

Low Literacy Impairs Comprehension of Prescription Drug Warning Labels

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BACKGROUND: Adverse events resulting from medication error are a serious concern. Patients' literacy and their ability to understand medication information are increasingly seen as a safety issue.

OBJECTIVE: To examine whether adult patients receiving primary care services at a public hospital clinic were able to correctly interpret commonly used prescription medication warning labels.

DESIGN: In-person structured interviews with literacy assessment.

SETTING: Public hospital, primary care clinic.

PARTICIPANTS: A total of 251 adult patients waiting for an appointment at the Louisiana State University Health Sciences Center in Shreveport (LSUHSC-S) Primary Care Clinic.

MEASUREMENTS: Correct interpretation, as determined by expert panel review of patients' verbatim responses, for each of 8 commonly used prescription medication warning labels.

RESULTS: Approximately one-third of patients ($n=74$) were reading at or below the 6th-grade level (low literacy). Patient comprehension of warning labels was associated with one's literacy level. Multistep instructions proved difficult for patients across all literacy levels. After controlling for relevant potential confounding variables, patients with low literacy were 3.4 times less likely to interpret prescription medication warning labels correctly (95% confidence interval: 2.3 to 4.9).

CONCLUSIONS: Patients with low literacy had difficulty understanding prescription medication warning labels. Patients of all literacy levels had better understanding of warning labels that contained single-step versus multiple-step instructions. Warning labels should be developed with consumer participation, especially with lower literate populations, to ensure comprehension of short, concise messages created with familiar words and recognizable icons.

KEY WORDS: literacy, warning labels, prescription drug labels, medication error, patient comprehension, lexile.

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Adverse events resulting from improper medication administration are a serious concern.¹ Patients are increasingly managing multiple prescription and over-the-counter medications; therefore, patient understanding is essential for proper adherence.^{2,3} This issue is relevant to the majority of adults in the United States; two-thirds of all adults use prescription drugs, representing 16% (\$73 billion) of all health care expenditures.⁴ According to the Medical Expenditure Panel Survey (MEPS), the average adult in the United States

fills 9 prescriptions annually. This number is even higher among adults over 65 years of age, who fill an average of 20 prescriptions a year.⁴

Low literacy may be an overlooked contributing factor to patient misuse of prescription medications. The Institute of Medicine's recent report, *A Prescription to End Confusion*, indicates that 90 million adults in the United States have trouble understanding and acting on health care information.⁵ Shame may prevent individuals with limited literacy from telling providers they need help with medication instructions.⁶ The recently released National Assessment of Adult Literacy (NAAL), the most accurate measurement of literacy in America today, found that adults who are socioeconomically disadvantaged belong to racial/ethnic minority groups, and/or are elderly are disproportionately hindered by such literacy barriers.⁷ These individuals are also more likely to be in poorer health and may be taking multiple medications.

The purpose of this descriptive study was to identify factors associated with patient understanding of prescription drug warning labels (PWLs). We hypothesized that low literacy would be associated with incorrect interpretations of PWLs.

METHODS

Subjects

Study participants were patients aged 18 and older attending the Primary Care Clinic (PCC) at Louisiana State University Health Sciences Center—Shreveport (LSUHSC) during July 2003. Patients were ineligible if they had severe visual or hearing impairments, were too ill to participate, or were non-English speaking. The LSUHSC Institutional Review Board approved the study and all patients gave informed consent for participation. A total of 276 patients were approached before the medical encounter, and 273 consented to participation. Twenty-two patients were excluded based on self-reported impairments with hearing ($n=5$) or vision ($n=12$), English as a second language ($n=3$), or incomplete information ($n=2$). A total of 251 patients participated in the study.

Structured Interview and Literacy Assessment

Interviews with community pharmacists ($N=9$) and primary care physicians ($N=5$) were conducted to identify the most important PWLs for patients to understand. Through consensus, 8 PWLs were identified for study inclusion; all were developed by the most commonly used pharmaceutical labeling software package.⁸

A trained research assistant (RA) administered a structured interview that included self-report of sociodemographic

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information (age, gender, race/ethnicity, education, source of payment for medications). Color copies (actual size) of each of the 8 PWLs were then shown in the same order to all of the patients for review. To assess patient comprehension, the RA asked "what does this label mean to you?" for each PWL. The RA then documented the verbatim response on a separate form. A panel of physicians and pharmacists trained the RAs to give a correct score only if the patient's response included all aspects of the PWL message. For quality assurance, an additional RA, blinded to patient information (including literacy) and following the same panel guidelines, independently reviewed all patient responses to the 8 labels ($N=2,008$). The RAs were unable to score 317 (15.8%) responses as either correct or incorrect. An expert panel that included 3 physicians, a clinical psychologist, and a pharmacist reviewed and graded the uncoded responses. Each member was blinded to subjects' literacy level, and decisions were made by majority rule.

After the patient had provided his or her interpretation on all of the PWLs, the RA administered the Rapid Estimate of Adult Literacy in Medicine (REALM), a health word recognition test that is the most common measure of adult literacy in medical settings.^{9,10} The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (TOFHLA).^{9,11}

Lexile Score

We used a measure of reading difficulty termed Lexile Framework to gauge reading level for the text on each PWL.¹²⁻¹⁵ Lexile scores are based on sentence length and word frequency in the popular literature, with higher values indicating higher levels of reading difficulty. The possible range of these scores is from below 0 (representing a beginning reading level) to 2000. A program available to registered users over the internet, called the Lexile Analyzer, calculated the Lexile score for each warning label text.¹² These values can be easily translated to corresponding reading grade levels. For instance, a Lexile value of 300 corresponds to a 2nd-grade level of reading difficulty, 400 to 3rd grade, and 1,300 to a 12th-grade level.

Analysis Plan

All statistical analyses were performed using STATA, version 8.0 (College Station, TX). Descriptive statistics were calculated for each variable. Chi-square or ANOVA tests were used to evaluate the association between literacy, sociodemographic characteristics, and correct interpretation of each of the 8 PWLs. In multivariate analyses, the 8 binary repeated responses per subject were modeled using a generalized linear model with logit link. A generalized estimating equation (GEE) approach was used to adjust model coefficients and standard errors for within-patient correlation.^{16,17} The final multivariate model included potential confounding variables age, gender, race/ethnicity, number of medications currently taken, and the additional risk factor of Lexile score. Patient literacy was classified either as low (6th grade and below), marginal (7th to 8th grade), or functional (9th grade and higher). Patient age was categorized by tertiles (<45 , 45 to 64 , ≥ 65), and Lexile score by quartiles (2 labels per category; ≤ 3 rd grade, 4th to 5th grade, 6th to 7th grade, and ≥ 8 th grade).

RESULTS

Among the 251 respondents, 70.9% were female and 66.1% African American. Patients ranged in age from 18 to 86, with a mean age of 47.2 years ($S.D.=14.9$). Patient literacy was limited; 29.5% were reading at or below a 6th-grade level (low literacy) and 31.1% were reading at the 7th to 8th grade level (marginal literacy). Forty-two percent of patients reported that they did not graduate from high school or receive a graduate equivalency diploma (GED).

Respondents were taking an average of 3 prescription medications, and nearly two-thirds (64.5%) lacked insurance for prescription medications. Low literacy was associated with male gender ($P<.05$), African-American race ($P<.001$), and less education ($P<.001$) (Table 1). No significant differences were reported between literacy level and age or source of payment for medications.

Lexile scores for each PWL were calculated and are listed in Table 2. Correct interpretation of the warning labels varied according to reading difficulty and complexity, with correct interpretation rates ranging from 83.7% for the simplest label (*Take with Food*, Lexile = beginning reading) to 7.6% for a label with multistep instructions (*Do not take dairy products, antacids, or iron preparations within 1 hour of this medication*, Lexile = 1,110). Patients with low literacy skills were less able to correctly interpret the meaning of 7 of the 8 warning labels, with the exception of the most basic single-step instruction, *Take with food* (Table 2). Patients who were 65 years of age and older were less able to correctly interpret the PWL, *Do not drink alcoholic beverages when taking this medication* ($P<.05$). No statistically significant differences in rates of correct interpretation of PWL were noted by number of prescription medications currently taken by patients. Verbatim examples of the most common incorrect interpretations for each of the PWLs by patients are detailed in Table 3.

Table 1. Patient Characteristics by Literacy Level

Characteristic	Literacy Level			P value
	≤ 6 th grade (n=74)	7th to 8th grade (n=78)	≥ 9 th grade (n=99)	
Age, mean (SD)	50.0 (15.5)	47.6 (15.0)	44.9 (14.2)	NS
Female, %	60.8	70.5	78.8	$<.050$
Race/ethnicity, %				$<.001$
African American	89.2	76.9	40.4	
White	9.5	20.5	56.6	
Other	1.3	2.6	4.0	
Education, %				$<.001$
Grades 1 to 8	21.6	6.4	4.0	
Grades 9 to 11	42.0	37.2	20.2	
Completed high school/GED	33.8	43.6	40.4	
>High school	2.7	12.8	35.4	
Payment source for medications, %				NS
Private insurance	5.4	6.4	12.1	
Medicaid	5.4	7.7	9.1	
Out of pocket	58.1	71.8	63.6	
Other	16.2	14.1	15.2	
Medications taken daily, mean (SD)	2.9 (0.62)	3.5 (0.40)	2.8 (0.21)	NS

NS, not significant ($P>.05$).

GED, graduate equivalency diploma.

Table 2. Percent of Respondents Correctly Interpreting Warning Labels by Literacy Level

Label (Lexile, Grade Level)	Literacy Level			P value
	≤ 6th grade (n=74)	7th to 8th grade (n=78)	≥ 9th grade (n=99)	
One-step instructions				
Take with food (<0, BR*)	78.4	85.9	85.9	NS
Do not chew or crush, swallow whole (600, 5th grade)	46.0	84.6	77.8	<.001
Medication should be taken with plenty of water (520, 4th grade)	36.5	73.1	65.7	<.001
Do not drink alcoholic beverages when taking this medication (870, 8th grade)	41.9	65.4	59.6	<.010
For external use only (100, <1st grade)	8.1	64.1	77.8	<.001
Multi-step instructions				
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication (1,300, 12th grade)	4.1	35.9	35.4	<.001
Refrigerate, shake well, discard after (date) (800, 7th grade)	8.1	18.0	22.2	<.050
Do not take dairy products, antacids, or iron preparations within 1 hour of this medication (1,110, 10th grade)	0.0	6.4	14.1	<.010

*BR, beginning reading; Text with a Lexile score of 0 or below.

NS, not significant ($P > .05$).

Multivariate analyses identified low literacy as a significant independent predictor of incorrect interpretation of warning labels (adjusted odds ratio [AOR] 3.4, 95% CI 2.3 to 4.9). Other factors associated with incorrect interpretation of PWLs included older age (65 and older), higher Lexile score (6th-grade reading difficulty and above), and male gender (Table 4). No interactions between literacy, Lexile

score, age, number of medications taken, and race were significant.

DISCUSSION

This is the first study to our knowledge to evaluate the relationship between patient literacy skills and correct

Table 3. Common Examples of Misinterpretations of Prescription Drug Warning Labels


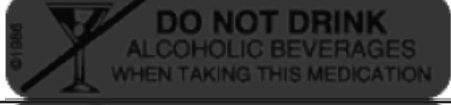
Labels	Misinterpretations
 TAKE WITH FOOD ©1990	Don't take food
 DO NOT CHEW OR CRUSH, SWALLOW WHOLE. ©1976	Chew pill and crush before swallowing Chew it up so it will dissolve, don't swallow whole or you might choke Just for your stomach
 MEDICATION SHOULD BE TAKEN WITH PLENTY OF WATER ©1976	Don't take when wet Don't drink hot water Don't need water
 DO NOT DRINK ALCOHOLIC BEVERAGES WHEN TAKING THIS MEDICATION ©1986	Don't drink and drive Don't drink alcohol, it's poison and it'll kill you
 FOR EXTERNAL USE ONLY ©1976	Use extreme caution in how you take it Medicine will make you feel dizzy Take only if you need it
 YOU SHOULD AVOID PROLONGED OR EXCESSIVE EXPOSURE TO DIRECT AND/OR ARTIFICIAL SUNLIGHT WHILE TAKING THIS MEDICATION. ©1986	Don't leave medicine in the sun Don't leave [medicine] in sunlight, but a cool place
 REFRIGERATE-SHAKE WELL DISCARD AFTER _____	Keep medicine chilled Mix it well, discard when done
 DO NOT TAKE DAIRY PRODUCTS, ANTACIDS, OR IRON PREPARATIONS WITHIN ONE HOUR OF THIS MEDICATION. ©1986 PHARMEX	If allergic to dairy, don't take medicine Don't eat for one hour after taking medicine

Table 4. Generalized Estimating Equation (GEE) Model for Incorrect Interpretation of Warning Labels

Variable	OR	95% CI	AOR	95% CI
Literacy level				
≥ 9th grade (Functional)	1.0	Referent	1.0	Referent
7th to 8th grade (Marginal)	1.1	0.8, 1.4	0.9	0.7, 1.3
≤ 6th grade (Low)	3.2	2.4, 4.3	3.4	2.3, 4.9
Age, y				
< 45	1.0	Referent	1.0	Referent
45 to 64	1.0	0.8, 1.3	1.1	0.8, 1.4
≥ 65	1.6	1.0, 2.4	1.7	1.1, 2.8
Race				
White	1.0	Referent	1.0	Referent
African American	1.8	1.4, 2.3	1.3	0.9, 1.8
Gender				
Female	1.0	Referent	1.0	Referent
Male	1.4	1.0, 1.8	1.3	1.0, 1.8
Number of prescription medications currently taken				
≥ 3	1.0	Referent	1.0	Referent
1 to 2	0.9	0.7, 1.2	1.0	0.7, 1.3
None	1.1	0.8, 1.5	1.3	0.9, 1.9
Lexile score, reading level				
≤ 3rd grade	1.0	Referent	1.0	Referent
4th to 5th grade	1.1	0.9, 1.4	1.2	0.9, 1.5
6th to 7th grade	3.7	3.0, 4.7	4.3	3.3, 5.6
≥ 8th grade	10.4	8.0, 13.6	12.9	9.6, 17.5

OR, odds ratio; CI, confidence interval; AOR, adjusted odds ratio.

interpretation of warning labels routinely used with prescription medications. Low literacy was significantly associated with more than a 3 times greater likelihood of incorrect interpretation of PWLs. Our findings indicate that these warning labels are not likely to be useful to patients in their current form, especially those with low literacy skills, and could result in misuse of medications (e.g., the text message: *Do not chew or crush, swallow whole* vs the patient interpretation of *Chew pill and crush before swallowing*).

The Lexile score (reading difficulty) attributed to each PWL was also a significant independent predictor of patient comprehension. Labels with text written at the 6th- to 7th-grade level were 4.3 times more likely to be interpreted incorrectly, and PWLs that had text written at the 8th-grade level and above were 12.9 times more likely to be interpreted incorrectly compared with PWLs that had text written at the 3rd-grade level or below. These findings suggest that existing recommendations by health educators that patient information materials be written below an 8th-grade level should be revised.¹⁸⁻²⁰ Instead, a more appropriate goal for health information in print might be a Lexile score below a 6th-grade level.

Most patients in our study were able to understand simple, routine tasks using uncomplicated words, such as the label, *Take with food*. However, the single-step label, *For external use only*, was written at a 1st-grade level and yet proved difficult for many patients, especially those with low literacy skills. Possibly this was due to the fact that this PWL does not clearly state a specific action to be taken and uses unfamiliar wording or concepts. Over half of low literate patients could not properly interpret moderately complicated messages such as *Do not drink alcoholic beverages when taking this medication* (written at a 7th- to 8th-grade level), and people across all literacy levels found it challenging to fully comprehend unfamiliar and complex, multistep health instructions written at a high school level (e.g., *Do not take dairy products, antacids, or iron preparations within 1 hour of this medication*).

The awareness of the impact of low literacy on health and health care has led to increased attention to "health literacy." Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.⁵ The IOM Patient Safety Report (2000), *To Err is Human*, stresses that health literacy is an essential aspect of addressing patient safety and is fundamental to quality care.¹ The 2004 IOM Report on Health Literacy and recent literature note a growing discordance among individual reading skills and the increasingly complex demands of the health care system, particularly the demands on patients and families in managing chronic diseases.^{5,21,22} Low literacy has been strongly linked to higher rates of hospitalization and use of emergency services,^{23,24} poorer understanding of one's medical condition,^{25,26} poorer adherence to medical instructions,^{27,28} and worse health outcomes.^{21,29} In our study, low literacy is related to limited understanding and misinterpretation of warning labels, and therefore may be a factor in unintentional nonadherence and therapeutic failure. Incomplete understanding of labels may be an unrecognized contributor to the estimated 2% to 11% of hospital admissions in the United States caused by misuse of prescription medications.³⁰

The elderly may be especially vulnerable to misunderstanding of prescription labels and instructions. Our finding that adults over 65 were less likely to interpret PWLs correctly is supported by previous studies that examined comprehension of medication instruction labels.³¹⁻³⁴ The elderly comprise an increasingly larger portion of the population and consume 2 to 3 times more medication than the general public. They are also more likely to have lower literacy skills.⁷

Study limitations should be noted. First, participation was limited to patients proficient in the English language. However, 2 of 3 prescription medication warning labels currently used by the majority of pharmacies in the United States are only available in English.⁸ Second, patients were sampled from a public hospital, which may limit the generalizability of findings. However, patients in the sample reflect a group disproportionately affected by poor health outcomes, and whose health and health care is targeted for improvement by Healthy People 2010.³⁵ Finally, sample size may have limited the ability to detect significant and clinically meaningful relationships in the multivariate analyses.

The Food and Drug Administration (FDA), the American Pharmaceutical Association (APA), the American Society of Health-System Pharmacists (ASHSP), and the National Association of Boards of Pharmacy (NABP) are increasingly directing attention to the quality of drug labels and accompanying patient educational handouts.³⁶⁻⁴² All of these organizations agree that for the information to be useful for the consumer, it must be read and understood before it can be acted upon. However, evidence-based evaluation of these goals is limited.⁴³⁻⁴⁵

Our findings suggest that there is a need for improving prescription drug warning labels. The U.S. Food and Drug Administration (FDA) has supported the development of useful consumer information and established standard guidelines for over-the-counter medication. Similar standards are needed for PWLs. The development process for warning labels needs to involve consumers, especially those with low literacy, and take advantage of tools such as the Lexile Framework and knowledge gained through patient education literature to produce warning labels that convey information that all patients can understand.

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