Predictors of Misunderstanding Pediatric Liquid Medication Instructions

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Background and Objectives: *Our objective was to determine the level of adult understanding of dosage instructions for a liquid medication commonly prescribed for children.* Methods: *Structured interviews were conducted with 373 adults waiting for an appointment at family medicine clinics serving low-income populations in Shreveport, La; Chicago; and Jackson, Mich, from July 2003–August 2004. Subjects were asked to read a prescription label for amoxicillin and explain how they would take the medication. Correct interpretation was determined by a panel of blinded physician reviewers who coded subjects' verbatim responses. Qualitative methods were used to determine the nature of incorrect responses.* Results: *Twenty-eight percent of subjects misunderstood medication instructions. The prevalence of misinterpreting instructions among subjects with adequate, marginal, and low literacy was 18%, 34%, and 43%, respectively. Common causes for misunderstanding included problems with dosage measurement (28%; ie, tablespoon instead of teaspoon) and frequency of use (33%; ie, every 3 hours instead of every 6–8 hours). In an adjusted analysis that excluded literacy, African Americans were more likely to misunderstand instructions than Caucasians (adjusted odds ratio [AOR] 1.63, 95% confidence interval [CI]=1.02–2.61). When literacy was included in the model, the effect of race on misunderstanding was reduced and nonsignificant. Inadequate and marginal literacy remained independent predictors of misunderstanding (inadequate—AOR 2.90, 95% CI= 1.41–6.00; marginal—AOR 2.20, 95% CI=1.19-3.97).* Conclusions: *Misinterpretation of pediatric liquid medication instructions is common. Limited literacy is a significant risk factor for misunderstanding and could contribute to racial disparities. Instructions should be written in a concise manner and standardized to ensure comprehension.*

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Medication errors are the most common form of mistakes that lead to patient injury, hospitalization, and death.[1] According to the 2006 report by the Institute of Medicine (IOM), "Preventing Medication Error," approximately 1.5 million preventable adverse drug events occur each year; more than one third of these take place in outpatient settings at a cost approaching $1 billion annually.[1] Both physicians and patients identify this as an area of serious concern, and a clear understanding of existing failures has been sought to reduce the potential for costly errors in the future.[2,3]

Attention to the root cause of medication error has more often been directed to the provider or health care system's contributing role in errors during the prescribing, ordering, dispensing, or administering of a medicine.[4-6] This may be an appropriate focus for inpatient hospital or nursing home settings. A large proportion of outpatient medication errors, however, occur as a result of patients or caregivers not administering a medicine as intended.[1,7] For ambulatory care, the patient or caregiver, rather than the provider, is ultimately responsible for correctly administering a medicine as prescribed.

While medication error has been studied in adult populations, less attention has been given to medication errors occurring in children.[7-11] This is of concern, as

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children represent an especially vulnerable population for medication error. More than half (56%) of children take one or more medications in any given week and rely upon others for their administration.[12] Studies conducted in ambulatory settings estimate that 15% of children who are prescribed a medication later suffer a medication error; most are caused by improper administration by parents or caregivers.[13,14]

Limited literacy is one risk factor for medication errors that is often overlooked, yet could account for a high number of medication errors occurring in children that are caused by improper administration by adult caregivers. Among adults, numerous studies have found low literacy to be significantly associated with poorer understanding of medication names, indications, instructions, and adherence to treatment regimens.[15-17]

The purpose of this study was to specifically investigate the prevalence of misunderstanding pediatric prescription liquid medication label instructions among a target population of parenting and/or parental-age adults. As prior studies have identified low literacy as a potential risk factor to misinterpretation of common prescription medication instructions, this was specifically investigated.

Methods

Patients and Methods

Study participants were adults who attended one of three outpatient family medicine clinics in Shreveport, La; Chicago, Ill; or Jackson, Mich. The Shreveport clinic was within a public university hospital, and the clinics in Chicago and Jackson were federally qualified health centers. Patient populations at each clinic were predominately indigent and African American. Subject recruitment took place from July 2003 through August 2004.

Subjects were eligible for the study if they were between 18 and 75 years of age. Research assistants (RAs) at each site approached consecutive adults waiting for an appointment for themselves or their children in clinic waiting rooms. Subjects were excluded from participation if they self-reported severe impaired vision, hearing problems, acute illness, or limited English proficiency. A total of 458 adults were approached; 12 patients refused participation, 26 were deemed ineligible, and 25 had incomplete information. According to American Association of Public Opinion Research guidelines, this study had a 92% response rate with a total of 395 patients completing the study.[18] The analysis reported here was conducted on a subset of 373 patients who were either African American or Caucasian; too few subjects representing other racial/ethnic backgrounds were enrolled in the study for any substantive analyses of racial/ethnic disparities among other groups. The institutional review boards of Northwestern University and Louisiana State University approved this study.

Structured Interview and Coding

RAs administered a structured, cognitive interview that included a self-report of sociodemographic information and the Rapid Estimate of Adult Literacy in Medicine (REALM), a word recognition test comprised of 66 health-related words that scores an individual's grade-equivalent reading level.[19,20] To assess subjects' understanding of prescription labels, the RA showed each patient a series of mock prescription bottles, including one for an oral suspension medication and asked "How would you give this medicine?" Subjects were allowed to examine the label for as long as desired and could review the label when responding to RA questions. The RA documented subjects' verbatim responses. Prescription label instructions were written as "Take one teaspoonful by mouth three times daily." We have used this procedure in prior published studies to assess patients' functional understanding of prescription drug instructions and warnings.[15,16,21] Auxiliary warning labels were also included on these bottles; subjects' attention to, and misunderstanding of, these warnings is reported elsewhere.[16]

Subject responses were independently rated as either correct or incorrect by three physicians from academic medical centers. Physicians were blinded to patient information and were trained to follow stringent coding guidelines previously agreed upon by the research team. Correct scores were given only if the patients' responses included both the dosage and timing instructions stated on the label. If subjects' responses were inaccurate or lacking any aspect of the instruction they were scored as incorrect.

Inter-rater reliability between the three physicians coding the patient responses was very high (Kappa > 0.80). Responses that received discordant ratings among the three reviewers were scored by a panel of one primary care physician and two behavioral scientists with expertise in health literacy. Each panel member, blinded to patient information, independently coded the responses as correct or incorrect. Any remaining responses with discordant ratings were coded by majority rule.

Data Analysis

Statistical analyses were performed using STATA software version 9.0 (College Station, Tex). Descriptive statistics were calculated for each variable, and chi-square tests were used for bivariate analyses between demographic variables, literacy level, and incorrect interpretation of dosage instructions. Patient literacy was classified by categorizing REALM scores as either low (sixth grade and below), marginal (seventh–eighth grade) or adequate (ninth grade and higher). Multivariate logistic regression models were used to investigate predictors of misinterpretation of pediatric liquid medication instructions while controlling for relevant covariates.

Mediational analysis, a form of regression, was used to explore the relationship between literacy, race, and medication label understanding. Mediating variables are those thought to lie in a causal pathway between the main predictor variable and the outcome. In this approach, the independent relationship between race (predictor variable) and misunderstanding of instructions (outcome) was first established, as was the association between literacy (mediating variable) and misunderstanding after adjusting for sex, age, and education. A final model was then evaluated in which literacy was added as the potential mediator to the race-misunderstanding relationship. Changes in odds ratios for race were then analyzed. Model calibration and discrimination were also estimated using the Hosmer-Lemeshow goodness-of-fit chi-square test and the c-statistic from ROC curves.

Results

Table 1 provides both an overall statistical description of the study population and stratifications by educational attainment and literacy level. The mean age of subjects was 44 years (SD=13.2); 68% were female, and 50% were African American. Subjects were recruited from each of the three study sites, 59% from Shreveport, 15% from Chicago, and 26% from Michigan. Almost one third of subjects (29%) did not complete high school. Almost 20% of subjects were classified as having inadequate literacy skills, and 29 % had marginal literacy.

Misunderstanding of Medication Label Instructions

Race and inadequate and marginal literacy were associated with misunderstanding of medication instructions (% incorrect by race [African American, white]: 33.3 and 22.5 respectively, P=.02; % incorrect by literacy [inadequate, marginal, adequate]: 43.2, 34.3, and 18.3, P<.001, Table 1). In multivariate analyses that did not make an adjustment for literacy, race was found to be a significant independent predictor of misunderstanding of medication labels after adjusting for age, sex, and education (African American race: adjusted odds ratio (AOR) 1.63, 95% CI=1.02– 2.61; AUROC=.63, Hosmer-Lemeshow X^2= 0.63). In another multivariate analysis that did not make an adjustment for race, inadequate and marginal literacy were found to be significant independent predictors after controlling for the same variables (inadequate literacy: AOR 3.18, 95% CI=1.60–6.32; marginal literacy: AOR 2.33, 95% CI=1.31–4.14; AUROC=0.66, Hosmer-Lemeshow X^2= 0.51).

Table 1

Misunderstanding of Dosage Instructions, Stratified by Sample Characteristics

Characteristic	*n*	*%*	*% Misunderstanding*	P *Value*
Age, %				.17
18–34	97	26.0	20.6	
35–44	86	23.1	31.4	
45–75	190	50.9	30.0	
Gender, %				.04
Female	253	67.8	24.5	
Male	120	32.2	35.0	
Race, %				.03
African American	206	58.0	35.9	
White	149	42.0	24.8	
Literacy level, %				<.001
Low	74	19.8	43.2	
Marginal	108	28.9	34.3	
Adequate	191	51.2	18.3	
Education, %				.25
More than high school or GED	103	27.8	23.3	
High school or GED	160	43.1	26.9	
Less than high school	108	29.1	33.3	
Study site, %				<.001
Shreveport, La	220	59.0	32.7	
Jackson, Mich	97	26.0	37.5	
Chicago	56	15.0	11.3	

GED—General (high school) equivalency diploma

Mediational Analyses

As mentioned earlier, we used mediational analysis to evaluate the potential mediating effect of literacy on the relationship between race and medication label understanding, as prior studies have shown literacy to explain racial disparities in various chronic disease outcomes.[22-24] The independent relationship between race and the outcome of misunderstanding instructions was established in the previously described baseline model, as was the association between literacy and misunderstanding after adjusting for sex, age, and education. When literacy was entered into the model, the association between race and misunderstanding attenuated to a point of nonsignificance, overall being reduced by 25% (African-American race: AOR=1.22, 95% CI=0.73–2.04; *P*=.438) Inadequate and marginal literacy remained significant independent predictors of misunderstanding of medication label instructions in the final model (inadequate literacy: AOR=2.90, 95% CI=1.41–6.00; *P*=.004, marginal literacy: AOR=2.20, 95% CI=1.19–3.97; *P*=.01; ROC=0.66, Hosmer-Lemeshow X^2=0.51). Table 2 displays the results of the meditational analyses.

Nature of Patient Misunderstanding

The 111 total responses that were independently coded as incorrect were qualitatively reviewed for common misinterpretations by two of the study authors. Any differences in coding were resolved through triangulation with the assistance of a third author. Overall, 28% of subjects misinterpreted dosage measurement. Specifically, these subjects misunderstood the term "teaspoon," commonly substituting it for the term "tablespoon" or simply stating "a spoonful." In another 33% of incorrect responses, patients demonstrated difficulty with frequency of use for "three times daily." Those who responded incorrectly most often stated a wrong dosage frequency (ie, two times a day instead of three times a day) or provided a dosing interval that was incorrect given the schedule (ie, every 3 hours). Table 3 shows examples of common misinterpretations and how these incorrect responses were coded by reviewers.

Table 2

Multivariate Models for Medication Understanding, With and Without Literacy

	Medication Misunderstanding			
Variable	*Model 1*		*Model 2*	
	AOR	*95% CI*	*AOR*	*95% CI*
Race				
White	1.00		1.00	
African-American	1.63†	1.02–2.61	1.22	.73–2.04
Gender				
Female	1.00		1.00	
Male	1.67†	1.03–2.72	1.59	.97–2.60
Education				
More than high school or GED	1.00		1.00	
High school or GED	1.08	.74–2.60	.85	.42–1.73
Less than high school	1.38	.60–1.94	.84	.45–1.56
Age				
18–34	1.00		1.00	
35–44	1.54	.77–3.07	1.41	.70–2.85
45–75	1.52	.84–2.76	1.31	.71–2.42
Literacy skills (REALM)				
Adequate	—		1.00	
Marginal	—		2.20†	1.19–3.97
Low	—		2.90†	1.41–6.00

AOR—adjusted odds ratio, CI—confidence interval, *P*<.05
Note: Each of the multivariate models include the following covariates: age, gender, and education
Model 1 Fit Statistics: AUROC=0.62, Hosmer-Lemeshow X^2=0.63
Model 2 Fit Statistics: AUROC=0.66, Hosmer-Lemeshow X^2=0.51
GED—general (high school) equivalency diploma
REALM—Rapid Estimate of Adult Literacy in Medicine

Discussion

This study offers new findings documenting problems with adults' interpretation of prescription drug labeling instructions for children's liquid medications. Proper understanding of medication instructions is crucial for family medical care, as adult caregivers assume responsibility for overseeing children's use of prescription medications. Findings from this study indicate that one in three adults misunderstood dosage instructions for one of the most commonly prescribed pediatric oral suspensions.

The results are applicable to many other medications with similar dosage regimens. Typical misinterpretations demonstrate the potential for overdosing (tablespoon versus teaspoon), administering the medication at a greater frequency than was intended (every 3 hours versus every 6 hours), or under-treatment (once daily versus three times daily). For drugs with a narrow therapeutic margin, these misinterpretations could possibly lead to an adverse event.

Subjects with limited literacy were more likely to misunderstand these seemingly simple instructions. Although the written label instructions used in this study were brief, the rate of misinterpretation was very high, especially among those with limited literacy. Previous studies have shown that adult patients

Table 3

Examples of Common Misunderstandings and Response Coding

Patient Response	*Coding*	*Explanation*
"I would take one tablespoon of it three times a day. Morning, noon, and night."	Incorrect Dosage Measurement	Patient used the term "tablespoon" instead of "teaspoon."
"Take three teaspoons a day at 10:00, 1:00, and 8:00."	Incorrect Frequency of Use	Patient would take second dose only 3 hours after the first dose.
"A spoonful, once or twice a day."	Incorrect Dosage Measurement and Incorrect Frequency of Use	Patient used the term "spoonful" instead of "teaspoon." Patient would take the medicine "once or twice" a day instead of three times a day.

with low literacy skills are at greater risk for making errors when interpreting common dosage instructions and warnings for common adult, pill-form medications.[15,16,21,25] Fewer studies have detailed the problem of limited health literacy within the context of pediatric drugs and the body of research describing the extent and associations of limited health literacy and pediatric outcomes is still relatively small.[26,27] Our study provides additional evidence of how adult literacy skills could negatively impact the health of a child.

Additionally, this study offers insight on the link between race, literacy, and misunderstanding of label instructions through a multi-site investigation among medically underserved patient populations. While African-American race appeared to be a significant, independent predictor of misunderstanding label instructions, further analyses determined that literacy mediated this relationship. Our findings suggest that limited literacy may possibly explain previous findings of racial disparities in medication errors and adverse drug events.[14,28]

For decades, the Food and Drug Administration (FDA), American Academy of Pediatrics, and several other professional health care organizations have recommended that families not use household teaspoons or tablespoons to administer pediatric liquid medications, whether they be prescription or non-prescription drugs.[29] Yet many physicians still prescribe dosage using the words "teaspoon" or its abbreviation, and these terms are also prevalent on package directions for non-prescription children's medications. Our study provides a strong reminder of the problems adults face when quickly interpreting instructions; errors in interpretation might lead to the administration of incorrect dosages of medication. Studies are now needed to determine what health care consumers find to be the most helpful, easy, and accurate way for measuring liquid medicines.

In addition to misinterpreting dosing instructions, subjects also reported incorrect dosage frequencies. Responses suggest that many subjects would not have allowed enough time between administration times of the medicine, while others interpreted too few doses per day. Wolf and colleagues explain in a prior study evaluating interpretation of instructions for adult, pill-form medicines that misunderstanding is often caused by patients not allowing enough time to adequately process the information on drug labels.[21] As many patients view medication administration to be an easy endeavor, they may not allocate the attention necessary to carefully review instructions and information about medication use. Simple, yet significant, mistakes can result.

Recent evidence supports improving label instructions by separating dose from interval and providing the explicit frequency of the drug (ie, "Take 1 [unit] at morning, take 1 [unit] at noon, and take 1 [unit] at bedtime" versus "take one teaspoonful by mouth three times daily").[30,31] Efforts should be made to lessen the literacy demands made on caregivers as they seek to comply with medication instructions. In addition to setting standards regarding prescription drug labeling, presentation of consistent messaging with other accompanying written materials and well-designed standardized dosing instruments is essential.[30,32]

Finally, only comprehension of one specific instruction (ie, "Take one teaspoonful by mouth three times daily') was assessed. Studies are currently underway to evaluate understanding of other similar instructions and to determine which measurement (ie, mL, teaspoon, cup) is easiest for caregivers to comprehend and use.[33]

Limitations

The limitations of this study should be acknowledged. We did not examine the association between

misunderstanding of medication instructions and actual medication error. The generalizability of our findings is limited as participation was restricted to English-speaking adults due to criteria for using the REALM as our literacy assessment. We also did not exclusively interview parents of small children, though subjects were recruited from clinics while waiting for a family medicine appointment. We believed it was appropriate to have more inclusive study eligibility requirements to account for all adults who are likely to play a significant role in the care of smaller children. Recent estimates indicate that one in 12 children in the United States are cared for by a person who is not their biological parent; this phenomenon is particularly prevalent among low-income communities such as those served by the study sites.[34]

Conclusions

While it is clear that improvements should be made in liquid medication instructions, efforts must be made to verbally counsel adult caretakers on how to appropriately administer prescribed drugs. Studies have repeatedly shown that physicians and pharmacists rarely communicate detailed information to patients to support their compliance with prescribed regimens.[35-37] At the point of prescribing, physicians should clearly review dosage instructions with patients and caregivers to maximize understanding of how and when to administer medication. Similarly, efforts should be taken by pharmacists at the point of dispensing to review instructions for use and confirm patient understanding of medication regimens. Both providers should strive to be simple, clear, and explicit in directing adult caregivers to reduce medication errors and to improve safe medication use for children.

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