit of measurement, absence of 1 or more definitions of abbreviations for unit of measurement, or unclear use of numeric text.

\[f\] Units of measurement considered atypical, including drams, cc, fluid ounces.

\[g\] Among products using a milliliter abbreviation, use of ml, mls, or ml rather than the standard term, mL.

\[h\] Among products using a teaspoon abbreviation, use of tsp or TSP rather than the standard term, tsp.

\[i\] Among products using a tablespoon abbreviation, use of Tbsp or Tbsp instead of TBSP (most commonly used abbreviation).

\[j\] Abbreviation used for milliliter, teaspoon, or tablespoon.

\[k\] Either no strategy to ensure measuring device used only with the product with which it was included, or no warning about use of appropriate delivery device when physician-recommended doses do not match a dose amount marked on the enclosed device.
for units of measurement was inconsistent between the product's label and the enclosed device in 89.0% of products.

A total of 11 products (5.5%) used nonstandard units of measurement, such as drams, cubic centimeters, or fluid ounces, as part of the doses listed. Across products, milliliter (143, 71.5%) and teaspoon (155, 77.5%) were the most frequently used units of measurement. Tablespoon was used in 37 products (18.5%). Seventy products (35.0%) specified all doses using 1 measurement unit (eg, milliliter only), 111 (55.5%) used 2 units (eg, milliliter and tablespoon only), and 19 (9.5%) specified doses using 3 or more different units of measurement.

Among the products that used milliliter, teaspoon, or tablespoon as units of measurement, most included 1 or more nonstandard abbreviations (Table 2). Among products using these abbreviations, only 2 provided definitions (eg, tsp=teaspoon) for all units of measurement used.

Of the 20.0% of products with a dose smaller than 1 presented in decimal format, 12.5% (5/40) did not use a leading zero. Of the 55.5% of products using fractions, 64.5% (71/110) used a nonstandard format.

More than half of products (62.2%) lacked a statement that the measuring device should only be used with its associated product. Only 5 products had an integrated device. No product contained a warning about how to use the device if a physician-recommended dose does not match the amounts marked on the device.

**COMMENT**

Our study reveals that at the time the FDA issued its voluntary guidance, almost all commonly purchased pediatric nonprescription liquid medications contained dosing directions and measuring devices that were highly variable...
and inconsistent. This study provides baseline data for assessing the degree and pace of industry conformity with the FDA’s voluntary guidelines. Given the high prevalence of baseline inconsistencies, regulatory oversight may be helpful in accelerating adoption of the guidance recommendations.

Several Institute of Medicine (IOM) reports have identified variable and poor-quality drug labeling as a leading root cause of consumer confusion with a high potential to lead to unintentional misuse of products.9,13 The priorities set forth by the FDA recommendations are designed to make pediatric drug dosing safer by reducing the variability and complexity of labels and associated measuring devices.

The lack of standardization of labeling and measuring devices has been cited as a contributor to confusion and medication error.7,9,14-16 National standards for medication-unit abbreviations (eg, mL) and numeric dosing formats (eg, leading zeros to prevent 10-fold errors) may contribute to safe medication use.5,6 The Joint Commission has made the adoption of these standards a key aim of hospital-based efforts to ensure patient safety.17 In the outpatient setting, lack of clear and consistent labels and devices impedes consumer ability to understand and correctly use medications.

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 US children are exposed to 1 or more medications in a given week, and more than half of these are OTC medications.18 Analgesics, cough/cold medications, antihistamines, and gastrointestinal drugs account for more than a quarter of medications administered to children.18 Liquid formulations are typically relied on for young children.

In addition, 1 in 3 US adults19 and at least 1 in 4 US parents20 have limited health literacy; an even greater percentage have poor numeracy.19 Decoding medication labels and understanding how to use measuring devices correctly are health literacy tasks that many find difficult.21-26 Studies report that 40% to 60% of parents make errors when administering medications to their children,21,27-30 with caregivers who have low health literacy at greatest risk.20,21 Understanding instructions for nonprescription medications can be particularly problematic for consumers, who typically rely on their own health literacy skills to determine how to correctly administer an OTC medication, without counseling from a clinician.32 Supporting consumer comprehension by providing clear, consistent, and standardized information increases the likelihood that consumers can safely and effectively use OTC medications.

Our study documents a high prevalence of deficits in medication labeling and measuring devices within the areas highlighted in the FDA guidance. Specifically, problems were identified in 3 critical areas.

First, a standardized measuring device should be included with all nonprescription liquid products. Failure to use a measuring device for nonprescription products has been cited as a contributor to clinically significant dosing errors in children.7 Although it is well established that use of a standardized device instead of a kitchen spoon decreases error,33-37 further evaluation is needed to examine which type of device should be included. Currently, dosing cups are the most common devices enclosed. Two recent studies have raised concerns about parents’ ability to dose accurately with cups. More than half made errors in dosing, primarily overdosing.31,38

Second, within each product, consistency should be ensured between the labeled dosing directions and markings on the associated measuring device. Devices that lack necessary markings make it harder to administer the correct dose. Devices with superfluous markings, especially of doses larger than those listed in the directions, raise the potential for overdosing. Minimizing markings on the device to only those relevant to the recommended doses is 1 strategy that may decrease medication errors.39,40 Limiting doses to those associated with 1 single unit of measurement on a measuring device that matches the units on the product label has also been recommended to decrease confusion.41

Although extra markings and additional units of measurement on a device may be helpful when clinicians rec-
ommend a dose not listed in the directions, nonprescription medications are generally used without guidance from a medical professional. There has been limited study of whether extra markings do in fact lead to a greater number of errors. It is recognized, however, that increased complexity in medical instructions may result in greater confusion. For example, significantly fewer patients understand multistep warning-label instructions on prescription labels compared with 1-step instructions, with those in the lowest literacy categories showing the greatest relative deficit with increased instruction complexity. Third, across products, measurement units, abbreviations, and numeric formats should be standardized. Using nonstandard units, such as cubic centimeters and drams, may lead to improper dosing, especially when a measuring device is not included or is misplaced. Even frequently used terms like teaspoon and tablespoon may be misinterpreted. Errors in understanding teaspoon vs tablespoon have been found to contribute to 3-fold errors. The use of abbreviations for teaspoon and tablespoon can be particularly confusing (eg, confusion between tsp and tbs). Moreover, terms like teaspoon and tablespoon endorse the use of kitchen spoons, which are known to be associated with measurement error.

There is also support for moving toward uniform implementation of metric volume measures for liquid medications. Recognizing the importance of this issue, the American Academy of Pediatrics recommends to parents that medications be dosed in milliliters, rather than in teaspoons or tablespoons.

Terms like teaspoon and tablespoon, while problematic, do have the advantage of providing the consumer with a grounded expression of the dose; a term like milliliter may not be as easy for consumers to interpret. Promoting milliliters as the standard unit for pediatric dosing will likely require education of the public on proper dosing and the importance of using standardized measuring devices with appropriate markings.

Use of decimal points without leading zeros may lead to unintended overdosing, as can use of nonrecommended fraction formats. Confusion with decimal points has been found to contribute to 10-fold overdose (eg, administration of 5 mL instead of 0.5 mL), and Joint Commission standards mandate the use of leading zeros in hospital prescriptions; however, no equivalent oversight exists for nonprescription medications. Additional study is needed to evaluate the implications of errors related to confusion about fraction formats.

There are limitations to our study. Although we found high rates of variability between labeled dosing instructions and measuring devices that could contribute to confusion, we did not directly assess consumer understanding and use of these products. To adequately address best practices under the FDA guidance, patient-centered research is needed to help define the impact of superfluous markings, abbreviations for units of measurement, and fraction formats. We also limited our data abstraction to those variables specified as areas of interest in the FDA guidance. Other aspects of packaging, such as the reading level, language, layout of directions, font type and size, use of pictograms, and use of color, may also be important but were not addressed.

This study also does not address other critical aspects of safe medication use such as weight versus age-based dosing, understanding of active ingredients, or maximum dosing. Finally, developing a comprehensive list of top-selling US nonprescription products was challenging. The list we obtained reported data related to private-label store-brand products in aggregate by product type rather than by individual product. However, the sample of products selected does represent 99% of US market share for pediatric OTC oral liquid analgesic, cough/cold, allergy, and gastrointestinal products.

CONCLUSIONS

The FDA introduced the OTC Drug Facts Panel in 1999 to increase the consistency and clarity of nonprescription medication instructions by setting a standard format and order for content in OTC medication labels. The FDA guidelines released in 2009 are another step toward the goal of providing clear, consistent, and actionable medication information to consumers. Our findings document that high levels of variability and inconsistency currently exist within medication labeling and measuring devices of OTC products. 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.

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