



HASSENFELD  
CHILDREN'S  
HOSPITAL  
AT NYU LANGONE

NYC  
HEALTH+  
HOSPITALS

Bellevue

# Nonprescription Analgesic/ Antipyretic Drug Development in Children 2 to <12 years of Age: A Health Literacy Perspective

**H. Shonna Yin, MD, MS**

Associate Professor of Pediatrics and Population Health  
NYU School of Medicine

November 15, 2024

FDA-University of Maryland CERSI Public Workshop: Nonprescription  
Analgesic / Antipyretic Drug Development in Children 2 to Less than  
12 Years of Age

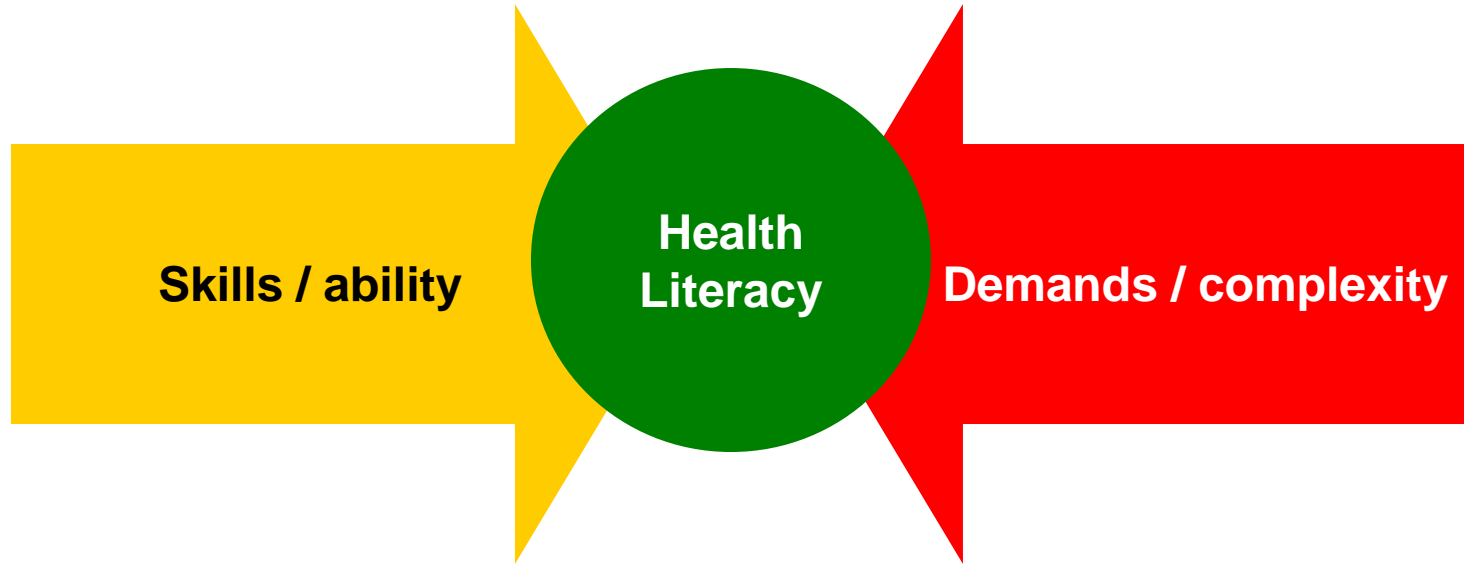
# Topics Covered

- Health literacy and medication errors
- Existing areas of confusion
  - Formulations / Concentrations
  - Active ingredients
  - Dosing
  - Age restrictions
- Conclusions

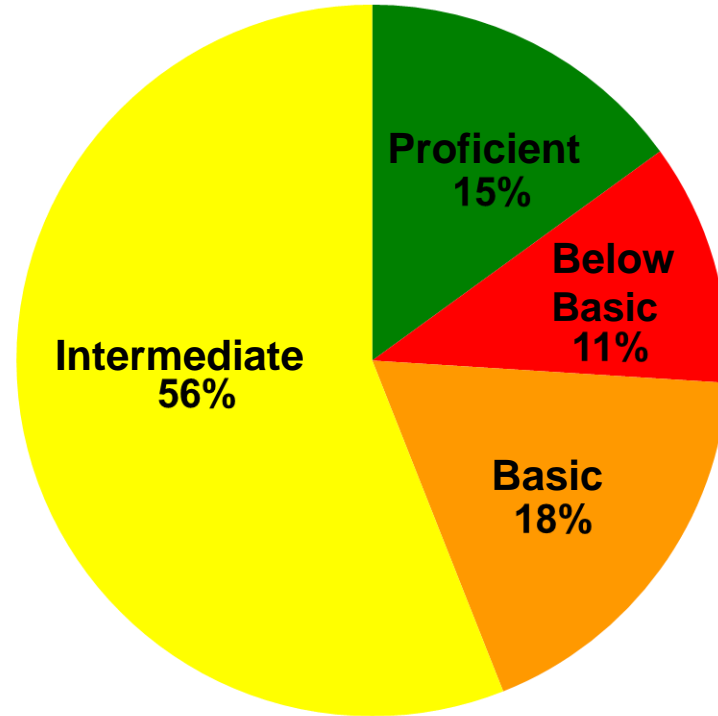
# What is Health Literacy?

- Health literacy
  - “is the degree to which individuals have the ability to **find**, **understand**, and **use information and services** to inform health-related decisions and actions for themselves and others.”
  - Includes ability to access / navigate the health care system

# Risk Factor for Medication Errors: Low Health Literacy



# Health Literacy of Parents in the US



Data from 2003  
National Assessment of  
Adult Literacy (NAAL):  
National Center for  
Educational Statistics

*Over 21 Million Parents with Basic or Below Basic Health Literacy*

Yin HS, Johnson M, Mendelsohn AL, Abrams MA, Sanders L, Dreyer BP. The health literacy of parents in the US: A nationally representative study. *Pediatrics* 2009; 124: S289-298.

# Health Literacy & Medications

- Caregivers with low health literacy
  - Greater difficulty understanding prescription and non-prescription (OTC) labels
  - More likely to be unaware of weight-based dosing
  - More likely to misunderstand active ingredient information
  - More likely to use nonstandard kitchen spoons
- Caregivers with limited health literacy have a **1.5 to 2.5-fold increased odds** of making a liquid medication dosing error

# Non-prescription (OTC) Medications

- Caregivers and patients often do not receive guidance from healthcare professionals on the use of OTC products
- Caregivers and patients thus often rely on their own health literacy skills or those of family members to determine which medications to purchase and how to appropriately administer them
- Nearly 60% of US caregivers report difficulty understanding OTC labels, with 1 in 3 reporting “great” or “moderate” difficulty
  - Parents with limited health literacy had **3.4 times the odds** of reporting difficulty understanding OTC medication labels

# Area of confusion: Formulations / concentrations



# OTC Medications: Formulations / Concentrations as a Source of Confusion

- Different formulations of liquid medication
  - Acetaminophen
    - INFANT's: 80 mg / 0.8mL (100 mg / mL)
    - CHILDREN's: 160 mg / 5 mL (32 mg / mL)
  - Ibuprofen
    - INFANT's: 50 mg / 1.25 mL (40 mg / mL)
    - CHILDREN's: 100 mg / 5 mL (20 mg / mL)
- Confusion re: formulations associated with cases of significant pediatric morbidity and mortality (Tzimenatos 2009; Schillie 2009)

← 3x more concentrated

← 2x more concentrated



# OTC Medications: Formulations / Concentrations as a Source of Confusion

- **Nearly 30%** of parents unaware of presence of different formulations of acetaminophen
- **65%** of parents thought CHILDREN's more concentrated than INFANT formulations

# OTC Medications: Formulations / Concentrations as a Source of Confusion

- Experimental study (n=270)
  - Hypothetical scenario
    - Doctor tells parent to give 1 teaspoon (5 mL) of Children's Tylenol / Acetaminophen
    - Parent has Infant Acetaminophen at home
    - ~80% would use Infant formulation
      - ~60% use instrument *other than* the infant dropper
      - ~50% would have given >2-fold dose
- Data presented to FDA Advisory Committee on Acetaminophen, June 2009
  - FDA Advisory Committee voted to recommend only one formulation of liquid acetaminophen

## Error-prone concentrations of ibuprofen suspensions

Parents who are told to give their child or infant over-the-counter ibuprofen oral suspension may not be aware that there are two different concentrations available. An infant's formulation (for infants 6-23 months or weighing 5.5-10.5 kg [12-23 lbs]) contains 50 mg/1.25 mL (40 mg/mL). This is twice as concentrated than the children's formulation (for children 2-11 years or weighing 10.9-43.1 kg [24-95 lbs]), which contains 100 mg/5 mL (20 mg/mL). Retail locations routinely stock both concentrations. Also, the labeling and packaging of the two concentrations can sometimes look similar.

Staff at children's hospitals might be familiar with this and have often made it a point of emphasis to educate parents about this issue at discharge. However, for many reasons, staff have told us about mix-ups that sometimes occur after discharge. One reason is that some hospital computer systems sometimes convert oral liquid doses to a metric volume to help parents measure each dose using a dosing cup or oral syringe. However, the concentration parents might purchase or already have at home is often unknown.

One hospital reported a close call involving a child who was discharged from an ambulatory surgery unit. The child's mother was concerned because she was familiar with giving her 8.6 kg child less than 2 mL of ibuprofen, as per the manufacturer's label instructions. However, the discharge instructions said to give 4.3 mL, or 86 mg of the 100 mg/5 mL concentration. After confirming that the mother had the 50 mg/1.25 mL and not the 100 mg/5 mL concentration at home, the hospital was able to tell the mother the appropriate volume of ibuprofen to administer to her child for each dose.

[May- August 2021 | Institute For Safe Medication Practices \(ismp.org\)](#)

# OTC Medications: Formulations / Concentrations as a Source of Confusion

- Experimental study involving ibuprofen (n=203)
  - Hypothetical scenario
    - Doctor tells parent to give 1 teaspoon (5 mL) of Children's Ibuprofen
    - Parent has Infant Ibuprofen at home
    - ~25% made a dosing error

# Resources exist to help parents navigate formulations

POLICY STATEMENTS Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

American Academy of Pediatrics  
DEDICATED TO THE HEALTH OF ALL CHILDREN<sup>SM</sup>

## Preventing Home Medication Administration Errors

H. Shonia Yin, MD, MSc, FAAP<sup>1</sup>; Daniel R. Neuspigel, MD, MPH, FAAP<sup>1</sup>; Ian M. Paul, MD, MSc, FAAP<sup>2</sup>  
COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY, COMMITTEE ON DRUGS

Medication administration errors that take place in the home are common, especially when liquid preparations are used and complex medication schedules with multiple medications are involved; children with chronic conditions are disproportionately affected. Parents and other caregivers with low health literacy and/or limited English proficiency are at higher risk for making errors in administering medications to children in their care. Recommended strategies to reduce home medication errors relate to provider prescribing practices; health literacy-informed verbal counseling strategies (eg, teachback and showback) and written patient education materials (eg, pictographic information) for patients and/or caregivers across settings (inpatient, outpatient, emergency care, pharmacy); dosing-tool provision for liquid medication measurement; review of medication lists with patients and/or caregivers (medication reconciliation) that includes prescription and over-the-counter medications, as well as vitamins and supplements; leveraging the medical home; engaging adolescents and their adult caregivers; training of providers; safe disposal of medications; regulations related to medication dosing tools, labeling, packaging, and informational materials; use of electronic health records and other technologies; and research to identify novel ways to support safe home medication administration.

**BACKGROUND**  
Errors in pediatric medication administration in the home environment are common<sup>1-3</sup> and can result in serious consequences.<sup>4-9</sup> These errors include dosing mistakes (both underdosing and overdosing), errors in frequency or duration of dosing (including missed doses), administration of incorrect medications or formulations, wrong route of administration, incorrect preparation or storage, and use of expired medications.<sup>2,4-7,9</sup> Many root causes have been identified that may contribute to errors.

**abstract**  
<sup>1</sup>Departments of Pediatrics and Population Health, Grossman School of Medicine, New York University, New York, New York; <sup>2</sup>Department of Pediatrics, Boston Children's Hospital, Boston (online); <sup>3</sup>Department of Pediatrics and Public Health Sciences, College of Medicine, Pennsylvania State University, Hershey, Pennsylvania  
Drs Yin, Neuspigel, and Paul participated in the conceptualization, writing, and revision of the policy statement, and all authors approved the final manuscript as submitted.  
This document is copyrighted and is property of the American Academy of Pediatrics and its Board of Directors. All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.  
Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and external (staff) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.  
The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.  
All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or extended at or before that time.  
**DOI:** <https://doi.org/10.1542/peds.2021-05-4668>  
**PEDIATRICS** (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).  
Copyright © 2021 by the American Academy of Pediatrics  
**FINANCIAL DISCLOSURE:** The authors have indicated they have no financial relationships relevant to this article to disclose.  
**FUNDING:** No external funding.  
**To cite:** Yin H-S, Neuspigel DR, Paul M, et al. Preventing Home Medication Administration Errors. *Pediatrics*. 2021;148(6):e2021054668.

## Preventing Home Medication Administration Errors Implementation Resources

Supported by:  
AAP Council on Quality Improvement and Patient Safety

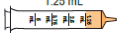
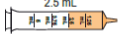
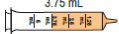






















November/December 2021

Listing of resources does not imply an endorsement by the American Academy of Pediatrics (AAP). The AAP is not responsible for the content of external resources.

**How to give the right amount of ACETAMINOPHEN (also known as Tylenol) is different depending on which medicine you plan to give.**

Dose: Give every 4 to 6 hours as needed for fever or pain. **DO NOT GIVE MORE THAN 4 DOSES IN 24 HOURS.**

Do NOT use with any other medicine containing acetaminophen.

Weight	Age	Infant's Acetaminophen (160 mg / 5 mL)	Children's Acetaminophen (160 mg / 5 mL)	Children's Acetaminophen Chewables (160 mg)	Children's Acetaminophen Dissolvable Packets (160 mg / powder pack)	Adult's Acetaminophen Tablets (325 mg)	Adult's Acetaminophen Tablets (500 mg)
6 to 11 pounds (3 to 5 kilograms)	0 to 3 months	1.25 mL 	—	—	—	—	—
12 to 17 pounds (about 5 to 7 kilograms)	4 to 11 months	2.5 mL 	—	—	—	—	—
18 to 23 pounds (about 8 to 10 kilograms)	12 to 23 months	3.75 mL 	—	—	—	—	—
24 to 35 pounds (about 11 to 15 kilograms)	2 to 3 years	—	5 mL 	1 tablet 	—	—	—
36 to 47 pounds (about 16 to 21 kilograms)	4 to 5 years	—	7.5 mL 	1 ½ tablets 	—	—	—
48 to 59 pounds (about 22 to 26 kilograms)	6 to 8 years	—	10 mL 	2 tablets 	2 packets 	1 tablet 	—
60 to 71 pounds (about 27 to 32 kilograms)	9 to 10 years	—	12.5 mL 	2 ½ tablets 	2 packets 	1 tablet 	—
72 to 95 pounds (about 33 to 43 kilograms)	11 years	—	15 mL 	3 tablets 	3 packets 	1 ½ tablets 	1 tablet 
96 pounds or more (more than 43 kilograms)	12 years or older	—	10 mL  and 10 mL 	4 tablets 	—	2 tablets 	1 tablet 

 **healthychildren.org**  
Powered by pediatricians. Trusted by parents.  
from the American Academy of Pediatrics.

**How to give the right amount of IBUPROFEN (also known as Motrin, Advil) is different depending on which type of ibuprofen you plan to give.**

Dose: Give every 6 hours if needed, for fever or pain. **DO NOT GIVE MORE THAN 4 DOSES IN 24 HOURS.** Do NOT use with any other medicine containing ibuprofen.



Weight	Age	Infant's Ibuprofen Drops (50 mg / 1.25 mL)	Children's Liquid Ibuprofen (100 mg / 5 mL)	Children's Ibuprofen Chewable Tablets (100 mg)	Adult's Ibuprofen Tablets (200 mg)
0 to 11 pounds (up to 5 kilograms)	0 to 5 months	—	—	—	—
12 to 17 pounds (about 6 to 7 kilograms)	6 to 11 months	1.25 mL 	2.5 mL* 	—	—
18 to 23 pounds (about 8 to 10 kilograms)	12 to 23 months	1.875 mL 	4 mL* 	—	—
24 to 35 pounds (about 11 to 15 kilograms)	2 to 3 years	2.5 mL 	5 mL* 	1 tablet 	—
36 to 47 pounds (about 16 to 21 kilograms)	4 to 5 years	3.75 mL 	7.5 mL* 	1 ½ tablets 	—
48 to 59 pounds (about 22 to 26 kilograms)	6 to 8 years	5 mL 	10 mL* 	2 tablets 	1 tablet 
60 to 71 pounds (about 27 to 32 kilograms)	9 to 10 years	—	12.5 mL* 	2 ½ tablets 	1 tablet 
72 to 95 pounds (about 33 to 43 kilograms)	11 years	—	15 mL* 	3 tablets 	1 ½ tablets 
96 pounds or more (44 kilograms or more)	12 years or older	—	10 mL*  and 10 mL* 	4 tablets 	2 tablets 

\*Note: This dosage is for children's liquid ibuprofen products given by dropper. See the previous column for correct dose-by-weight for infant ibuprofen drops, which are more concentrated.

<https://www.healthychildren.org/English/safety-prevention/at-home/medication-safety/Pages/Acetaminophen-for-Fever-and-Pain.aspx>

<https://www.healthychildren.org/English/safety-prevention/at-home/medication-safety/Pages/Ibuprofen-for-Fever-and-Pain.aspx>

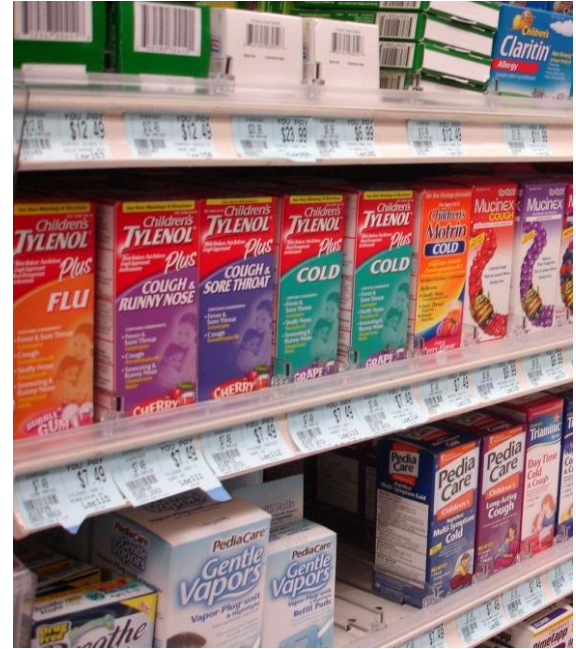
**Yin HS, Neuspiel DR, Paul IM. AAP Policy Statement: Preventing home medication administration errors. Pediatrics 2021; 148(6) -- Implementation Resources**

# Area of confusion: Active ingredients



# OTC Medications: Active Ingredients as a Source of Confusion

- Parents must determine if the same active ingredients are present when giving >1 medicine
  - ~1 in 3 pediatric cough/cold products contain acetaminophen
  - Can lead to double dosing if parents already giving acetaminophen



# OTC Medications: Active Ingredients as a Source of Confusion

- Experimental study (n=300)
  - Hypothetical scenario
    - Parent has already given acetaminophen to child
    - Now wants to give a cold/ cough medication



Acetaminophen



Acetaminophen  
Chlorpheniramine maleate  
Dextromethorphan  
Phenylephrine



Acetaminophen  
Dextromethorphan



Dextromethorphan  
Phenylephrine

# OTC Medications: Active Ingredients as a Source of Confusion

**1 in 3** correct choice

- No different than chance  
(Chi square, goodness of fit,  $p=0.4$ )
- **1 in 5** who made correct choice gave rationale of overlapping ingredients

**1 in 5** who looked for overlapping ingredients made wrong choice

Parents with low HL had  
**10x the odds** of making an error

## Use of Active Ingredient Information for Low Socioeconomic Status Parents' Decision-Making Regarding Cough and Cold Medications: Role of Health Literacy

*H. Shonna Yin, MD, MS; Alan L. Mendelsohn, MD; Perry Nagin, MSED; Linda van Schaick, MSED; Maria E. Cerra, BA; Benard P. Dreyer, MD*

From the Department of Pediatrics, New York University School of Medicine and Bellevue Hospital Center, New York, NY  
The authors have no conflicts of interest to disclose.  
Address correspondence to H. Shonna Yin, MD, MS, New York University School of Medicine, Department of Pediatrics, 550 First Avenue, NY 10016 (e-mail: yinh02@med.nyu.edu).  
Received for publication September 8, 2012; accepted January 8, 2013.

### ABSTRACT

**OBJECTIVE:** Parent administration of multiple medications with overlapping active ingredients places children at risk for overdose. We sought to examine how parents use active ingredient information as part of the process of selecting a cough/cold medication for their child and how health literacy plays a role.

**METHODS:** Experimental study of parents of children presenting for care in an urban public hospital pediatric clinic. Parents were asked to determine which of 3 cough/cold medications could be given to relieve a child's cold symptoms, as part of a scenario in which they had already given a dose of acetaminophen; only 1 did not contain acetaminophen. Primary dependent variable: correct selection of cough/cold medication by using active ingredient as the rationale for choice. Primary independent variable: parent health literacy (Newest Vital Sign test).

**RESULTS:** Of 297 parents, 79.2% had low health literacy (Newest Vital Sign score 0-3); 35.4% correctly chose the cough/cold medication that did not contain acetaminophen.

The proportion of those who made the correct choice was no different than expected from chance alone (Goodness of fit test;  $\chi^2 = 2.1, P = .3$ ). Only 7.7% chose the correct medication and used active ingredient as the rationale. Those with adequate literacy skills were more likely to have selected the correct medication and rationale (25.8% vs 3.0% ( $P = .001$ ); adjusted odds ratio 11.1 (95% confidence interval 3.6-33.7), after we adjusted for sociodemographics, including English proficiency and education.

**CONCLUSIONS:** Many parents, especially those with low health literacy, do not use active ingredient information as part of decision-making related to administering multiple medications.

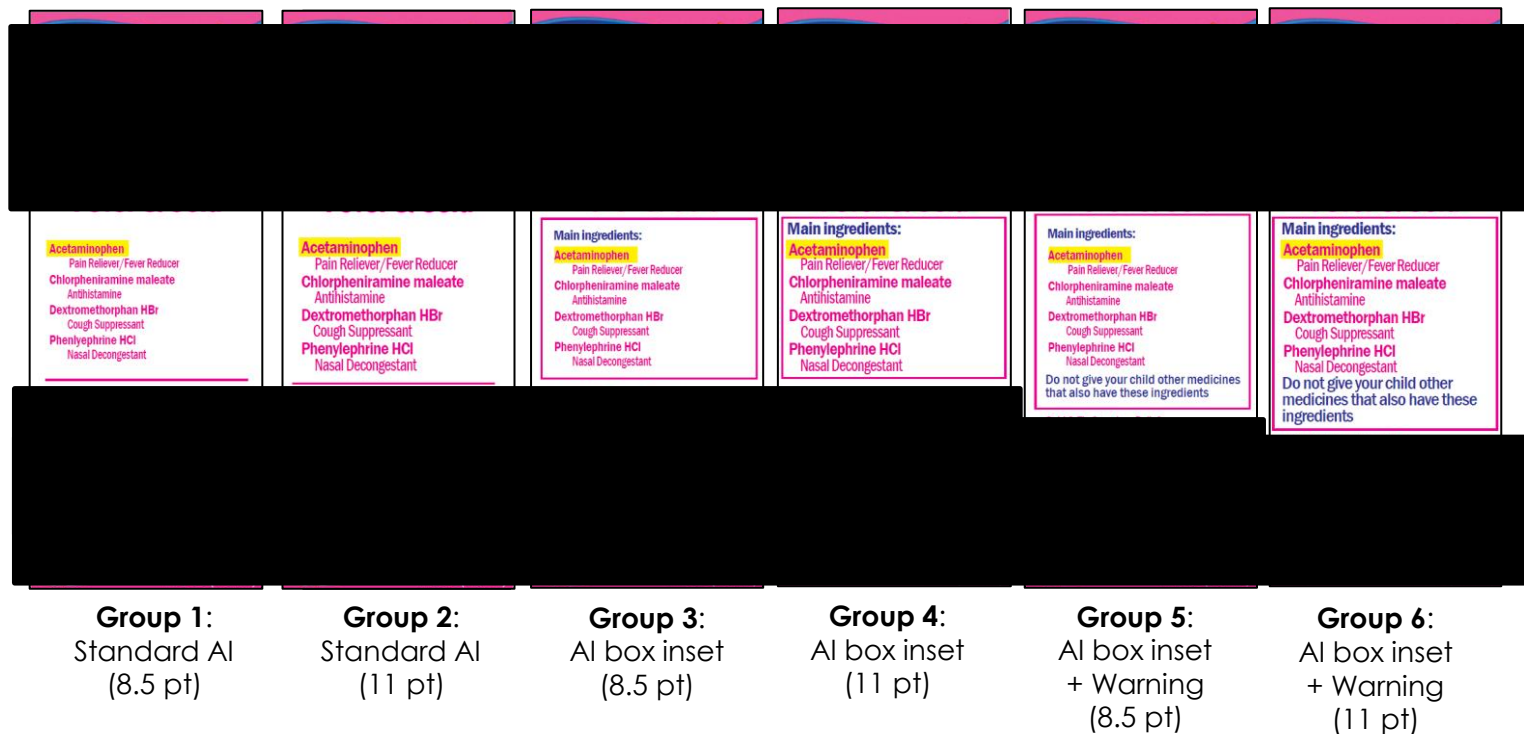
**KEYWORDS:** acetaminophen; active ingredient; cough/cold medication; health literacy; medication error

**ACADEMIC PEDIATRICS** 2013;13:229-235

# Can labeling changes improve parent understanding of active ingredients?

## Randomized Controlled Experiment (n=297)

- English/Spanish speaking parents
- Each parent reviewed 4-pairs of medications



# Can labeling changes improve parent understanding of active ingredients?

Randomized  
Controlled  
Experiment  
(n=297)

- English/Spanish speaking parents
- Each parent reviewed 4-pairs of medications

3-fold increased odds of correctly determining whether two medications are safe to give together in the groups that got the explicit warning vs. the groups who got the standard list

**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant  
Do not give your child other medicines that also have these ingredients

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant  
Do not give your child other medicines that also have these ingredients

**Group 1:**  
Standard AI  
(8.5 pt)

**Group 2:**  
Standard AI  
(11 pt)

**Group 3:**  
AI box inset  
(8.5 pt)

**Group 4:**  
AI box inset  
(11 pt)

**Group 5:**  
AI box inset  
+ Warning  
(8.5 pt)

**Group 6:**  
AI box inset  
+ Warning  
(11 pt)

# Can labeling changes improve parent understanding of active ingredients?

Randomized  
Controlled  
Experiment  
(n=297)

- English/Spanish speaking parents
- Each parent reviewed 4-pairs of medications

3-fold increased odds of correctly determining whether two medications are safe to give together in the groups that got the explicit warning vs. the groups that got the inset box

**Acetaminophen**  
Pain Reliever / Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Acetaminophen**  
Pain Reliever / Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever / Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever / Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever / Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant  
Do not give your child other medicines that also have these ingredients

**Main ingredients:**  
**Acetaminophen**  
Pain Reliever / Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant  
Do not give your child other medicines that also have these ingredients

**Group 1:**  
Standard AI  
(8.5 pt)

**Group 2:**  
Standard AI  
(11 pt)

**Group 3:**  
AI box inset  
(8.5 pt)

**Group 4:**  
AI box inset  
(11 pt)

**Group 5:**  
AI box inset  
+ Warning  
(8.5 pt)

**Group 6:**  
AI box inset  
+ Warning  
(11 pt)

# Can labeling changes improve parent understanding of active ingredients?

Randomized  
Controlled  
Experiment  
(n=297)

- English/Spanish speaking parents
- Each parent reviewed 4-pairs of medications

No difference in groups who received the standard list vs. inset box

**Acetaminophen**

Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Acetaminophen**

Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**

**Acetaminophen**  
Pain Reliever/ Fever Reducer  
**Chlorpheniramine maleate**  
Antihistamine  
**Dextromethorphan HBr**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

**Main ingredients:**

**Acetaminophen**  
Pain Reliever/ Fever R  
**Chlorpheniramine m**  
Antihistamine  
**Dextromethorphan I**  
Cough Suppressant  
**Phenylephrine HCl**  
Nasal Decongestant

Labeling changes can improve parent understanding of active ingredients

**Group 1:**  
Standard AI  
(8.5 pt)

**Group 2:**  
Standard AI  
(11 pt)

**Group 3:**  
AI box inset  
(8.5 pt)

**Group 4:**  
AI box inset  
(11 pt)

**Group 5:**  
AI box inset  
+ Warning  
(8.5 pt)

**Group 6:**  
AI box inset  
+ Warning  
(11 pt)

# Area of confusion: Dosing



# OTC Medications: Dosing Directions as a Source of Confusion

- **50-60%** of parents have difficulty determining correct dose using the dosing chart
- Only **~30-45%** know weight is primary basis for dosing
- Parents who know about weight-based dosing more likely to dose correctly
  - Less likely to give an incorrect dose (RR 0.71 [95% CI 0.52-0.97])

**Drug Facts** (continued)

**Directions** - do not take more than directed (see overdose warning)

- shake well before using
- find right dose on chart below. If possible, use age.

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2	ask a doctor
24-35	2-3	1 tsp or 5 mL
36-47	4-5	1 1/2 tsp or 7.5 mL
48-59	6-8	2 tsp or 10 mL
60-71	9-10	2 1/2 tsp or 12.5 mL
72-95	11	3 tsp or 15 mL

4 hours in 24 hours

**Dose (tsp or mL)**

- ask a doctor
- 1 tsp or 5 mL
- 1/2 tsp or 7.5 mL
- 2 tsp or 10 mL
- 2 1/2 tsp or 12.5 mL

72-95	11	3 tsp or 15 mL
-------	----	----------------

**Attention:** Specifically designed for use with enclosed measuring cup. Do not use any other dosing device.

**Other information**

- each teaspoon contains: sodium 2 mg
- do not use if bottle wrap, or foil inner seal imprinted "Safety Seal®" is broken or missing
- store between 20-25°C (68-77°F)
- see bottom panel for lot number and expiration date

**Inactive ingredients**

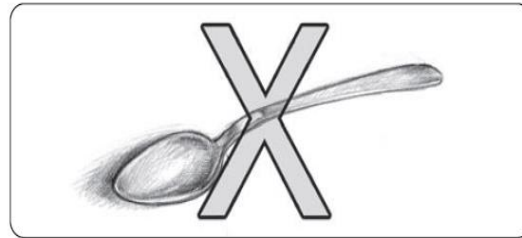
butylparaben, carboxymethylcellulose sodium, cellulose, citric acid, corn syrup, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Questions or comments?**

call toll-free 1-877-895-3665 (English) or 1-888-466-8746 (Spanish).

# Dosing tools as a source of confusion

- Many parents not aware that they should avoid use of kitchen spoons
  - Kitchen spoons vary widely in size and shape; measure 2-9 mL
  - Kitchen spoon use associated with higher rates of dosing error



AAP Plain Language Pediatrics 2009

# Range of tools provided in clinical & pharmacy settings

- Variability in type of dosing tools provided
  - For OTC products, dosing cups most commonly provided



Dosing spoon



Dosing cup



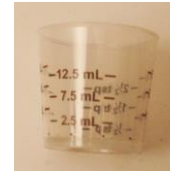
Oral syringe



Dropper

# Range of tools provided in clinical & pharmacy settings

- Experimental study of parent ability to dose with range of tools (n=302)
  - Parents asked to dose 5 mL using 4 types of tools
  - Order of dosing randomized



DOSING  
CUP #1



DOSING  
CUP #2



DOSING  
SPOON



DROPPER



ORAL  
SYRINGE +/-  
PRESS-IN  
BOTTLE  
ADAPTER

Table 4. Multiple Logistic Regression Models Using Generalized Estimating Equations to Determine the Effect of Dosing Instrument and Health Literacy on Dosing Errors

Model	Any Dosing Error <sup>a</sup>		Large Dosing Error <sup>b</sup>	
	AOR (95% CI) <sup>c</sup>	P Value	AOR (95% CI) <sup>c</sup>	P Value
<b>Instrument</b>				
Dosing cup with printed calibration markings	26.7 (16.8-42.4)	<.001	7.3 (4.1-13.2)	<.001
Dosing cup with etched calibration markings	11.0 (7.2-16.8)	<.001	6.3 (3.5-11.2)	<.001
Dropper	0.6 (0.4-1.04)	.07	0.8 (0.5-1.5)	.59
Dosing spoon	1.7 (1.1-2.7)	.02	0.3 (0.1-0.9)	.02
Oral syringe with bottle adapter	1.1 (0.7-1.6)	.69	0.8 (0.5-1.5)	.56
Oral syringe	1 [Reference]	NA	1 [Reference]	NA
<b>Health literacy level<sup>d</sup></b>				
High likelihood of limited literacy	1.7 (1.1-2.8)	.02	2.3 (1.2-4.6)	.01
Possible limited literacy	1.6 (1.02-2.6)	.04	1.9 (0.95-3.7)	.07
Adequate literacy	1 [Reference]	NA	1 [Reference]	NA

Dosing cup use associated with **6-7x** odds of large error

Intended dose 5 mL, range= 2.1-23.0 mL

## Parents' Medication Administration Errors

### Role of Dosing Instruments and Health Literacy

H. Shonna Yin, MD, MS; Alan L. Mendelsohn, MD; Michael S. Wolf, PhD, MPH;  
Ruth M. Parker, MD; Arthur Fierman, MD; Linda van Schaick, MEd; Isabel S. Bazan, BA;  
Matthew D. Kline, MA; Benard P. Dreyer, MD

**Objectives:** To assess parents' liquid medication administration errors by dosing instrument type and to examine the degree to which parents' health literacy influences dosing accuracy.

**Design:** Experimental study.

**Setting:** Interviews conducted in a public hospital pediatric clinic in New York, New York, between October 28, 2008, and December 24, 2008.

**Participants:** Three hundred two parents of children presenting for care were enrolled.

**Main Outcome Measures:** Parents were observed for

with etched markings, while more than 85% dosed accurately with the remaining instruments. Large dosing errors (>40% deviation) were made by 25.8% of parents using the cup with printed markings and 23.3% of parents using the cup with etched markings. In adjusted analyses, cups were associated with increased odds of making a dosing error (>20% deviation) compared with the oral syringe (cup with printed markings: adjusted odds ratio [AOR]=26.7; 95% confidence interval [CI], 16.8-42.4; cup with etched markings: AOR=11.0; 95% CI, 7.2-16.8). Compared with the oral syringe, cups were also associated with increased odds of making large dosing errors (cup with printed markings: AOR=7.3; 95% CI, 4.1-13.2; cup with etched markings: AOR=6.3; 95% CI, 3.5-11.2). Limited health literacy was associated with

# Dosing errors common

- Caregivers commonly make errors administering medications
  - **>40%** make dosing errors with Rx and OTC medications

Use of health literacy-informed strategies  
can help support parent understanding of  
correct dosing

- Patient- and medication-specific pictogram-based instruction sheets
  - Daily dose
  - As needed (predominantly acetaminophen, ibuprofen)
- Used as part of provider counseling
  - Plain language pictographic instruction sheets as framework for counseling
  - Demonstration
  - Teachback/showback
  - Standardized dosing tool provided
  - ~2 minutes


Name: Carlos      Nombre: Carlos

Information on your prescription for: Amoxicillin      Información sobre su receta para: Amoxicillin


To treat an infection of the ear      Para tratar una infección del oído

**5 mL (1 teaspoon) by mouth**  
2 times a day for 10 days


**5 mL (1 cucharadita) por la boca**  
2 veces al día por 10 días




Shake well  
Agite bien




Take 2 times a day by mouth  
Tome 2 veces al día por la boca



Store in refrigerator  
Guárdese en la nevera



Give this medicine for 10 days,  
even if your child is feeling better.  
Dé esta medicina por 10 días,  
aunque su niño se sienta mejor.



If you have questions call  
(212) 562-5524 day or night.  
Si tiene preguntas llame a  
(212) 562-5524 día o noche.

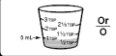
Read instructions from your pharmacist about your prescription. Lea las instrucciones de su farmacéutico sobre su receta.

The H.E.L.P. Project - Behavioral Inequality - Pediatric Resource Center - (212) 682-6224  
© 2008 New York University Center of Excellence - HealthCare Professionals for Low-Resource Settings

Keeping track of Carlos's Amoxicillin      Anotando las dosis de Amoxicillin de Carlos

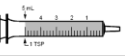
**5 mL (1 teaspoon) by mouth**  
2 times a day for 10 days

**5 mL (1 cucharadita) por la boca**  
2 veces al día por 10 días



5 mL  
1 tsp



Or



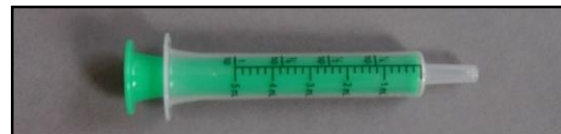
5 mL  
1 tsp

• Date of first dose February 4, 2008      Fecha de la primera dosis Febrero 4, 2008

Review: Please check to be certain how each time you give your child the medicine. 22 checks (✓) total.      Revisar: Por favor, asegúrese con el/la médico/a cuántas veces usted da la medicina a su niño. 22 marcas (✓) totales.

DAY / DIA	Time/Hora		
Monday / Lunes			
Tuesday / Martes			
Wednesday / Miércoles			
Thursday / Jueves			
Friday / Viernes			
Saturday / Sábado			
Sunday / Domingo			
Monday / Lunes			
Tuesday / Martes			
Wednesday / Miércoles			
Thursday / Jueves			

• Pediatrician - Please circle the starting dose and ending dose.  
The H.E.L.P. Project - Behavioral Inequality - Pediatric Resource Center - (212) 682-6224  
© 2008 New York University Center of Excellence





# HELPIx Efficacy Study

- RCT, NYC public hospital pediatric ED (n=245) (Yin 2008)

- English / Spanish-speaking parents of children prescribed a liquid medication (daily dose short course ( $\leq 14$ d) or prn)
- **Fewer dosing errors** (daily medications;  $>20\%$  deviation)
  - Standard care: 48%
  - HELPIx: 5%
  - $p < 0.001$
- **Decreased rates non-adherence** (within 20% of # expected total doses)
  - Standard care: 38%
  - HELPIx: 9%
  - $p < 0.001$

ARCHIVES OF  
**PEDIATRICS**  
& ADOLESCENT MEDICINE

ARTICLE

## Randomized Controlled Trial of a Pictogram-Based Intervention to Reduce Liquid Medication Dosing Errors and Improve Adherence Among Caregivers of Young Children

*H. Shonna Yin, MD, MS; Benard P. Dreyer, MD; Linda van Schaick, MS Ed; George L. Foltin, MD; Cheryl Dinglas, BA; Alan L. Mendelsohn, MD*

**Objective:** To evaluate the efficacy of a pictogram-based health literacy intervention to decrease liquid medication administration errors by caregivers of young children.

**Design:** Randomized controlled trial.

**Setting:** Urban public hospital pediatric emergency department.

**Participants:** Parents and caregivers (N=245) of children aged 30 days to 8 years who were prescribed liquid medications (daily dose or "as needed").

**Intervention:** Medication counseling using plain language, pictogram-based medication instruction sheets. Control subjects received standard medication counseling.

**Outcome Measures:** Medication knowledge and practice, dosing accuracy, and adherence.

**Results:** Of 245 randomized caregivers, 227 underwent follow-up assessments (intervention group, 113; control group, 114). Of these, 99 were prescribed a daily dose medication, and 158 were prescribed medication taken as needed. Intervention caregivers had fewer errors in observed dosing accuracy ( $>20\%$  deviation from prescribed dose) compared with caregivers who received routine counseling (daily dose: 5.4% vs 47.8%; absolute risk reduction [ARR], 42.4% [95% confidence interval, 24.0%-57.0%]; number needed to treat [NNT], 2 [2-4]; as needed: 15.6% vs 40.0%; ARR, 24.4% (8.7%-38.8%); NNT, 4 [3-12]). Of intervention caregivers, 9.3% were nonadherent (ie, did not give within 20% of the total prescribed doses) compared with 38.0% of controls (ARR, 28.7% [11.4%-43.7%]; NNT, 3 [2-9]). Improvements were also seen for knowledge of appropriate preparation for both medication types, as well as knowledge of frequency for those prescribed daily dose medications.

**Conclusion:** A plain language, pictogram-based intervention used as part of medication counseling resulted in decreased medication dosing errors and improved adherence among multiethnic, low socioeconomic status caregivers whose children were treated at an urban pediatric emergency department.

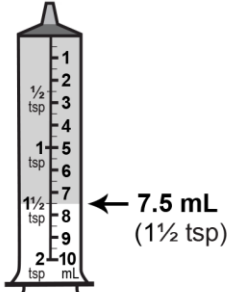
**Trial Registration:** [clinicaltrials.gov](http://clinicaltrials.gov) Identifier: NCT00537433

*Arch Pediatr Adolesc Med.* 2008;162(9):814-822

# Labels with pictograms can also reduce medication dosing errors

- NIH-funded randomized controlled study
- Text+pictogram instructions associated with **nearly 2x reduction** in large dosing errors (>2x dose) compared to text-only instructions

Take **7.5 mL** (1½ tsp):



**CARLOS HERNANDEZ**  
444 Main St., Chicago, IL 60611

**Amoxicillin 250 mg / 5 mL**  
Take 7.5 mL (1½ tsp) by mouth  
in the morning and at night  
for 10 days.  
Take for ear infection.

**Rx: 0664978-5527** Do not use after: 4/15/15  
Amount: 150 mL No refills  
Provider: Shonna Yin, MD

## Pictograms, Units and Dosing Tools, and Parent Medication Errors: A Randomized Study

H. Shonna Yin, MD, MS<sup>1,2,3,4</sup>, Ruth M. Parker, MD<sup>5</sup>, Lee M. Sanders, MD, MPH<sup>6</sup>, Alan Mendelsohn, MD<sup>4,8</sup>, Benard P. Dreyer, MD<sup>9</sup>, Stacy Cooper Bailey, PhD, MPH<sup>10</sup>, Deesha A. Patel, MS<sup>11</sup>, Jessica J. Jimenez, BA<sup>12</sup>, Kwang-Youn A. Kim, PhD<sup>13</sup>, Kara Jacobson, MPH<sup>14</sup>, Michelle C.J. Smith, BA<sup>15</sup>, Laurie Hedlund, MA<sup>16</sup>, Nicole Meyers, BS<sup>17</sup>, Terri McFadden, MD<sup>18</sup>, Michael S. Wolf, PhD, MPH<sup>19</sup>

abstract

**BACKGROUND AND OBJECTIVES:** Poorly designed labels and dosing tools contribute to dosing errors. We examined the degree to which errors could be reduced with pictographic diagrams, milliliter-only units, and provision of tools more closely matched to prescribed volumes.

**METHODS:** This study involved a randomized controlled experiment in 3 pediatric clinics. English- and Spanish-speaking parents (n = 401) of children of 2 years old were randomly

action  
r/  
es [2,  
order.  
).  
ent in  
impact  
ose

0.4];  
ors were  
ent-

aOR =  
ons or  
aOR =

es is an

1/1/15

**IMPORTANT: Finish all of this medicine (unless your doctor tells you to stop).**

Pink liquid

**CITY PHARMACY**<sup>+</sup>  
10 E. Wabash  
Chicago, IL 60601  
**(312) 555-5555**

NIH

**ON THIS SUBJECT:** Poorly designed labels and dosing tools contribute to dosing errors. Initial findings from the Safe Administration for Every Rx for Kids study identified high rates of error with cups compared with syringes, especially for small dose amounts, and greater confusion when labels included teaspoon-only instructions.

**WHAT THIS STUDY ADDS:** Dosing tools should be provided that more closely match prescribed dose volumes, such that there is little room to overdose and no need to measure

# Area of confusion: Age restrictions

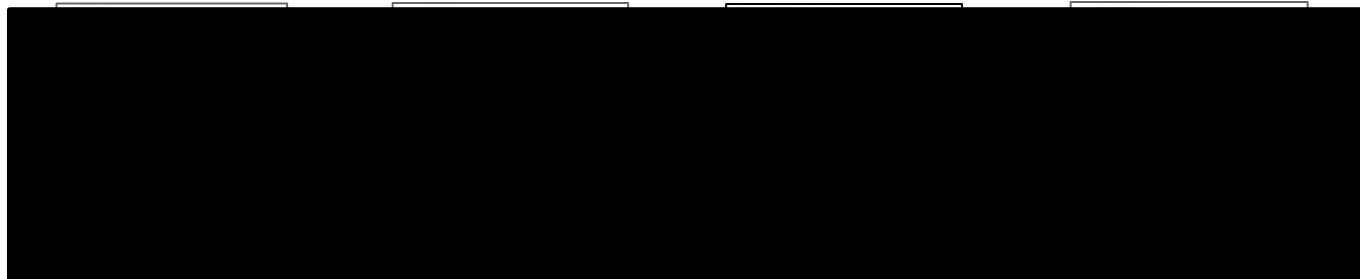
# Age Restrictions for OTC Pediatric Cough/Cold Medications (CCMs)

- In 2008, FDA issued a national public health advisory recommending CCMs not be used in children **less than 2 years old**
  - Voluntary extension to children **less than 4 years old** by manufacturers of OTC CCMs
  - AAP cautions against the use of CCMs until **over 6 years old**
- Consumers continue to use CCMs in young children, and consumer confusion is common

# Can labeling changes improve parent understanding of age restrictions for OTC Cough/Cold medications?

Randomized  
Controlled  
Experiment (n=297)

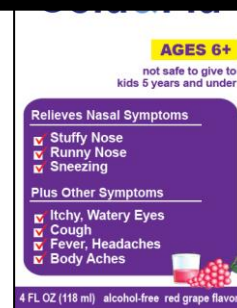
- English/Spanish speaking parents
- Each parent reviewed 5 medication labels



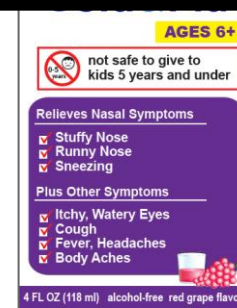
**Group 1:**  
No age  
information on  
front panel



**Group 2:**  
Age information



**Group 3:**  
Age information  
+ safety warning  
for younger ages



**Group 4:**  
Age information  
+ safety warning  
for younger ages  
+ pictogram

# Can labeling changes improve parent understanding of age restrictions for OTC Cough/Cold medications?

4-fold increased odds of correctly determining medication safe for their child based on age info in the group who got the explicit warning vs. group with no age info

Randomized  
Controlled  
Experiment (n=297)

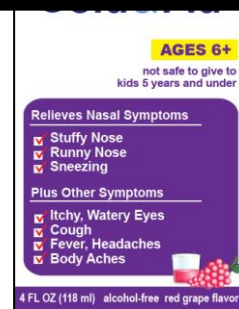
- English/Spanish speaking parents
- Each parent reviewed 5 medication labels



**Group 1:**  
No age information on front panel



**Group 2:**  
Age information



**Group 3:**  
Age information + safety warning for younger ages



**Group 4:**  
Age information + safety warning for younger ages + pictogram

# Can labeling changes improve parent understanding of age restrictions for OTC Cough/Cold medications?

2-fold increased odds of correctly determining medication safe for their child based on age info in group with the explicit safety warning vs. group with basic age info

Randomized  
Controlled  
Experiment (n=297)

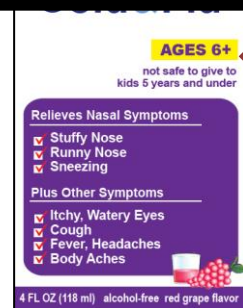
- English/Spanish speaking parents
- Each parent reviewed 5 medication labels



**Group 1:**  
No age information on front panel



**Group 2:**  
Age information



**Group 3:**  
Age information + safety warning for younger ages

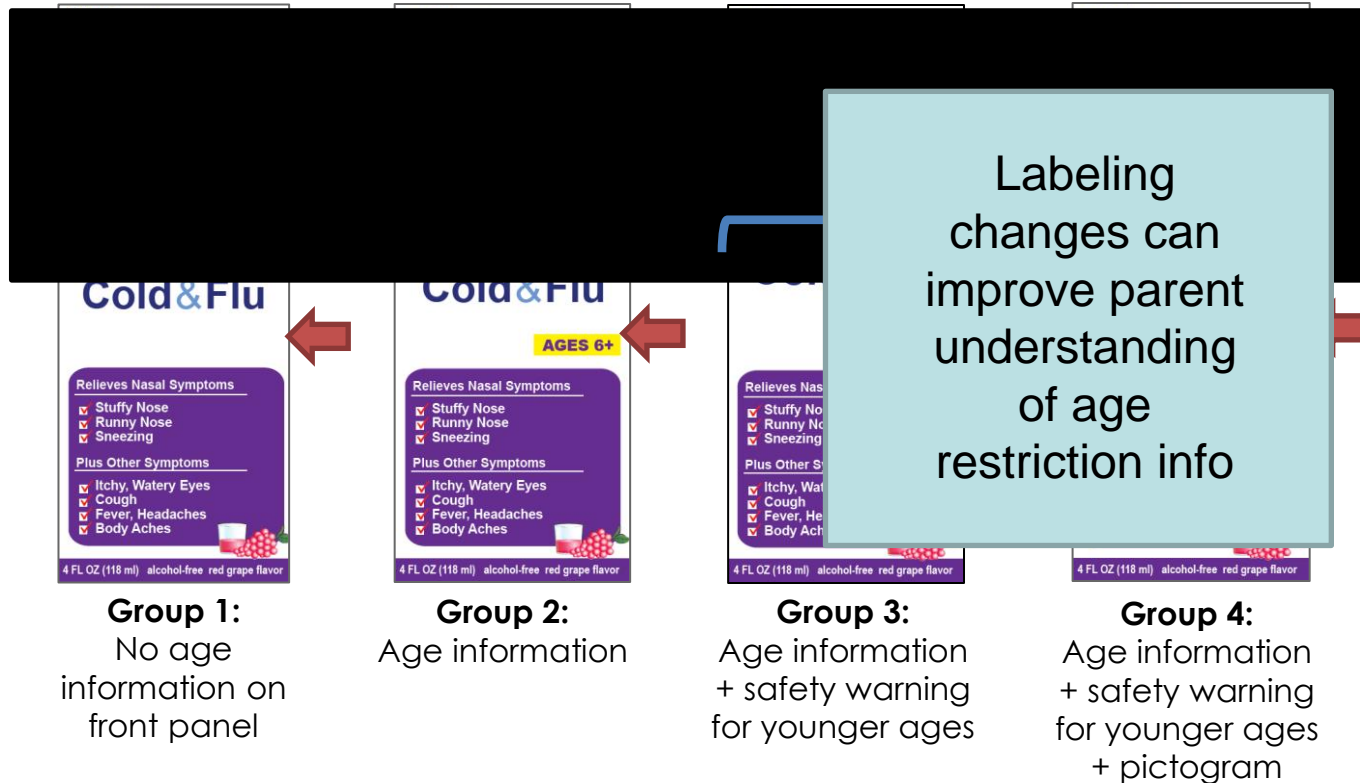


**Group 4:**  
Age information + safety warning for younger ages + pictogram

# Can labeling changes improve parent understanding of age restrictions for OTC Cough/Cold medications?

Randomized  
Controlled  
Experiment (n=297)

- English/Spanish speaking parents
- Each parent reviewed 5 medication labels





# Conclusions

- Many sources of existing confusion for parents using medications
  - Formulations / concentrations, active ingredients, dosing, age restrictions
- If we change product characteristics, health literacy-informed approaches should be considered to support parent understanding and ability to act on medication changes, including
  - **Education / counseling** (verbal and written approaches, including teachback, use of pictographic information)
  - **Improved labeling**
- Need for extensive consumer testing, especially with those with low health literacy



HASSENFELD  
**CHILDREN'S  
HOSPITAL**  
AT NYU LANGONE

NYC  
HEALTH+  
HOSPITALS

Bellevue

**H. Shonna Yin, MD, MS**

[YINH02@med.nyu.edu](mailto:YINH02@med.nyu.edu)

Department of Pediatrics and Population Health  
NYU School of Medicine / Bellevue Hospital Center  
550 First Avenue NBV 8S-4-11  
New York, NY 10016