

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

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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

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WHAT'S NEW

A large proportion of parents do not use active ingredient information as part of decision-making regarding the administration of multiple medications. Parents with low literacy are less likely to recognize the importance of active ingredient information.

INTRODUCTION

COUGH/COLD PRODUCTS FREQUENTLY contain more than one active ingredient; 1 in 5 popular cough/cold products for children include an antipyretic/analgesic, most commonly acetaminophen.¹ Parents unaware of the presence of acetaminophen as an ingredient in a cough/cold product may inadvertently administer 2 products containing acetaminophen at the same time.^{2–5} This has been linked to cases of acetaminophen overdosing involving significant pediatric morbidity and mortality.^{3,5–7}

The US Food and Drug Administration has issued labeling requirements that mandate the inclusion of active ingredient information within the Drug Facts Panel for all

over-the-counter (OTC) products.⁸ Despite the presence of this information on product labeling, consumers have difficulty identifying active ingredients, with up to three-quarters unable to do so.^{4,9–11}

Low health literacy has been associated with difficulty interpreting medication labels as well as dosing errors^{2,12–14} and is one factor that is likely to play a role in parent's ability to use active ingredient information. This may be especially true with OTC products, as parents typically receive limited guidance from health care providers when medications are not prescribed.¹⁵ Those from low socioeconomic status (SES) are more likely to have low health literacy and are at particular risk for errors.¹⁵ Suboptimal presentation of active ingredient information further contributes to parent confusion. A recent assessment of OTC labels found that active ingredient names were absent on the front panel in 1 in 5 products, and font sizes of active ingredients were on average smaller than product brand name and flavor.^{2,16}

An additional factor that may play a role, particularly in low-income, immigrant populations, is limited English proficiency (LEP). LEP is a well-recognized risk factor

for adverse health outcomes.^{17,18} One mechanism through which LEP acts is through the ability to comprehend written materials, a skill that overlaps with health literacy, particularly in the U.S. where medication labels are typically in English.^{2,19,20} To date, there has been limited study of how LEP may act in tandem with health literacy in impacting health-related issues.²¹ Disentangling the impact of the 2 would be useful, as LEP may be an important confounder of health literacy.

To our knowledge, in no previous study have authors examined the use of active ingredient information as part of decision-making when administering multiple medications, and the role of health literacy among low SES families who are at particular risk for error. We therefore sought to examine how parents use active ingredient information in selecting a cough/cold medication for their child and the degree to which health literacy impacts this process, as well as the extent to which LEP confounds or moderates health literacy-related impacts.

METHODS

DESIGN AND RECRUITMENT

This was an experimental study of parents/legal guardians of children presenting for care in the pediatric clinic at Bellevue, a public hospital in New York City. The clinic averages ~65,000 visits annually and primarily serves low SES families. The New York University School of Medicine Institutional Review Board and the Bellevue Facility Research Review Committee granted approval for this study.

For the purposes of this article, we refer to both parents and legal guardians as parents. Parents were approached while waiting in the clinic. Study information was presented in English or Spanish, based on parent preference. If the parent agreed to participate, informed consent was obtained, and an interview conducted. Research assistants were trained to present information in a health literacy-sensitive manner. Consent information was presented verbally to all subjects, who were then offered the opportunity to review the written consent as well as ask questions. No study incentive was provided. Inclusion criteria were as follows: parent/legal guardian who is English or Spanish speaking and who is responsible for administering medications to their child.

ASSESSMENTS

Assessment questions were presented by an English- or Spanish-speaking research assistant based on parent language preference. The primary outcome variable was parent ability to select the correct medication and indicate the use of active ingredient information as part of the rationale for their choice. In addition, parent health literacy and potential confounders were assessed.

DEPENDENT VARIABLES

CHOICE OF COUGH/COLD MEDICATION

Parents were presented with a hypothetical scenario in which they had just given their 6-year-old child a 10-mL

dose of Tylenol. Parents were told that half an hour later, they notice their child also has cold symptoms and were asked to determine which of 3 possible cough/cold medications could be given at that time to relieve their child's symptoms. The following instructions were provided: "Your child is coughing a lot. He is congested, and complains that his throat hurts. You want to give your child a medicine so that he can rest and get better. Here are three cough and cold medicines. Which one of these three medicines would you give your child?" The parent was then given 3 boxes of cough/cold medicine: Children's Tylenol Plus Multi-Symptom Cold (Johnson & Johnson Co., New Brunswick, NJ; acetaminophen, chlorpheniramine maleate, dextromethorphan, phenylephrine), Children's Triaminic Cough & Sore Throat (Novartis Consumer Health, Inc., Parsippany, NJ; acetaminophen, dextromethorphan), and Children's Triaminic Day Time Cold & Cough (dextromethorphan, phenylephrine), along with the Tylenol box. The 3 medications were chosen because they are popular medications available for purchase at drug stores. Children's Tylenol Plus Multi-Symptom Cold was included to examine whether parent rationale for selection is influenced by a preference to continue to give the same brand product as previously used. Of the 2 Triaminic products, one contained acetaminophen, and one did not. Those parents who selected the Triaminic Day Time Cold and Cough medication were considered to have chosen the correct medication.

OTC medication labels used in this study were written in English, consistent with OTC medication labels in the U.S., which are typically available only in English,² and followed the approach of the US Department of Education's National Assessment of Adult Literacy,²² which used written materials in English as part of tasks to assess health literacy. This approach allowed us to examine both health literacy and LEP using written materials reflective of the challenges families face in real-world settings.

RATIONALE FOR CHOICE OF COUGH/COLD MEDICATION

Parents were asked to explain the rationale for their selection of cough/cold medication ("Why did you pick this medicine, instead of one of the other two medicines?"). Verbatim responses were documented. Ten categories, divided into 3 topics, were created for rationales on the basis of post hoc review of responses and investigator consensus blinded to parent health literacy category. The topics divided rationales into those: (1) involving comparison of 2 medications (eg, concern about overlap in active ingredients), (2) involving consideration of symptoms (eg, wanting symptoms of child to match symptoms covered by medication), and (3) not related to comparing medications/ symptoms or no rationale given (eg, brand recognition). Two reviewers (H.S.Y., P.N.) independently assessed each parent response; interrater reliability was high (mean κ across categories 0.94; range, 0.84–1.0). A third rater (L.V.S.) reviewed instances of disagreement, with final results reflecting agreement of 2 of the 3 investigators. Those parents whose response reflected a concern about

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