



Research Paper

Do pediatric oral suspension acetaminophen and ibuprofen product labeling and online resources facilitate intended use?

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ARTICLE INFO

Keywords:

Child safety
Drug labeling
Health literacy
Medication errors
Nonprescription drugs

ABSTRACT

Background: Caregivers often have difficulty administering pediatric medications which frequently results in increased dosing error risk.

Objective: We examined health literacy characteristics of pediatric over-the-counter (OTC) oral suspension acetaminophen and ibuprofen instructional materials and dosing instruments.

Methods: We conducted a descriptive analysis of dosing instructions, measuring syringe characteristics, and internet-based resources among a sample of OTC pediatric oral suspension acetaminophen and ibuprofen products ($n = 14$).

Results: All products included Drug Facts Panels, employed consistent abbreviation use, and stated measuring dosage with syringe provided. However, oral syringe dosing increment markings did not match box or bottle dosing charts. Most products had supplemental English-language internet-based content resources available.

Conclusions: While OTC pediatric oral suspension acetaminophen and ibuprofen products labeling included key drug fact elements, there were inconsistencies between medication dosing chart labeling guidelines and oral syringe dosing increments/markings. It is vital that oral dosing syringes are clearly marked to match product dosing chart labeling as a means of potentially reducing caregiver dosing errors.

1. Introduction

Over-the-counter (OTC) oral suspension acetaminophen and ibuprofen are routinely administered by caregivers to treat ailments such as fever and pain in young children. Comprehensive reviews, conducted over the past two decades, clearly document a plethora of health literacy-related inadequacies (e.g., exceedingly high reading demands, poor layout features) among a wide variety of OTC and prescription medication labeling and accompanying instructions.^{1–4} In 2009, the United States (US) Food and Drug Administration (FDA) released voluntary industry OTC product labeling guidelines to promote consistent dosing directions and use of standardized measuring devices.⁵ Soon after FDA guideline issuance, Yin and colleagues conducted comprehensive instruction and dosing evaluations of top-selling US OTC pediatric liquid medications and subsequently identified ample opportunities for widespread improvement in the future.^{4,6}

Caregiver difficulty administering pediatric medications often results

in increased dosing error risk across diverse populations.^{7,8} For example, nearly half of pediatric patients presenting to Puerto Rican emergency departments were administered an inappropriate dose—both subtherapeutic and supratherapeutic—of acetaminophen by their caregiver.⁹ Similarly, women of child-bearing age struggled to not only draw an accurate oral medication dose, but also describe how to administer medication over a 24-h time-period to their child.¹⁰ Recently, the Council on Quality Improvement and Patient Safety's Committee on Drugs outlined a battery of evidence-based strategies—using health literacy-informed counseling and written educational materials, providing appropriate and consistent dosing-tool measurements—to reduce likelihood of pediatric medication administration errors in the home environment.¹¹

Recognizing that over a decade has passed since Yin's landmark studies were conducted,^{4,6} the overarching purpose of this study was to assess health literacy-related characteristics (e.g., dosing instructions, formatting complexity and readability) of pediatric oral suspension

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acetaminophen and ibuprofen instructional materials and dosing instruments. This study addressed two research questions, including: (1) Do OTC pediatric oral suspension acetaminophen and ibuprofen product labeling characteristics, dosing directions, and measuring devices facilitate intended use? and (2) What was the scope and content of product-specific OTC pediatric oral suspension acetaminophen and ibuprofen internet-based information and instructions?

2. Methods

2.1. Selection of over-the-counter (OTC) pediatric oral suspension acetaminophen and ibuprofen products

In September 2021, through visits to national chain superstores, pharmacies, and online distributors we identified a sample of brand and generic OTC pediatric oral suspension acetaminophen and ibuprofen products currently available for purchase in the US. A total of fourteen ($n = 14$) OTC pediatric oral suspension acetaminophen and ibuprofen products were included in our sample.

We purchased 2.0 fluid ounce (59 mL) bottles of OTC pediatric—packaged for children 2–3 years of age—oral suspension acetaminophen products. Brand name OTC oral suspension acetaminophen products averaged \approx \$7.00 US each, while generics were \approx \$4.00 US each. OTC pediatric oral suspension acetaminophen products included: (1) Infants' Tylenol: Pain + Fever (Johnson & Johnson), (2) Infant Fever & Pain Reliever (Little Remedies®), (3) Infants' Pain & Fever (CVS Health®), (4) Infants' Pain & Fever (Rite Aid®), (5) Infants' Pain & Fever (Amazon.com, Inc.), (6) Infants' Pain & Fever (Kroger®), and (7) Infants' Pain & Fever (DG Health™).

We purchased 0.5 (29.5 mL) or 1.0 (14.75 mL) fluid ounce bottles of OTC pediatric—packaged for children 6–23 months of age—oral suspension ibuprofen products. Brand name OTC oral suspension ibuprofen products averaged \approx \$8.00 US each, while generics were \approx \$4.00 US each. OTC pediatric oral suspension ibuprofen products included: (1) Concentrated Motrin Infants' Drops (Johnson & Johnson), (2) Infants' Advil Concentrated Drops (Pfizer), (3) Infants' Dye-Free Ibuprofen (Walgreens®), (4) Infants' Dye-Free Ibuprofen (Target®), (5) Infants' Ibuprofen Oral Suspension (DG Health™), (6) Infants' Concentrated Drops Ibuprofen (GoodSense®), and (7) Infants' Ibuprofen Oral Suspension (Amazon.com, Inc.).

2.2. Assessment of OTC pediatric oral suspension acetaminophen and ibuprofen box and bottle instructional content and layout features

Mirroring methodology described in Yin and colleagues' pediatric non-prescription liquid medication labeling study,⁴ we evaluated OTC pediatric oral suspension acetaminophen and ibuprofen liquid product box and bottle labeling using a similar approach. We also noted English- and Spanish-language information/instruction availability across all OTC pediatric oral suspension acetaminophen and ibuprofen products.

Our box content assessment included reviews of both Principal Display and Drug Facts Panels. On the Principal Display Panel, we measured text point font size of product name, purpose/symptom(s), flavor, and active ingredient. On Drug Facts Panels—on both boxes and bottles—we assessed active ingredient and standard text (i.e., predominantly used) point font size. Text point font size was determined by measuring distance from ascent line (top of the capital letters) to descent line (lowermost portion of the lower-case letter g or y) with a Westcott Graphic Arts Ruler (Seneca Falls, NY). Drug Facts Panels, on both boxes and bottles, were reviewed for inclusion (yes or no) of the following FDA elements: active ingredient highlighted, active ingredient section, drug facts title, uses section, warnings section, directions section, dosing chart, and pictographic dosing diagram.

2.3. Consistency in measuring syringe markings/units and dosing directions of OTC pediatric oral suspension acetaminophen and ibuprofen products

We noted whether each OTC pediatric oral suspension acetaminophen or ibuprofen product included a measuring syringe. Next, we recorded measuring syringe dose markings/units and assessed within-product consistency (i.e., measuring syringe dose markings/units versus box and bottle dosing charts) mirroring Yin et al.'s previous work.⁶ We also examined (1) consistent abbreviation use, (2) instruction to measure dosage using only the product syringe provided, and (3) instructions to contact a physician if an alternate dosage was recommended.

2.4. Evaluation of OTC pediatric oral suspension acetaminophen and ibuprofen product supplemental internet-based content resources

To determine whether supplemental internet-based content resources were available for OTC pediatric oral suspension acetaminophen and ibuprofen products, we reviewed labeling (e.g., hyperlink and/or Quick Response [QR] code) and/or queried the Google online search engine. We assessed inclusion (yes or no) of drug facts across brand and generic products—in all available languages—including: (1) overview, (2) directions, (3) ingredients, (4) intended uses, and (5) warnings. We also examined inclusion (yes or no) of general information across brand and generic products—in all available languages—including: (1) additional information (e.g., toll-free number), (2) purchase details, and (3) consumer reviews. We also captured dosing chart format, across product type (brand versus generic) and language, including: (1) not available, (2) box label, (3) lines/rows describing weight (lb)/age (years) and dose (mL), and (4) pictographic diagram.

2.5. Data analyses

Descriptive analyses (e.g., frequencies, means, standard deviations) were calculated to depict OTC pediatric oral suspension acetaminophen and ibuprofen instructional content and layout features, measuring syringe markings/units and dosing directions, and supplemental internet-based content resources. All data were entered and analyzed using the IBM® Statistical Package for the Social Sciences,® Version 28.0 (SPSS+, Chicago, Illinois).

3. Results

As displayed in Table 1, all OTC pediatric oral suspension acetaminophen and ibuprofen products ($n = 14$) included a Drug Facts Panel on both the box and bottle. Drug Facts Panels displayed on the box included seven of eight key FDA elements. All products ($n = 14$) lacked a pictographic dosing diagram—an FDA key element—on both the box and bottle. Overall, Product Name text point font sizes (acetaminophen = 21.34 ± 8.40 ; ibuprofen = 23.43 ± 9.27) were largest on the Principal Display Panel. Text point on both box and bottle Drug Facts Panels—for active ingredient and standard instructions—averaged \approx 6.0 font size. Box and bottle instructions, for all OTC pediatric oral suspension acetaminophen and ibuprofen products, were limited to English-language exclusively.

All OTC oral suspension acetaminophen and ibuprofen products (1) employed consistent abbreviation use, (2) explicitly stated to measure dosage using only the product syringe provided, and (3) directed the caregiver to contact a physician if an alternate dosage was recommended. All OTC oral suspension acetaminophen and ibuprofen products included an oral dosing syringe. As shown in Fig. 1, all acetaminophen syringes ($n = 7$) included four mL dosing increment markings—1.25 mL, 2.5 mL, 3.75 mL, and 5 mL—that did not exactly match either the accompanying box or bottle dosing chart where only a 5 mL dose was indicated. All ibuprofen syringes ($n = 7$) included three

Table 1
Over-the-counter pediatric oral suspension acetaminophen and ibuprofen box and bottle content and layout features.

Box Content and Layout Features	Acetaminophen (n = 7)	Ibuprofen (n = 7)
Principal Display Panel		
Product Name (font size)	21.34 ± 8.40	23.43 ± 9.27
Purpose/Symptom(s) (font size)	21.29 ± 3.86	10.43 ± 2.37
Flavor (font size)	9.86 ± 2.91	10.14 ± 3.29
Active Ingredient (font size)	10.29 ± 1.50	20.29 ± 6.85
Drug Facts Panel		
Active Ingredient (font size)	6.86 ± 0.69	6.43 ± 0.98
Standard Instructions (font size)	6.00 ± 0.00	5.86 ± 0.38
Active Ingredient Highlighted (% included)	100%	100%
Active Ingredient Section (% included)	100%	100%
Drug Facts Title (% included)	100%	100%
Uses Section (% included)	100%	100%
Warnings Section (% included)	100%	100%
Directions Section (% included)	100%	100%
Dosing Chart (% included)	100%	100%
Pictographic Dosing Diagram (% included)	0%	0%
Bottle Content and Layout Features		
Drug Facts Panel		
Active Ingredient (font size)	6.00 ± 0.00	6.86 ± 0.90
Standard Instructions (font size)	6.00 ± 0.00	5.71 ± 0.49
Active Ingredient Highlighted (% included)	100%	100%
Active Ingredient Section (% included)	100%	100%
Drug Facts Title (% included)	28.57%	0%
Uses Section (% included)	100%	85.71%
Warnings Section (% included)	100%	100%
Directions Section (% included)	100%	100%
Dosing Chart (% included)	100%	100%
Pictographic Dosing Diagram (% included)	0%	0%
Box Content and Layout Features		
Principal Display Panel		
Product Name (font size)	21.34 ± 8.40	23.43 ± 9.27
Purpose/Symptom(s) (font size)	21.29 ± 3.86	10.43 ± 2.37
Flavor (font size)	9.86 ± 2.91	10.14 ± 3.29
Active Ingredient (font size)	10.29 ± 1.50	20.29 ± 6.85
Drug Facts Panel		
Active Ingredient (font size)	6.86 ± 0.69	6.43 ± 0.98
Standard Instructions (font size)	6.00 ± 0.00	5.86 ± 0.38
Active Ingredient Highlighted (% included)	100%	100%
Active Ingredient Section (% included)	100%	100%
Drug Facts Title (% included)	100%	100%
Uses Section (% included)	100%	100%
Warnings Section (% included)	100%	100%
Directions Section (% included)	100%	100%
Dosing Chart (% included)	100%	100%
Pictographic Dosing Diagram (% included)	0%	0%
Bottle Content and Layout Features		
Drug Facts Panel		
Active Ingredient (font size)	6.00 ± 0.00	6.86 ± 0.90
Standard Instructions (font size)	6.00 ± 0.00	5.71 ± 0.49
Active Ingredient Highlighted (% included)	100%	100%
Active Ingredient Section (% included)	100%	100%
Drug Facts Title (% included)	28.57%	0%
Uses Section (% included)	100%	85.71%
Warnings Section (% included)	100%	100%
Directions Section (% included)	100%	100%
Dosing Chart (% included)	100%	100%
Pictographic Dosing Diagram (% included)	0%	0%

mL dosing increment markings (0.625 mL, 1.25 mL, and 1.875 mL). However, ibuprofen dosing charts—both box and bottle—did not include a 0.625 mL dose as marked on the accompanying product syringe.

Overall, 12 of 14 (85.7%) OTC oral suspension acetaminophen (brand = 2/2; generic = 4/5) and ibuprofen (brand = 2/2; generic = 4/

5) products had supplemental English-language internet-based content resources available. Three (n = 3) brand name products (acetaminophen = 1/2; ibuprofen = 2/2) had supplemental Spanish-language internet-based content resources available as well. Availability of internet-based drug facts and general information across product type (brand versus generic) and language are presented in [Table 2](#).

A.

Box Dosing Chart Directions

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under two years	ask a doctor
25-35	2-3 years	5 mL

*or as directed by a doctor

B.

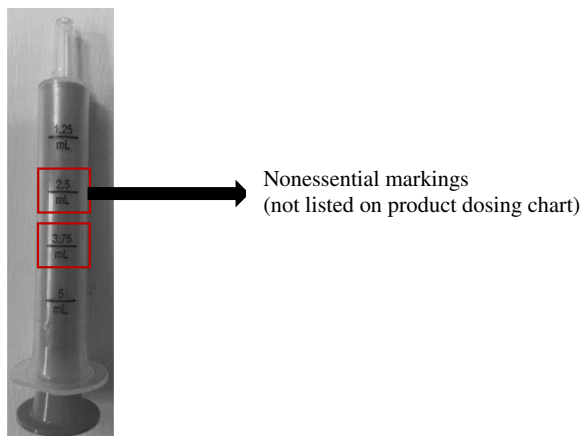


Fig. 1. Example over-the-counter pediatric suspension acetaminophen box dosing directions (A) versus syringe dosing increment markings (B).

Table 2

Over-the-counter pediatric oral suspension acetaminophen and internet-based content resource features across type (brand versus generic) and language.

Internet-based Content Resource Product Features	Type (Brand versus Generic)-Language		
	Brand-English	Generic-English	Brand-Spanish
	(n = 4)	(n = 8)	(n = 3)
Drug Facts			
Overview	4	7	3
Directions	4	5	3
Ingredients	4	7	3
Intended Uses	4	8	3
Warnings	3	5	2
General Information			
Additional Information	3	4	2
Purchase Details	4	7	3
Consumer Reviews	2	6	3

Eleven ($n = 11$) OTC oral suspension acetaminophen (brand = 2/2; generic = 3/5) and ibuprofen (brand = 2/2; generic = 4/5) products included a dosing chart. Seven of 8 generic products included an English-language dosing chart in either box label ($n = 4$) or line/row ($n = 3$) format. One ($n = 1$) brand name product, providing information in the English-language exclusively, included a dosing chart in lines/rows format. The remaining three ($n = 3$) brand name products provided identical dosing charts in English- and Spanish-languages as follows: lines/rows ($n = 1$) and pictogram ($n = 2$).

4. Discussion

Our review of OTC pediatric oral suspension acetaminophen and ibuprofen instructional materials and dosing instruments revealed both positive findings as well as aspects to improve upon in the future. Notably, all OTC pediatric oral suspension acetaminophen and ibuprofen products, in our sample, included both English-language Drug Facts Panels on both boxes and bottle. Apart from a pictographic dosing chart, products included all other key FDA elements (Active Ingredient Highlighted, Active Ingredient Section, Drug Facts Title, Uses Section, Warnings Section, Directions Section, and Dosing Chart) on boxes and

bottles. Given physical space limitations, it was not surprising that all products lacked a pictographic dosing diagram on both box and bottle labels. An Internet-linked Quick Response (QR) code would provide adequate space to include step-by-step dosing instructions via an interactive pictogram-type format.

All OTC pediatric oral suspension acetaminophen products included an oral dosing syringe inside each box. This finding was a notable improvement as compared to Yin et al.'s previous study where just 74% of OTC liquid products reviewed included a standardized measuring device.⁶ However, despite these positive findings, we noted widespread discrepancies between medication dosing chart guidelines and oral syringe dosing increments/markings. In their comprehensive review of pediatric discharge medications at an a large academic medical center, Nguyen and colleagues found that 12.5% of all liquid medications were unrounded.¹² As such, liquid medication dosing should be rounded to facilitate improved accuracy (e.g., 1.875 mL could be listed as 1.9 mL) and administration of both OTC products and prescriptions.

Our findings point to the need for manufacturers to develop consistent OTC pediatric oral suspension acetaminophen and ibuprofen dosing instructions across boxes/bottles and oral syringe increments/markings. Additionally, healthcare providers should be cognizant of current OTC product instructional shortcomings and tailor caregiver dosing directions accordingly. To promote appropriate OTC pediatric oral suspension acetaminophen and ibuprofen administration, healthcare providers could implement strategies including the following: (1) providing instructions in languages reflective of their patient population, (2) ensuring that caregivers know their child's current body weight, and (3) demonstrating proper dosing measurement and timing through an evidence-based approaches such as the LARA (Listen, Affirm, Respond, and Add) and Teach-Back methods.¹³

One important finding to emerge, across OTC packaging and internet-based resources, was lack of language availability beyond English. Given the vast number of Spanish speakers in the US,¹⁴ this finding potentially limits caregiver accessibility of OTC acetaminophen and ibuprofen pediatric instructions. Additionally, development of materials to reflect other frequently spoken languages, in the US, should be prioritized as well. Providing caregivers with OTC pediatric oral suspension acetaminophen and ibuprofen instructions to match their preferred language choice could potentially promote proper product dosing and administration. While physical packaging space is very limited, boxes and/or bottles could include a QR code to product websites where instructions were available in multiple languages and delivery modalities (e.g., large font, video-based).

While the majority OTC pediatric oral suspension acetaminophen and ibuprofen products included online resources, a current Internet website link was not included on any box or bottle. All brand name product internet-based content resource features—in both English and Spanish—provided an overview, directions, dosing chart, ingredients, and intended uses. Nearly all generic products—limited to English-language exclusively—provided an overview, ingredients, intended uses, and purchase details. Interestingly, several products included a dosing scheduler where caregivers could track medication administration over time. However, current dosing schedule formatting requires that caregivers download, print, and record medication administration in paper and pen format. Future dosing scheduler iterations should leverage available technologies (e.g., Smartphone application, virtual platform) to allow caregivers to track medication administration in real-time.

4.1. Limitations

Our findings should be considered within the context of several limitations. First, our study was limited to a relatively small sample of OTC pediatric oral suspension acetaminophen and ibuprofen products ($n = 14$). However, our study did include major OTC pediatric brand name acetaminophen and ibuprofen products (e.g., Infants' Tylenol:

Pain + Fever [Johnson & Johnson], Infants' Advil Concentrated Drops [Pfizer]) and generic products available at five of the ten (Amazon.com, Inc., CVS Health®, Kroger®, Target®, and Walgreens®) largest worldwide retailers.¹⁵ Second, we did not directly assess parent/caregiver comprehension and/or understanding of dosing instructions. However, our study employed similar approaches used in previous studies.^{3,4,6} Third, our online resources review was limited to OTC pediatric oral suspension acetaminophen and ibuprofen products included in our sample exclusively. Fourth, we did not assess accuracy of dosing syringe measurements. Future studies should include an objective evaluation of syringe measurement accuracy to ensure proper OTC pediatric oral suspension acetaminophen and ibuprofen product dosing.

5. Conclusions

In conclusion, our findings suggest that over the past decade, OTC pediatric oral suspension acetaminophen and ibuprofen products have been improved upon regarding inclusion of FDA elements on labeling and enclosure of an oral dosing syringe inside each box. However, while each product included a dosing syringe, there were inconsistencies between medication dosing chart labeling guidelines and oral syringe dosing increments/markings. As such, it is vital that oral dosing syringes are clearly marked to match product box and bottle medication dosing charts as a means of potentially reducing caregiver dosing errors. Additionally, future efforts should not only focus on further refinement of English-language instructions, but also expansion of OTC pediatric oral suspension acetaminophen and ibuprofen instructions into many other languages (e.g., Spanish, Tagalog, Arabic) to meet current population needs.

Funding

No funding was received for this work.

Author contributions

All authors contributed to study conceptualization, methodology, validation, visualization and writing. Formal analyses and data interpretation were performed by AL and HM under supervision of LSW. The first draft of the manuscript was written by AL and HM and all authors commented on previous versions of the manuscript. LSW revised the final manuscript draft.

Declaration of Competing Interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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