Adherence to Label and Device Recommendations for Over-the-Counter Pediatric Liquid Medications

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KEY WORDS
dosing error, unintentional overdose, medication label, dosing device, over-the-counter medicines

ABBREVIATIONS
CHPA—Consumer Healthcare Products Association
FDA—US Food and Drug Administration
OTC—over-the-counter

Dr Budnitz conceptualized the study, assisted with study design, drafted the initial manuscript, and reviewed and revised the manuscript; Ms Lovegrove assisted with study design, data collection, and drafting the manuscript, conducted the analyses, and reviewed and revised the manuscript; Ms Rose assisted with study design and data collection, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC). The Consumer Healthcare Products Association (CHPA) contacted member manufacturers and requested products to be sent directly to the CDC for review and provided SymphonyIRI InfoScan Tracking data on consumer sales from food, drug, and mass merchandisers. CHPA members did not contribute to data abstraction, data analysis, writing or revising the manuscript for publication.

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WHAT’S KNOWN ON THIS SUBJECT: Due to reports of unintentional overdoses, in 2011 the US Food and Drug Administration finalized voluntary recommendations for dosing devices included with over-the-counter (OTC) liquid medications. The Consumer Healthcare Products Association previously endorsed similar recommendations for devices and dosing directions.

WHAT THIS STUDY ADDS: This study assessed dosing directions and devices for national brand name OTC liquid medications, available after a voluntary FDA guidance, and found high levels of adherence to most recommendations. Further improvement efforts should prioritize recommendations directly addressing potential dosing errors.

abstract

OBJECTIVE: To reduce dosing errors when administering orally ingested over-the-counter liquid medications, the US Food and Drug Administration (FDA) and the Consumer Healthcare Products Association released voluntary recommendations for dosing directions and dosing devices. This study assessed recommendation adherence for national brand name orally ingested over-the-counter liquid pediatric analgesics/antipyretics and cough, cold, and allergy medications available after the FDA guidance was finalized in 2011 to identify and prioritize specific improvements to dosing directions and devices.

METHODS: Recommendations were categorized as top tier or low tier based on potential to directly address ≥3-fold dosing errors. Two independent reviewers assessed dosing directions and accompanying dosing devices for adherence to recommendations.

RESULTS: Of 68 products, 91% of dosing directions and 62% of dosing devices adhered to all top tier recommendations; 57% of products adhered to every top tier recommendation, and 93% adhered to all or all but one. A dosing device was included with all products. No dosing directions used atypical volumetric units (eg, drams), and no devices used volumetric units that did not appear in dosing directions. Six products used trailing zeros or failed to use leading zeros with decimal doses; eight did not use small font for fractions. Product adherence to low tier recommendations ranged from 26% to 91%.

CONCLUSIONS: Products adhered to most recommendations in the final FDA guidance and Consumer Healthcare Products Association guideline, suggesting that these voluntary initiatives promote adherence to recommendations. Improving adherence to recommendations should be prioritized based on potential to reduce harm. Pediatrics 2014;133:e283–e290
In response to reports of unintentional overdoses of orally ingested over-the-counter (OTC) liquid medications due to dosing devices with markings that were inconsistent or incompatible with labeled dosing directions, the US Food and Drug Administration (FDA) released a draft guidance for industry.1 This voluntary guidance, “Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products” (hereafter “FDA Guidance”), finalized in May 2011, outlines specific recommendations for aligning dosing devices with the accompanying dosing directions for orally ingested OTC liquid medications.2 Because many OTC liquid medications are intended for pediatric use, minimizing potential errors during dose measurement and administration by caregivers is a key focus of the guidance.

In 2009, concurrent to the initial draft FDA Guidance, the Consumer Healthcare Products Association (CHPA), a trade organization representing OTC medication manufacturers, released a voluntary guideline, “Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤12 years of Age” (hereafter “CHPA Guideline”), to standardize volumetric measures used in dosing directions as well as devices.3 The following year, using a sample of “baseline” products, Yin et al4 reported the concerning finding that 98.8% of evaluated OTC liquid medications had “inconsistencies” between dosing directions and device markings.

We assessed adherence to recommendations in the final FDA Guidance and CHPA Guideline in a sample of national brand name orally ingested OTC liquid medications with pediatric dosing available on the market after the final FDA Guidance was released. To prioritize areas for improvement in labeled dosing directions and accompanying devices, recommendations were categorized based on their potential to directly address ≥3-fold dosing errors.

**METHODS**

**Sample Selection**

In December 2011, CHPA member manufacturers were asked to submit sample products for all currently available orally ingested OTC liquid medications with specified dosing for children <12 years of age. National brand name analgesics/antipyretics and cough, cold, and allergy products (eg, PediaCare [Prestige Brands, Inc (Tarrytown, NY)], Robitussin [Pfizer, Inc (New York, NY)]) were included in the study; generic products, including those branded for specific retailers (eg, Walgreens, Wal-Mart) were not included. Market share of individual brands within each drug class was determined by using SymphonyIRI InfoScan Tracking (Chicago, IL) data on units sold to consumers from food, drug, and mass merchandisers (excluding Wal-Mart) for the 1-year period ending January 22, 2012.

**Definitions**

Drug classification (analgesics/antipyretics or cough, cold, and allergy products) was based on labeled indications. Medications were categorized as infants’, children’s, or family products based on the age group indicated on the front panel of the outer packaging (ie, the outer box or medication bottle), because such visual cues are used by consumers when deciding which medication to purchase.5 Within each brand, unique products were identified based on the product trade name and targeted age group. If products were available in multiple flavors, bottle sizes, or dye-free versions, 1 version (eg, a single flavor) was randomly selected, so that each unique product would be given equal weight.

Standard abbreviations for volumetric units were identified by recommended or customary use. The FDA Guidance, CHPA Guideline, US Pharmacopeial Convention, Institute for Safe Medication Practices, and others specify that milliliters should be abbreviated as “mL.”2,3,6,7 The FDA Guidance and CHPA Guideline specify that teaspoon should be abbreviated as “tsp,” but as there is no uniformly recommended abbreviation for tablespoon units, “TBSP” was considered the standard abbreviation based on common use.8 Pluralization of abbreviations is not addressed by the FDA Guidance or CHPA Guideline and was considered acceptable.

**Outcomes**

Adherence to specific recommendations in the final FDA Guidance and CHPA Guideline was assessed (Fig 1). Recommendations were categorized as “top tier” or “low tier” by the authors based on potential for reducing clinically meaningful dosing errors (Supplemental Table 5). Top tier recommendations directly address potential dosing errors of 3-fold or more. For example, use of trailing zeros in the dosing directions can lead to 10-fold overdoses if the decimal point is overlooked (ie, a labeled dose of 1.0 mL is mistaken for 10 mL).6,7,9–12 Low tier recommendations improve consistency and maintain conventional standards of abbreviation and capitalization, but do not directly address ≥3-fold dosing errors. For example, milliliters should always be abbreviated mL (ie, not ml or mL)2,3,6,7.

The recommendation that dosing devices should not be significantly larger than the largest dose in the dosing directions does not quantify “significantly larger.” For this study a dosing device with total volume ≥3 times the largest labeled dose was considered significantly larger. Two other recommendations without objective parameters (device markings should be “clearly visible” after product is added and devices should allow “clear measurement” of the smallest intended dose) were not assessed.
Data Collection and Analysis

Products were evaluated independently by 2 investigators (Ms Lovegrove and Ms Rose). A third reviewer (Dr Budnitz) resolved discordant assessments. Adherence to recommendations was assessed by reviewing dosing directions on bottle labels and attributes of the accompanying dosing devices. Dosing directions on the outer boxes and other written materials were not reviewed because some products are packaged only in the immediate container (ie, medication bottle) and outer packaging and other written materials may be discarded after purchase. Adherence to recommendations was tabulated and analyzed by using SAS version 9.2 (SAS Institute, Cary, NC). Product-specific findings were shared with respective manufacturers.

RESULTS

A total of 89 national brand name analgesic/antipyretic and cough, cold, and allergy products were collected from January to April 2012. Of these, 68 products representing 21 brands from 12 manufacturers were included in the final analysis. Four products did not meet study inclusion criteria, and 17 were identical to an included product except for flavor, bottle size, or use of dye. The final sample included 100% of analgesic/antipyretic national brands and 98.6% of cough, cold, and allergy product national brands available during the study period based on units sold from food, drug, and mass merchandiser stores. Of the 68 products, 81% were cough, cold, and allergy medications, and 88% were marketed as infants’ or children’s products (Table 1). Of the 55 cough, cold, and allergy medications, 9 (16%) were homeopathic products. A dosing device was provided with all products, most often a dosing cup (85%); all infants’ products were analgesics/antipyretics packaged with oral syringes. Across the 68 products, agreement between the 2 reviewers on adherence to 22 specific top tier and low tier recommendations was high; only 8 of 1496 independent assessments required resolution by a third reviewer.
Sixty-eight percent of dosing devices used extraneous units; all 68 dosing devices only used volumetric units that were specified in the dosing directions. Twelve children’s products included dosing cups with total volumes that were ≥3 times larger than the largest dose in the directions; the 12 cups averaged 3.4 times larger than the largest labeled dose (range, 3.3–3.8 times larger). All doses from the dosing directions were explicitly marked on devices for all but 4 products (94%; 64 of 68); these 4 products included droppers and syringes that needed to be filled >1 time to measure labeled doses. Adherence to low tier recommendations varied (Table 3). Most products used standard abbreviations in the dosing directions (91%; 59 of 65) and on devices (72%; 49 of 68); all nonstandard abbreviations only differed in capitalization. Of 19 products that used nonstandard abbreviations, 14 used ml and 2 used ML for milliliters (instead of mL) and 3 used TSP for teaspoons (instead of tsp). Of 65 products that used abbreviations for volumetric units both in dosing directions and on devices, 80% used exactly the same abbreviations in the dosing directions and on devices, 10% used exactly the same abbreviation in both locations. Again, all differences were related to capitalization (eg, use of mL in dosing directions and ml on the device).

Few devices (28%; 19 of 68) only had the numeric markings for doses specified in the directions (eg, directions specify doses of 5 mL or 10 mL; accompanying device only has 5 mL and 10 mL markings). Most devices had multipurpose numeric dosing scales (eg, 2.5 mL increments starting with 5 mL and ending with 20 mL). Seventy-two percent of products (49 of 68) included a statement to only use the enclosed device with the product, used a physical mechanism (eg, dosing cup that attaches to bottle cap) to link devices with accompanying products, or had both. The 6 cough, cold, and allergy products with dosing directions that used tablespoon units, in addition to other units, included a statement that doses could be measured by using the device provided or a spoon.

The volumetric units used on the dosing devices were exactly the same as the units used in the directions for 90% of products (61 of 68) (Table 4). Dosing directions on 7 other products included additional volumetric units not found on accompanying devices. Of the 68 products, 19 dosing directions (28%) and 25 devices (37%) followed the CHPA Guideline’s primary preference to use only milliliter units. Alternatively, the CHPA Guideline recommends using milliliters in combination with teaspoon units; 74% of products (50 of 68) used milliliters alone or in combination with teaspoons. A dosing chart was used to specify doses in the dosing directions on 76% of products.

**DISCUSSION**

This study is the first to assess dosing directions and dosing devices in a sample of products available after the voluntary FDA Guidance was finalized in 2011. Among 68 national brand name orally ingested OTC liquid medications, 91% of dosing directions and 62% of included devices adhered to all recommendations that directly address ≥3-fold dosing errors (top tier recommendations). Adherence to individual recommendations intended to improve the clarity and consistency of labeled doses and accompanying devices (low tier recommendations) ranged from 26% to 91%. Specific findings help identify areas for product improvement and recommendation refinement.

In this sample of 68 products, there was 100% adherence to several key recommendations, which address issues that have been directly implicated in clinically significant errors. All 68

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TABLE 1 Characteristics of OTC Liquid Products Assessed for Adherence to Recommendations From the 2011 FDA Voluntary Guidance and 2009 CHPA Voluntary Guideline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analgesic/antipyretic</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>Cough, cold, and allergy</td>
<td>55</td>
<td>81</td>
</tr>
<tr>
<td>Age category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infants</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Children</td>
<td>55</td>
<td>81</td>
</tr>
<tr>
<td>Family</td>
<td>8</td>
<td>12</td>
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<tr>
<td>Device type</td>
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<td></td>
</tr>
<tr>
<td>Printed cup</td>
<td>38</td>
<td>56</td>
</tr>
<tr>
<td>Etched cup</td>
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<td>29</td>
</tr>
<tr>
<td>Oral syringe</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Dosing spoon</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Dropper</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>68</td>
<td>100</td>
</tr>
</tbody>
</table>
products included dosing devices to discourage use of household spoons or other noncalibrated devices.\textsuperscript{13,14} No dosing directions or devices used atypical volumetric units (eg, drams, milligrams, or dropperfuls), and no devices had extraneous units that did not appear in the dosing directions.\textsuperscript{15,16} Two products used both teaspoon and tablespoon units in the dosing directions (a cause of 3-fold errors),\textsuperscript{17,18} but both have since been discontinued.

There is opportunity to improve the expression of decimals and fractions. Most nonadherence to these recommendations occurred with dosing devices, but for overdose prevention, nonadherence in dosing directions is most critical. Two products used trailing zeros in the directions, which could lead to 10-fold overdosing errors (eg, interpreting “1.0” as “10”).\textsuperscript{6,7,9–12} One product did not use leading zeros, and 5 products used trailing zeros on dosing devices; however, overlooking decimal points on devices would likely lead to underdosing. Expressing fractional

\begin{table}[h]
\centering
\caption{Product Adherence to Top Tier Recommendations From the 2011 FDA Voluntary Guidance and 2009 CHPA Voluntary Guideline}
\begin{tabular}{|l|l|l|l|l|}
\hline
Recommendation$^a$ & Relevant Sample & Dosing Directions & Dosing Device \\
\hline
 & & No./Total & \% of Relevant Sample & No./Total & \% of Relevant Sample \\
\hline
Dosing device included & All products & — & — & 68/68 & 100 \\
Atypical units not used (eg, drams) & All products & 68/68 & 100 & 68/68 & 100 \\
Teaspoon and tablespoon units not used together & Products using teaspoon or tablespoon units & 47/49 & 96 & 43/43 & 100 \\
Trailing zeros not used & Products using decimals & 15/17 & 88 & 35/40 & 88 \\
Leading zeros used & Products using decimal doses \textless 1 & 1/1 & 100 & 8/8 & 89 \\
Small font used for numerals in fractions (eg, \( \frac{1}{2} \) instead of 1/2) & Products using fractions & 8/10 & 80 & 20/27 & 74 \\
No extraneous units appear on the dosing device that do not correspond to units in the directions & Products with dosing devices & — & — & 68/68 & 100 \\
Dosing device not significantly larger than largest recommended dose (\textgreater{}=3-fold) & Products with dosing devices & — & — & 56/68 & 82 \\
All doses from directions marked on dosing device & Products with dosing devices & — & — & 64/68 & 94 \\
\hline
\end{tabular}
\textsuperset{Not applicable denoted by em dash.}

$^a$ Top tier recommendations are those that directly address potential \( \geq 3 \)-fold dosing errors. Products were assessed for adherence to recommendations in “Guidance for Industry: Dosage Delivery Devices for Oral Liquid Drug Products,” FDA, May 2011 and “Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children \( \leq 12 \) years of Age,” CHPA, November 2009.

\begin{table}[h]
\centering
\caption{Product Adherence to Low Tier Recommendations From the 2011 FDA Voluntary Guidance and 2009 CHPA Voluntary Guideline}
\begin{tabular}{|l|l|l|l|l|}
\hline
Recommendation$^a$ & Relevant Sample & Dosing Directions & Dosing Device \\
\hline
 & & No./Total & \% of Relevant Sample & No./Total & \% of Relevant Sample \\
\hline
Standard abbreviations used for volumetric units (eg, mL used instead of ml) & Products using abbreviations & 59/65 & 91 & 49/68 & 72 \\
Abbreviations for volumetric units on dosing device match the directions (eg, if mL used in directions, mL used on device) & Products using abbreviations in directions and on dosing device & — & — & 52/65 & 80 \\
Abbreviations for volumetric units defined (eg, mL = milliliter)$^b$ & Products using abbreviations & 18/68 & 26 & 0/68 & 0 \\
No extraneous numeric doses appear on the dosing device that do not correspond to amounts in the directions & Products with dosing devices & — & — & 19/68 & 28 \\
Statement included that only enclosed dosing device should be used or mechanism used to secure dosing device to the bottle$^c$ & Products with dosing devices & 33/68 & 49 & 32/68 & 47 \\
\hline
\end{tabular}
\textsuperset{Not applicable denoted by em dash.}

$^a$ Low tier recommendations maintain conventional standards of abbreviation and capitalization. They improve clarity and consistency but are not directly linked to potential \( \geq 3 \)-fold dosing errors. Products were assessed for adherence to recommendations in “Guidance for Industry: Dosage Delivery Devices for Oral Liquid Drug Products,” FDA, May 2011 and “Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children \( \leq 12 \) years of Age,” CHPA, November 2009.

$^b$ FDA guidance recommends that abbreviations should be defined on the dosing device (eg, mL = milliliter) or, if they are not, should be defined in the labeled dosing directions, outside packaging, bottle, and any accompanying written instructions.

$^c$ FDA guidance recommends that manufacturers should try to ensure that the dosing devices are used only with the products with which they are included. Possible ways of accomplishing this are to include a related statement on the drug product’s bottle and/or carton labeling and, if possible, on the dosing device or to devise a mechanism to secure the dosing device to the drug product.
doses with small font has been suggested as a means to prevent errors from misinterpreting “1/2” as “1 or 2” (ie, a potential 4-fold error) or overlooking the fraction bar altogether. Small font was not used for fractional doses in 2 dosing directions (potential for overdose) and on 7 devices (potential for underdose).

Two recommendations related to device size required interpretation to assess adherence. First, to limit the magnitude of overdoses from patients or caregivers assuming that a full device holds “one dose” or “one unit,”18 dosing devices should not be significantly larger than doses specified in the directions. Twelve devices were slightly larger than the 3-fold cutoff (3.3–3.8 times larger) used to define significantly larger than doses specified in the directions. Twelve devices were slightly larger than the 3-fold cutoff (3.3–3.8 times larger) used to define significantly larger in this study. Second, to prevent situations in which doses are provided with prescription medications (and sometimes patients must explicitly request them) the large majority are not tailored to the prescription but are “off-the-shelf” devices that have general numeric scales and may have multiple volumetric units to accommodate numerous doses and units.19

One recommendation with <75% adherence is to link medications and accompanying devices. One rationale is that devices are calibrated to account for product viscosity and other factors; however, such fine measurement accuracy is unlikely to cause clinically significant overdoses of OTC products. Another rationale is to discourage use of household spoons, which can vary considerably in fill capacity.14,20,21 The dosing directions for 6 products stated that the included dosing cup or a teaspoon and/or tablespoon could be used. Although 2 of these products have been discontinued, the remaining products’ directions should not suggest use of household spoons.

Three low tier recommendations focus on capitalization conventions and definition of abbreviations. Capitalization differences (eg, ml instead of mL) accounted for all instances of non-adherence to the recommendations to use standard abbreviations for volumetric units and to ensure device abbreviations match dosing direction abbreviations. Although abbreviations should generally be defined, definitions for common abbreviations may not be necessary.22 particularly when the same abbreviation is used both in the dosing directions and on the device. Fifty-six products used milliliters both in the directions and on devices; all 56 used an abbreviation in both locations. In this situation, it is unclear if defining the abbreviation aids in error prevention.

Using milliliters (expressed as mL), as the primary volumetric unit could address many guidance/guideline goals. An “mL only” approach discourages use of household spoons, avoids confusion between teaspoons and tablespoons, and limits confusion from use of multiple units. Milliliters are the standard units for dosing orally ingested liquid medications in inpatient settings,6,11,23 and there is increasing consensus that use of milliliters for dosing orally ingested liquid medications is preferred for outpatient settings as well.24–27

Nearly three-fourths of products in this study (74%) followed CHPA’s recommendation to use milliliters alone or in combination with teaspoon units, and success in adopting milliliters on OTC products has facilitated efforts to encourage use of milliliters on prescription product labels.28–30 Nonetheless, ongoing monitoring would be
appropriate to identify unintended consequences of milliliter-only dosing.

The manner in which results are reported can substantially impact interpretation of findings. A previous study by Yin et al evaluated a sample of products available before release of the draft FDA Guidance and concluded that 98.6% had at least 1 “inconsistency.” However, aggregating inconsistencies by combining serious issues (eg, representation of decimal doses) with less serious issues (eg, inconsistent capitalization for milliliter abbreviations) and giving equal weight to serious and less serious issues could lead to overstatement of problems. In addition, reporting measures of inconsistency that combine issues with the dosing directions and issues with dosing devices clouds rather than clarifies where dosing direction improvements are needed and where device improvements are needed. Although differences in study design and inclusion criteria do not allow direct comparisons, findings from this study suggest that, overall, products collected after the CHPA Guideline and final FDA Guidance adhered to most recommendations, particularly those addressing clinically meaningful errors. After analyses were completed for this study, product-specific findings were shared with respective manufacturers and several label and device updates have been made. Study findings are subject to several limitations. This study assessed national brand name analgesic/antipyretic and cough, cold, and allergy medications with pediatric dosing available on the market during the study period.

Findings may not be generalizable to national brand name products that were not available during the study period (eg, due to product recalls) or to generic products. Adherence of generic products available after the final FDA Guidance should be assessed. Findings also may not be generalizable to other OTC drug classes, but analgesic/antipyretic and cough, cold, and allergy medications are the OTC medications involved in most emergency visits for therapeutic errors involving children ≤5 years of age. Products were collected through a request sent to CHPA member manufacturers, and possibly eligible products from non-member manufacturers were not included. However, the products evaluated represented over 98% of units of national brand name products in the included drug classes sold during the study period. Lastly, we did not evaluate other product characteristics such as use of concentration (mg/mL) or pictures or graphics on product packaging.

CONCLUSIONS

Findings suggest that these voluntary initiatives promote adherence to label and device recommendations. Further improving adherence to top tier recommendations addressing potential for ≥3-fold errors should be prioritized, but detailed reporting by patients and care providers is needed to identify the specific ways labeling and dosing devices contribute to errors. Additional opportunities for standardization include design and marking of dosing devices and promotion of milliliter as the standard unit for dosing orally ingested liquid medications. Evaluation and continued improvement of labels and devices for OTC liquid medications should be ongoing and transparent as new products are introduced and recommendations are revised.

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