

NIH Public Access

Author Manuscript

Acad Pediatr. Author manuscript; available in PMC 2014 May 01.

Published in final edited form as: *Acad Pediatr.* 2013 ; 13(3): 229–235. doi:10.1016/j.acap.2013.01.004.

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, MS¹, Alan L. Mendelsohn, MD¹, Perry Nagin, MSEd¹, Linda van Schaick, MSEd¹, Maria E. Cerra, BA¹, and Benard P. Dreyer, MD¹

¹Department of Pediatrics, New York University School of Medicine and Bellevue Hospital Center, New York, New York

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, using active ingredient as the rationale for choice. Primary independent variable: parent health literacy (Newest Vital Sign (NVS)).

RESULTS—Of 297 parents, 79.2% had low health literacy (NVS score 0–3). 35.4% correctly chose the cough/cold medication which 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; χ^2 =2.1, p=0.3). 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=0.001); AOR=11.1 [95%CI: 3.6–33.7], adjusting 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

medication error; health literacy; cough/cold medication; active ingredient; acetaminophen

CONFLICTS OF INTEREST: The authors have no conflicts of interest to disclose.

CORRESPONDENCE: H. Shonna Yin, MD, MS, New York University School of Medicine, Department of Pediatrics, 550 First Avenue, NBV 8S4-11, New York, NY 10016, Telephone: (212) 562-2821; Fax: (212) 263-8172, yinh02@med.nyu.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

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 two 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 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 ⁸, with up to three-quarters unable to do so.^{4,9–117}

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 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) backgrounds 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 US, 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 two would be useful, as LEP may be an important confounder of health literacy.

To our knowledge, no prior study has examined 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 NYU School of Medicine Institutional Review Board and the Bellevue Facility Research Review Committee granted approval for this study.

For the purposes of this paper, 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, 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. Additionally, 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 three boxes of cough/cold medicine: Children's Tylenol Plus Multi-Symptom Cold (acetaminophen, chlorpheniramine maleate, dextromethorphan, phenylephrine), Children's Triaminic Cough & Sore Throat (acetaminophen, dextromethorphan), and Children's Triaminic Day Time Cold & Cough (dextromethorphan, phenylephrine), along with the Tylenol box. The three 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 two Triaminic products, one contained acetaminophen, and one did not.

Those parents who selected the Triaminic Daytime Cold and Cough medication were considered to have chosen the correct medication.

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

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 three topics, were created for rationales based on post hoc review of responses and investigator consensus blinded to parent health literacy category. The topics divided rationales into those: 1) involving comparison of two 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 (HSY, PN) independently assessed each parent response; interrater reliability was high (mean k across categories=0.94; range=0.84–1.0). A third rater (LVS) reviewed instances of disagreement, with final results reflecting agreement of 2 of the 3 investigators. Those parents whose response reflected a concern about overlapping active ingredients were considered to have used a correct rationale.

Independent Variables

Health Literacy—Health literacy level was assessed using the Newest Vital Sign (NVS) in English or Spanish (language of parent preference).²³ Scores on the NVS range from 0–6, with a score of 0–1 indicating a "high likelihood of limited literacy," 2–3 a "possibility of limited literacy," and 4–6 adequate literacy.²³ Parents who were categorized as having a "high likelihood of limited literacy" or "possibility of limited literacy" were combined into one "low health literacy" category, and compared to those with adequate literacy.

Sociodemographics and Other Characteristics—The following sociodemographic data was obtained from the parent: age; relationship to child; marital status; ethnicity; language; English proficiency; country of birth; SES; and education level. Characteristics of the children in the household were assessed by asking the age of each child and history of chronic disease.

Relationship to the child present at the visit was categorized as mother, father or legal guardian. Marital status was categorized as single (single/separated/divorced) or with partner (living together/married). Race/ethnicity was categorized as Hispanic, White, Black, Asian and other. For the purposes of analyses, race/ethnicity was categorized as Latino or non-Latino, as Latinos represent the majority of patients seen at Bellevue and no other racial/ ethnic group comprised a large enough proportion of the sample to define separately. Language was categorized based upon language of NVS administration. English proficiency was dichotomized based on whether the parent reported speaking English "very well" (English proficient) vs. all other responses ("well" "not well," "not at all"; LEP). Country of birth was categorized as US-born or birthplace outside of US. The Hollingshead Index was used to assess SES (5-point scale: 1 representing highest and 5 lowest resource level).²⁴ We compared those with an SES score of 4 or 5 to those with scores of 1 to 3. Education was categorized based on whether or not the parent completed high school.

Ages of children in the household was used to categorize whether or not there was presence of children 8 years old.²² Presence of any child in the home with a chronic medical problem was assessed using questions adapted from the Children with Special Health Care Needs Screener.²⁵

Statistical Analysis

Data were analyzed using SPSS 20.0 (SPSS Inc., Chicago, IL). For all analyses, a 2-tailed pvalue of <0.05 was considered to be statistically significant. We used a chi-square Goodness of Fit test to determine whether or not the proportion of those who chose the correct medication was greater than chance. We assessed associations between dependent variables (correct choice of cough/cold medication, correct rationale for choice, and composite variable for correct medication plus correct rationale) and health literacy, using bivariate (χ^2 or Fisher's exact test) and adjusted analyses (multiple logistic regression analyses). Adjusted analyses were performed with inclusion of potential confounders based on theoretical and empirical considerations, including caregiver age, language, English proficiency, ethnicity, US country of birth, and SES, presence of child 8 years of age in household, and child chronic disease. Given debate about the relationship between education and health literacy,

and inclusion of both as independent factors, we analyzed models with and without education.^{26–28} Bivariate associations between rationale categories and health literacy were also assessed using χ^2 or Fisher's exact tests. To examine LEP as a potential moderator of the relationship between health literacy and dependent variables, we performed subgroup analyses by LEP, as well as tested for the presence of an interaction, using the full model described above, as well as without inclusion of language.

RESULTS

From August 2009 through October 2010, 300 parents were enrolled. Approximately twothirds of potential study subjects who were approached agreed to participate. Concern about missing/being delayed for their appointment was the primary reason given for refusal. Of 300 parents, 3 caregivers did not complete the health literacy assessment, and were excluded. The majority of study subjects were mothers (93.6%), with over three quarters (76.1%) Latino (Table 1). Over half had LEP (63.6%).

Health Literacy

The majority of families had low health literacy (49.2% high likelihood of limited literacy; 30.0% possible limited literacy) (Table 1). Mean (SD) NVS score was 2.0 (1.7).

Choice of Cough/Cold Medication

Approximately a third of parents (35.4%) selected the correct medicine, Triaminic Daytime Cold and Cough; 26.6% Triaminic Cough and Sore Throat and 38.0% Tylenol Plus Multi-symptom Cold. The proportion of those who selected the correct medication was no different from what would have been expected from chance alone (Goodness of fit χ^2 =2.1; p=0.3).

Rationale for Choice of Cough/Cold Medication

The majority of parents (78.5%) provided one rationale for their choice (mean (SD)=1.2 (0.6)) (4.4\% none, 18.5\% two, 3.0% three). One in ten (10.4%) provided a correct rationale that reflected an understanding that two medications with overlapping ingredients should not be given (Table 2). Of parents who provided a correct rationale, 1 in 4 (25.8%) did not select the correct medication.

Correct Choice of Cough/Cold Medication Plus Correct Rationale

Of those who selected the correct medicine, only 1 in 5 (21.9%) cited the correct rationale. For the sample as a whole, only 7.7% of parents chose the correct medication with correct rationale.

Association Between Parent Health Literacy and Choice of Cough/Cold Medication

Overall, more parents with adequate health literacy choose the correct medication compared to parents with low literacy (43.5 vs. 33.2%), but this was not statistically significant in unadjusted or adjusted analyses (Table 3).

Association Between Parent Health Literacy and Rationale for Choice of Cough/Cold Medication

Parents with adequate health literacy were more likely to report a rationale that reflected an understanding about overlapping active ingredients (29.0 vs. 5.5%; p<0.001) (Table 2). In adjusted analyses, adequate health literacy was associated with a >6 times odds of identifying the correct rationale (Table 3). parents with adequate literacy chose the correct medication compared to those with low literacy (88.9 vs. 58.3%; p=0.04).

Associations Between Other Characteristics and Dependent Variables of Interest

No associations were found between other parent and child characteristics and correct medication choice. In unadjusted analyses, having a child >8 years old, higher SES, US country of birth, English language, and education were associated with use of active ingredient as a rationale, as well as both choosing the correct medication and rationale. None of these characteristics remained significantly associated with these dependent variables in adjusted models.

With respect to LEP, in unadjusted analyses, English proficiency was associated with increased use of the correct rationale (16.7 vs. 6.9%; p=0.01), although there was no statistically significant difference by LEP with respect to choosing the correct medication (66.7 vs. 63.5%; p=0.6) or choosing the correct medication with the appropriate rationale (11.1 vs. 5.8%; p=0.1). In adjusted models (with and without health literacy, and confounders as described above, as well as without language), LEP was not statistically significantly related to any dependent variable. In subgroup analyses of those both with and without LEP, adequate health literacy was associated with increased odds of citing both the correct medication and rationale, similar to the full group model in both unadjusted and adjusted analyses (eg. Model 2: LEP (n=189): AOR=8.2 [95%CI: 1.7–39.8]; not LEP (n=108): AOR=21.3 [2.2–205.1]). No statistically significant interaction was found between health literacy and LEP, consistent with subgroup analyses.

DISCUSSION

To our knowledge, this is the first study looking at the decision-making process of parents when administering more than one medication to children, and the role of literacy skills. A majority of parents in our study, including over half with adequate literacy, chose an OTC product that would have led to administration of two medications with overlapping active ingredients. Few parents indicated that they used active ingredient information as part of decision-making, with low literacy parents less likely to do so.

While there has been limited study of the use of active ingredient information as part of decision-making about medications, our results are consistent with prior research which found that nearly half of adults would overdose by 'double-dipping' with two acetaminophen-containing products.²⁹ In our study, nearly two-thirds of parents would have given two medications containing acetaminophen. Of those parents who correctly chose the cough/cold medication without acetaminophen, only 1 in 5 used active ingredient information as part of their rationale. The proportion of those who made the correct choice of medication was no different than what would have been expected from chance alone.

We also found that even among parents who considered active ingredient information as part of their decision-making process, 1 in 4 were unable to make the correct choice of medication, suggesting that they may not have been able to identify and compare the active ingredients listed on the boxes of the different products. Prior studies have found that only a quarter to a third of adults are able to report the active ingredients of OTC products they use.^{9,10}

We found that adequate literacy was associated with a >10 times odds of choosing the appropriate medication along with use of active ingredients as part of their rationale. While there has been limited study of the role of low health literacy and use of active ingredient information, our study findings are consistent with those of prior studies which link low health literacy to poor medication management issues such as dosing errors and non-adherence.^{2,16,30–32}

Understanding medication labeling can be especially challenging for those with low health literacy. It has been previously recommended that medication labels be redesigned using a health literacy perspective to improve consumer comprehension.^{2,16,29,33} Reduction of competing content as well as use of pictographic information have been cited as potential strategies that may improve consumer ability to identify active ingredient information.^{2,15,33}

Parent perceptions related to product brand names may contribute to lack of use of active ingredient information in decision-making.² Nearly 20% of parents in our sample described a rationale for choice of medication based on brand name. Brand name information is generally more prominently displayed than active ingredient information, on average 3 times larger on the front panel of pediatric OTC products,¹⁶ which may affect the amount of attention paid to this information by consumers.

A small number of parents in our study (6%) recognized the need to compare two medications being given at the same time (eg. can't mix brands), but did not specifically cite overlapping active ingredients as part of their rationale. Those with adequate literacy were more likely to cite this concern compared to those with lower levels of literacy, although this was not statistically significant (p=0.06). This finding suggests that recognizing the importance of comparing two medications being given at the same time may involve complex information processing skills that are more likely used by those with higher literacy levels.^{34–36}

The majority of parents in our study used matching of symptoms as the primary rationale for choosing the cough/cold medication. Overall, more parents with low literacy wanted the symptoms of the child to match the symptoms covered by the medication, which may reflect more concrete thinking among those with low literacy.

Our finding that even among those with adequate literacy, only 1 in 4 were able to choose the correct medication using active ingredient information, suggests that the task of decision-making related to the administration of multiple medications may place too high of a cognitive load on parents, affecting parents across literacy levels, but especially impacting those with low literacy. With 1 in 4 US children exposed to 2 or more medications in a given week, two-thirds of cases which involve OTC products,³⁷ this issue is a public health concern. ²⁹

We recognize that one challenge related to the interpretation of our study findings is that parents were presented with medication packaging in English, reflecting what is usually accessible on store shelves. This approach was consistent with that taken by the federal government in the assessment of US health literacy.²² While it is possible that our findings were related to LEP rather than health literacy, associations with HL were present in models including LEP as a potential confounder or moderator, supporting a robust independent effect of health literacy. This study was not specifically designed to test impacts of LEP per se on parent use of active ingredient information, but we found no relationship between LEP and dependent variables in adjusted models. Further focused studies on pathways by which LEP influences health-related outcomes may be indicated.

There are limitations to this study. First, our assessments were based on a hypothetical scenario, which may not accurately reflect a parent's true ability to manage medications for their child. Second, we presented parents with three popular cough/cold medications to select from, but recognize that future studies could evaluate a wider array of products to more fully represent the choices that parents face in the real world situation of purchasing products in the pharmacy. Third, adjusted analyses were potentially limited by small subgroup cell sizes, sometimes resulting in wide confidence intervals. Finally, we conducted

this study in an urban public hospital which serves a predominantly low SES, Latino population. Our results may not be generalizable to other groups.

In conclusion, this study highlights the complexity of the task of using active ingredient information to choose an appropriate medication for a child when multiple medications are available for administration. Parents with low literacy are less able to use and incorporate active ingredient information in decision-making. Strategies to improve the use of active ingredient information for parents across literacy levels are needed, including exploring how to improve the prominence of active ingredient information presented on medication packaging. Educational campaigns to teach parents about how to use active ingredient information may be beneficial, and should involve both health care providers as well as public health officials. Additional studies are needed to identify which strategies are most effective in improving understanding of active ingredient information, and should engage consumers across literacy levels in the design and testing of these strategies.

Acknowledgments

FUNDING: Dr. Yin is supported in part by the Robert Wood Johnson Physician Faculty Scholars Program. The Robert Wood Johnson Foundation had no role in the design and conduct of the study, in the collection, management, analysis, or interpretation of the data, or in the preparation, review, or approval of the manuscript. Dr. Yin is also supported by HRSA Grant 12-191-1077- Academic Administrative Units in Primary Care, and the NIH Loan Repayment Program (L40 HD062191).

REFERENCES

- Yin HS, Wolf MS, Dreyer BP, Sanders LM, Parker RM. Evaluation of consistency in dosing directions and measuring devices for pediatric nonprescription liquid medications. JAMA: The Journal of the American Medical Association. 2010; 304(23):2595–2602. [PubMed: 21119074]
- King JP, Davis TC, Bailey SC, et al. Developing Consumer-Centered, Nonprescription Drug Labeling: A Study in Acetaminophen. American Journal of Preventive Medicine. 2011; 40(6):593– 598. [PubMed: 21565649]
- 3. Gunn VL, Taha SH, Liebelt EL, Serwint JR. Toxicity of over-the-counter cough and cold medications. Pediatrics. 2001; 108(3):e52. [PubMed: 11533370]
- 4. Hanoch Y, Gummerum M, Miron-Shatz T, Himmelstein M. Parents' decision following the Food and Drug Administration recommendation: the case of over-the-counter cough and cold medication. Child: Care, Health & Development. 2010; 36(6):795–804.
- Larson AM, Polson J, Fontana RJ, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. Hepatology. 2005; 42(6):1364–1372. [PubMed: 16317692]
- Kearns GL, Leeder JS, Wasserman GS. Acetaminophen overdose with therapeutic intent. The Journal of Pediatrics. 1998; 132(1):5–8. [PubMed: 9469992]
- Webster P, Roberts D, Benson R, Kearns G. Acetaminophen toxicity in children: diagnostic confirmation using a specific antigenic biomarker. The Journal of Clinical Pharmacology. 1996; 36(5):397–402.
- 8. New OTC drug facts label. FDA Consum. 2002; 36(4):35.
- Hornsby LB, Whitley HP, Hester EK, Thompson M, Donaldson A. Survey of patient knowledge related to acetaminophen recognition, dosing, and toxicity. Journal Of The American Pharmacists Association: JAPhA. 2010; 50(4):485–489. [PubMed: 20621866]
- NCPIE. [Accessed August 10, 2012] Attitudes and Beliefs About the Use of Over-the-Counter Medicines: A Dose of Reality. 2002. http://bemedwise.org/survey/final_survey.pdf
- Birchley N, Conroy S. Parental management of over-the-counter medicines. Paediatr Nurs. 2002; 14(9):24–28. [PubMed: 12510331]
- 12. Davis TCWM, Bass PF3rd, et al. Literacy and misunderstanding of prescription drug labels. Annals of Internal Medicine. 2006; 145(12):887–894. [PubMed: 17135578]

- Davis TCWM, Bass PF3rd, et al. Low literacy impairs comprehension of prescription drug warning labels. Journal of General Internal Medicine. 2006; 21(8):847–851. [PubMed: 16881945]
- Yin HS, Mendelsohn AL, Wolf MS, et al. Parents' medication administration errors: Role of dosing instruments and health literacy. Archives of Pediatrics and Adolescent Medicine. 2010; 164(2):181–186. [PubMed: 20124148]
- Rothman RL, Yin HS, Mulvaney S, Co JP, Homer C, Lannon C. Health literacy and quality: focus on chronic illness care and patient safety. Pediatrics. 2009; 124(3):S315–s326. [PubMed: 19861486]
- Yin HS, Parker RM, Wolf MS, et al. Health Literacy Assessment of Labeling of Pediatric Nonprescription Medications: Examination of Characteristics that May Impair Parent Understanding. Acad Pediatr. 2012; 12(4):288–296. [PubMed: 22579032]
- 17. Betancourt, JR.; Rendrew, MR.; Green, AR.; Lopez, L.; M, W. Rockville, MD: Agency for Healthcare Research and Quality; 2012. Improving patient safety systems for patients with limited English proficiency: a guide for hospitals. (Prepared by the Disparities Solutions Center, Mongan Institute for Health Policy at Massachusetts General Hospital and Abt Associates, Cambridge, MA, under Contract No. HHSA290200600011I). AHRQ Publication No. 12-0041; http:// www.ahrq.gov/populations/lepguide/lepguide.pdf [Accessed 12/1/2012]
- Bailey SC, Agarwal N, Sleath B, Gumusoglu S. Improving Drug Labeling and Counseling for Limited English Proficient Adults. Journal of Health Care for the Poor and Underserved. 2011; 22(4):1131–1143. [PubMed: 22080698]
- Bradshaw M, Tomany-Korman S,GF. Language Barriers to Prescriptions for Patients With Limited English Proficiency: A Survey of Pharmacies. Pediatrics. 2007; 120(2):e225–e235. [PubMed: 17671036]
- 20. Weiss L, Gany F, Rosenfeld P, et al. Access to Multilingual Medication Instructions at New York City Pharmacies. Journal of Urban Health. 2007; 84(6):742–754. [PubMed: 17926130]
- McKee MM, Paasche Orlow MK. Health Literacy and Disenfranchised: The Importance of Collaboration Between Limited English Proficiency and Health Literacy Researchers. Journal of Health Communication: International Perspectives. 2012; 17(3):7–12.
- 22. Kutner M, Greenberg E, Jin Y, Paulsen C, White S. The health literacy of America's adults: results from the 2003 National Assessment of Adult Literacy: National Center for Education Statistics: US Department of Education. 2006
- 23. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. Annals of Family Medicine. 2005 Nov 1; 3(6):514–522. 2005. [PubMed: 16338915]
- 24. Hollingshead, AB. Four Factor Index of Social Status. New Haven, CT: Yale University; 1975.
- 25. van Dyck PC, McPherson M, Strickland BB, et al. The national survey of children with special health care needs. Ambulatory Pediatrics. 2002; 2:29–37. [PubMed: 11888436]
- 26. DeWalt DADM, Rosenthal MS, Pignone MP. Low Parental Literacy Associated with Worse Asthma Care Measures in Children. Ambulatory Pediatrics. 2007; 7(1):7.
- 27. DeWalt DAPM. Reading Is Fundamental: The Relationship Between Literacy and Health. Arch Intern Med. 2005; 165(17):1943–1944. [PubMed: 16186462]
- Baker DW. The meaning and measure of health literacy. Journal of General Internal Medicine. 2006; 21:878–883. [PubMed: 16881951]
- 29. Wolf MS, King J, Jacobson K, et al. Risk of Unintentional Overdose with Non-Prescription Acetaminophen Products. J Gen Intern Med. 2012
- Bailey SC, Pandit A, Yin HS, et al. Predictors of misunderstanding pediatric liquid medication instructions. Family Medicine. 2009; 41(10):715–721. [PubMed: 19882395]
- Shone LP, Conn KM, Sanders L, Halterman JS. The role of parent health literacy among urban children with persistent asthma. Patient Education and Counseling. 2009; 75(3):368–375. [PubMed: 19233588]
- Wolf MSDT, Curtis LM, et al. Effect of Standardized, Patient-Centered Label Instructions to Improve Comprehension of Prescription Drug Use. Medical Care. 2011; 49(1):96–100. [PubMed: 21150800]

- Shrank WH, Avorn J, Rolon C, Shekelle P. Effect of content and format of prescription drug labels on readability, understanding, and medication use: a systematic review. Annals of Pharmacotherapy. 2007; 41:783–801. [PubMed: 17426075]
- 34. Wolf MW EA, Rapp DN, Waite KR, Bocchini MV, Davis TC, Rudd RE. Literacy and learning in health care. Pediatrics. 2009; 124(Suppl 3)(3):81.
- 35. Wolf MS, Curtis LM, Wilson EAH, et al. Literacy, Cognitive Funtion, and Health: Results of the LitCog Study. J Gen Intern Med. 2012 in press.
- 36. Yin HS, Mendelsohn AL, Fierman A, van Schaick L, Bazan IS, Dreyer BP. Use of a Pictographic Diagram to Decrease Parent Dosing Errors With Infant Acetaminophen: A Health Literacy Perspective. Academic Pediatrics. 2011; 11(1):50–57. [PubMed: 21272824]
- Vernacchio L, Kelly JP, Kaufman DW, Mitchell AA. Medication Use Among Children <12 Years of Age in the United States: Results From the Slone Survey. Pediatrics. 2009; 124(2):446–454. [PubMed: 19651573]

WHAT'S NEW

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

TABLE 1

Characteristics of study population (n=297)^a

	n (%) or mean (SD)
Characteristics of Children in Household	
Presence of Child in Household less than age 8 years, n (%)	261 (87.9)
Presence of Child with Chronic Medical Problem, n (%)	91 (30.6)
Caregiver Characteristics	
Caregiver Age, mean (SD), y	31.8 (8.8)
Relationship to Child, n (%)	
Mother	278 (93.6)
Father	12 (4.0)
Legal Guardian	7 (2.4)
Marital Status Single, n (%) ^b	99 (33.3)
Hollingshead SES Level 4 or 5, n $(\%)^{\mathcal{C}}$	228 (76.8)
Caregiver Non-US Born, n (%)	218 (73.4)
Caregiver Race/Ethnicity, n (%)	
Hispanic	226 (76.1)
Non-Hispanic	
White	11 (3.7)
Black	33 (11.1)
Asian	20 (6.7)
Other	7 (2.4)
Caregiver Language Spanish, n (%)	136 (45.8)
Caregiver Limited English Proficiency, n (%)	189 (63.6)
Caregiver Education, n (%)	
HS Graduate / Equivalent or above	176 (59.3)
Caregiver Health Literacy, n (%) ^d	
High Likelihood of Limited Literacy	146 (49.2)
Possible Limited Literacy	89 (30.0)
Adequate Literacy	62 (20.9)

Abbreviations: SES, socioeconomic status; NVS, Newest Vital Sign.

^aData are mean (SD) or n (%).

^CMarital status categorized as single (single, never married; separated; divorced; widowed) or with partner (living with partner; married).

Yin et al.

 $^{\it C}$ Lower number represents higher SES and greater family resources.

 d Health literacy measured using NVS.

TABLE 2

Rationale for choice of cough/cold medication by health literacy level ^a

		Health]	Literacy	
		Low Literacy	Adequate Literacy	
		n=235	n=62	ĺ
	n (%)	n (%)	n (%)	p-value
Rationale involving comparison of the two medications	48 (16.2)	23 (9.8)	25 (40.3)	< 0.001
Concerned about overlap in active ingredient ^b	31 (10.4)	13 (5.5)	18 (29.0)	< 0.001
Concerned about mixing brands ^C	17 (5.7)	10 (4.3)	7 (11.3)	0.06
Rationale involving consideration of child's symptoms	181 (60.9)	145 (61.7)	36 (58.1)	0.7
Wanted symptoms of child to match symptoms covered by medication	162 (54.5)	131 (55.7)	31 (50.0)	0.5
Wanted medication with a broad range of symptoms covered	23 (7.7)	17 (7.2)	6 (9.7)	0.6
Rationale not related to comparing medications or symptoms, or no rationale given	131 (44.1)	112 (47.7)	19 (30.6)	0.02
Brand recognition	51 (17.2)	42 (17.9)	9 (14.5)	0.7
Time of day of medicine	54 (18.2)	44 (18.7)	10 (16.1)	0.7
Strength of medicine	3 (1.0)	3 (1.3)	0 (0)	1.0
Concern about safety / side effects (unrelated to active ingredient) i	6 (2.0)	6 (2.6)	0 (0)	0.4
Liked the flavor of the medication	8 (2.7)	8 (3.4)	0 (0)	0.2
Child age ^{<i>k</i>}	2 (0.7)	2 (0.9)	0 (0)	1.0
Don't know	13 (4.4)	13 (5.5)	0 (0)	0.08

 a^{a} Total n may not add up to sample n as parents could cite more than 1 reason for choosing a cough and cold medication.

^bSpecifically described concern about potential of giving too much acetaminophen (eg. "the other two have acetaminophen," "do not want to double dose on acetaminophen").

 C Non-specific concern about mixing medication; did not specifically cite overlapping acetaminophen (eg. "can't mix brands," "stay with the same brand").

 d^{\prime} Named specific symptoms on medication label that were consistent with the child's symptoms (eg. "because the child has cough and sore throat – matched the symptoms," "because it treats what he has").

^eMentioned desire to choose a medication which covered multiple symptoms (eg. "Multisymptom covers it all," "because it is for everything," "has a wider range of treatment for more symptoms").

^{*f*}Cited familiarity / brand recognition as one of primary reasons (eg. "I recognize the brand Tylenol," "because I know the brand," "I trust Tylenol, the brand").

^gCited medication suitable due to time of day (eg. "because it's for daytime").

^hCited strength of medication as rationale (eg. "works faster," "it is a little stronger").

Expressed concern about side effects (eg. "it has less side effects," "would not make him drowsy").

Yin et al.

jCited flavor as one of their primary reasons for selecting the medication (eg "Easier to give – child likes grape flavor," "kids like cherry").

kCited child age as part of rationale (eg. "more for kids," "is for the child's age").

NIH-PA Author Manuscript

TABLE 3

Health literacy, correct choice of cough/cold medication, and use of active ingredient information as rationale for choice

		Health	Literacy ^a									
		Low	Adequate					Model 1			Model 2	
		n=235	n=62	Uní	adjusted an:	alyses	Adj	usted analy:	sesd	Adj	usted analy	sese
	0%) u	(%) U	(%) u	OR^b	95% CI	p- value ^c	AOR^b	95% CI	p- value	AOR ^b	95% CI	p- value
Chose correct cough and cold medication	105 (35.4)	78 (33.2)	27 (43.5)	1.5	0.7–3.1	0.1	1.8	0.97–3.5	0.06	1.7	0.9–3.3	0.1
Used active ingredient as rationale for choice of medication	31 (10.4)	13 (5.5)	18 (29.0)	7.0	3.2–15.3	<0.001	7.1	2.8–18.0	<0.001	6.7	2.6–17.2	<0.001
Both^f	23 (7.7)	7 (3.0)	16 (25.8)	11.3	4.4–29.1	<0.001	12.9	4.3–38.8	<0.001	11.1	3.6–33.7	<0.001

OR= odds ratio; AOR=adjusted odds ratio; NVS=Newest Vital Sign

Acad Pediatr. Author manuscript; available in PMC 2014 May 01.

^aHealth literacy measured using the NVS; low health literacy combination of high likelihood of low literacy and possibility of low literacy.

 $b_{
m Comparing}$ adequate to low health literacy.

 $^{\mathcal{C}}$ Chi square or Fisher's exact test

d Model 1: controlling for caregiver age, language, LEP, ethnicity, country of birth, SES; presence of child <8 years of age in household, child with chronic disease.

 e Model 2: controlling for variables in Model 1 and parent education.

fChose the correct cough and cold medication plus used active ingredient as rationale for choice of medication.