Misunderstanding of prescription drug warning labels among patients with low literacy

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Purpose. The common causes for misunderstanding prescription drug warning labels (PWLs) among adults with low literacy were studied.

Methods. A total of 74 patients reading at or below the sixth-grade level and receiving care at the primary care clinic at the Louisiana State University Health Sciences Center in Shreveport were recruited to participate in structured interviews. Patients were asked to interpret and comment on eight commonly used warning labels found on prescription medications. Correct interpretation was determined by expert panel review of patients' verbatim responses. Qualitative methods were employed to code responses and generate themes regarding the misunderstanding of these PWLs.

Results. Among this sample of patients with low literacy skills, rates of correct interpretation for the eight warning labels ranged from 0% to 78.7%. With the exception of the most basic label, less than half of all patients were able to provide adequate interpretations of the warning label messages. Five themes were derived to describe the common causes for misunderstanding the labels: single-step versus multiple-step instructions, reading difficulty of text, use of icons, use of color, and message clarity. Labels were at greater risk for being misunderstood if they included multiple instructions, had a greater reading difficulty, included unfamiliar terms, or used confusing icons that were discordant with text messages. Participants also frequently imposed an incorrect meaning on label colors, which led to further confusion.

Conclusion. Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.

Index terms: Comprehension; Labeling; Patients; Prescriptions; Readability

Am J Health-Syst Pharm. 2006; 63:1048-55

Nearly half of the adult population in the United States lack the reading and numeracy skills required to process, understand, and act on health information.[1] Forty million U.S. adults are reading at the lowest levels of literacy proficiency and may have profound difficulty understanding health information for their own or a loved one's needs.[2,3] Prior studies have linked low literacy to a poor understanding of one's medical condition and nonadherence to medical instructions.[4-7]

Individuals with low literacy skills may be at particular risk for misunderstanding information on pharmaceutical drug labels and package inserts, thus misusing these medications.[8,9] Recent concern over patient safety has increased awareness of the poor quality of consumer information describing proper use of medications and associated risks.[10,11] This has led to an expanded interest in the causes of medication-related errors, from a focus on physician or health care system failure to analysis of potential patient errors.[8-12] As health care delivery continues to shift from inpatient to outpatient settings, the burden of quality control over proper medication use will also shift from provider to patient.[1,9,13,14] An alarming trend has already emerged as a result: between 1983 and 1993, there was a ninefold increase in deaths due to outpatient medication errors in

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Thomas McGinnis is acknowledged for his guidance and comments on this article.

DOI 10.2146/ajhp050469

the United States.[15] A recent study reported that 28% of emergency department visits are drug related, with over two thirds of these visits deemed preventable and 24% resulting in hospital admission.[16]

The Food and Drug Administration (FDA), along with the American Pharmacists Association, the American Society of Health-System Pharmacists, and the National Association of Boards of Pharmacy (NABP), is directing greater attention to the quality of labels on prescription and nonprescription drugs and accompanying patient educational handouts and package inserts.[17-23] In 1997, the Keystone Dialogue, initiated by the Department of Health and Human Services and the abovementioned organizations, was charged with developing an action plan for improving medication information and labeling.[24] One of the many recommendations made was to directly involve consumers to ensure that information included on medication labels and package inserts could be properly understood by patients across all literacy levels.

Our research team previously investigated the quality of prescription drug warning labels (PWLs) that appear as stickers placed on the outside of medication bottles.[8] These adhesive labels are widely used and provide important information regarding the safe administration of prescription medications. Failure to heed the warnings or special instructions on these labels could lead to a loss of drug potency or a change in the rate of absorption of the medication. As a consequence, patients may become ill or gain little or no treatment benefit from taking the prescribed drug.[25] For example, many long-acting antihypertensive agents should be swallowed whole, as chewing or crushing them would intensify the dose and could possibly cause acute hypotension.

Our findings revealed very low rates of comprehension of PWLs and that low literacy was a significant independent predictor of an incorrect interpretation of their meaning. In the present study, the causes for misunderstanding text and icons found on eight commonly used PWLs among patients reading at or below the sixth-grade level (low literacy) were explored.

Methods

Subjects. Study participants were adult patients who attended the primary care clinic (PCC) at the Louisiana State University Health Sciences Center—Shreveport (LSUHSC) in July 2003. The PCC is a public hospital clinic that serves an indigent adult population. Seventy-five percent of PCC patients are African American, 50% are female, 25% receive Medicaid, and 5% have private insurance. Patients were ineligible for study inclusion if they were under 18 years of age; if a physician or a trained research assistant (RA), through the course of an interview, identified them as having hearing problems or a visual impairment not correctable with eyeglasses; if they were too ill to participate; or if they did not speak English.

The LSUHSC institutional review board approved this study, and oral informed consent was obtained from all participants. Patients were approached by one of five RAs immediately after seeing their physician for a routine, scheduled visit. Each RA had been specifically trained by one of three study investigators to administer a literacy assessment, conduct a structured research interview, and objectively rate patient interpretations of PWLs. The RA described the study to patients and sought their participation. If patients agreed, the RA orally reviewed informed-consent procedures and administered the survey instrument and literacy assessment.

Structured interview and literacy assessment. A structured interview was developed to assess correct interpretation of eight common medication warning labels developed by Pharmex, the largest U.S. pharmacy supplier of adhesive warning labels. After patients orally consented to the study, an RA administered the structured interview that included self-report of sociodemographic information (age, sex, race, education, and source of payment for medications). Color copies (actual size) of each PWL were then shown to each patient in the same order. After the patients had provided their interpretation of all eight PWLs, the RA administered a brief literacy assessment, concluding the interview. The entire protocol took approximately 15 minutes per patient.

To assess patient comprehension for each PWL, the RA asked each patient what the label meant. The RA would follow by asking several probing questions about specific attributes of the label (i.e., what is the picture saying?, is the picture helpful?, what do you think about the color of the label?, do the different colors mean different things to you?). The RA then documented the verbatim responses on a separate form, and these responses were later transcribed for content analysis.

The RAs rated each response as either correct or incorrect, using stringent guidelines developed by a panel of pharmacists and physicians. The panel trained the RAs to give a correct score only if the patient's response included all aspects of the PWL message and an incorrect score if the patient's response was inaccurate or contained only a partial meaning of the 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 eight labels. If the two RAs produced discordant ratings, an expert panel consisting of a pharmacist, two general internal medicine physicians, and two behavioral scientists with expertise in

health literacy made a determination based on majority rule.

At the end of the structured interview, patients' literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test of 66 health-related words.[26] Reading recognition tests are useful predictors of general reading ability of English. Using the REALM, raw scores (0–66) can be converted into one of four reading grade levels: third grade or less (0–18), fourth to sixth grade (19–44), seventh to eighth grade (45–60), and ninth grade or above (61–66). The REALM, which can be administered and scored in less than three minutes, is the most commonly used test of patient literacy in medical settings.[27] The REALM is highly correlated with standardized reading tests, including the Wide Range Achievement Test—Revised (WRAT-R) (r = 0.88), the Slosson Oral Reading Test—Revised (SORT-R) (r = 0.96), and the Peabody Individual Achievement Test—Revised (PIAT-R) (r = 0.97).[26,27] The REALM is also highly correlated with the Test of Functional Health Literacy in Adults (TOFHLA) (r = 0.84).[28]

Lexile score. We used a Lexile framework to gauge the reading level for the text on each PWL.[29] Lexile scores are based on sentence length and word frequency in popular literature, with higher values indicating higher levels of reading difficulty. The possible range of scores is below 0 (representing a beginning reading level) to 2000. A program available to registered users over the Internet, called the Lexile Analyzer (MetraMetrics, Inc., Durham, NC), was used to calculate the Lexile score for each label's text. These values can be easily translated to corresponding reading grade levels. For instance, a Lexile score of 300 might correspond to a second-grade reading level, 400 to a third-grade level, and 1300 to a 12th-grade level.

Data analysis. Statistical analyses were conducted using STATA, version 8.0 (Stata Corp., College Station, TX). Descriptive statistics were calculated for each variable. Chi-square tests were used to evaluate the association between sociodemographic characteristics and correct interpretation (yes or no) of each of the eight PWLs. For qualitative analyses, a grounded theory approach was used to explore the basis for patients' incorrect interpretations of each of the eight PWLs using their documented verbatim responses. Grounded theory, according to Strauss and Corbin,[30] is a systematic method for generating theoretical statements from case studies. Based on our qualitative, cognitive interviews, grounded theory guides the inductive process of organizing content derived from patient responses. For this study, patients' misinterpretations were reviewed and classified using both predetermined and emergent coding schemes. The qualitative data were coded according to predetermined factors, including text difficulty, use of icons, and use of color. Responses were then examined for additional coding of emergent factors.

Results

Of the 1162 patients seen at the PCC in July 2003, 276 were asked to participate in the study. Of these, 3 refused participation, 17 were excluded based on self-reported impairments with hearing (n = 5) or vision (n = 12), 3 were excluded because English was their second language, and 2 were excluded due to incomplete information. A total of 251 patients were assessed for literacy. Of these 251, 74 were reading at the sixth-grade level or below and were included in our study.

The characteristics of study participants are detailed in Table 1. The mean ± S.D. age for the participants was 50.0 ± 15.5 years (range, 19–81 years). Most patients were African American, older, and female, with the average REALM score corresponding to approximately the fifth-grade reading level. Approximately one third of patients had completed high school or received a general equivalency diploma. The mean ± S.D. number of prescription medications patients were taking was 2.9 ± 0.6 (range, 0–15).

Label comprehension. Rates of correct interpretation of the eight PWLs ranged from 0% to 78.7% (Table 2). With the exception of the label "Take with food," less than half of all patients were able to provide adequate interpretations of the warning labels' messages. None of the respondents were able to correctly interpret the label "Do not take dairy products, antacids, or iron preparations within one hour of this medication."

Compared with patients reading at the fourth- to sixth-grade level, those with very low literacy skills (reading at or below the third-grade level) were less able to correctly interpret six of the eight labels (Table 3). No significant differences in correct interpretation were noted by age, sex, number of years of education, race, payment method, number of medications currently taken, or the two literacy categories.

Causes of misunderstandings. The types of misunderstanding of PWLs by patients with low literacy were first determined by preselecting a coding scheme for the likely cause leading to misunderstanding and then allowing additional causes to emerge within the qualitative review process. Predetermined causes included single-step versus multiple-step instructions, reading difficulty of text, use of icons, and use of label color. One emergent cause of misunderstanding PWLs was identified and referred to as message clarity.

Single-step versus multiple-step instructions. Three of the eight PWLs were considered by the expert panel as having multiple precautions or steps instructing proper use of the medication. These included "Refrigerate, shake well, discard after

(date)," "Do not take dairy products, antacids, or iron preparations within one hour of this medication," and "You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication." Rates of comprehension among patients were the lowest for these PWLs (8.0%, 0%, and 5.3%, respectively). Respondents frequently became confused when interpreting the multiple-step instructions or did not address all messages of the PWL in their response (Table 2).

Reading difficulty of text. Overall, comprehension was lowest for two PWLs that had higher Lexile scores: "You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication" (Lexile score = 1300) and "Do not take dairy products, antacids, or iron preparations within one hour of this medication" (Lexile score = 1110). Both labels were written at a high school level or higher. Comprehension was highest for the label "Take with Food," which was written at below the first-grade level.

Use of icons. Many of the icons used on the PWLs appeared to confuse patients. This was especially true if the text was difficult to comprehend. On the label "For external use only," the pictogram was often interpreted as "radioactive," "chills or shaking," or "take anywhere." One patient's interpretation clearly relied on the pictogram and not the text: "Medicine will make you feel dizzy." For the label "Do not chew or crush, swallow whole," interpretations of the icon itself included "someone

Table 1.
Participant Characteristics (*n* = 74)

Characteristic	No. (%)
Female	45 (61)
Race	
African American	66 (89)
White	7 (10)
Other	1 (1)
Literacy level	
3rd grade or below	28 (38)
4th–6th grade	46 (62)
Highest grade completed	
Grades 1–8	16 (22)
Grades 9–11	34 (46)
High school or GED[a]	21 (29)
Secondary education	3 (4)
Payment source for medications	
Private insurance	16 (22)
Medicaid	5 (7)
Self-pay	45 (61)
Other	8 (11)
Sources of medication information[b]	
Physician	53 (72)
Pharmacist	33 (45)
Family	16 (22)

[a]GED = general equivalency degree.
[b]Participants could list multiple sources.

Table 2.
Prescription Drug Warning Labels and Respondent Interpretations (*n* = 74)

Label	Lexile Score/ Grade Level	No. (%) Participants With Correct Interpretations	Incorrect Interpretations
Take with food	BR[a]	58 (78)	Don't take food; bread with food
For external use only	100/1st grade	7 (9)	Use extreme caution in how you take it; medicine will make you feel dizzy; take only if you need it; for adults not kids
Medication should be taken with plenty of water	520/4th grade	28 (38)	Don't take when wet; don't drink hot water; don't need water
Do not chew or crush; swallow whole	600/5th grade	35 (47)	Chew it up so it will dissolve; don't swallow whole or you might choke; just for your stomach; have something on medicine before you take it
Refrigerate—shake well. Discard after ____	800/7th grade	6 (8)	Keep medicine chilled; mix it well, discard when done; put in refrigerator
Do not drink alcoholic beverages when taking this medication	870/8th grade	31 (42)	Don't drink and drive; don't drink alcohol, it's poison and it'll kill you
Do not take dairy products, antacids, or iron preparations within one hour of this medication	1110/10th grade	0	If allergic to dairy, don't take medicine; don't eat for one hour after taking medicine
You should avoid prolonged or excessive exposure to direct or artificial sunlight while taking this medication	1300/12th grade	4 (5)	Don't leave medicine in the sun; don't leave [medicine] in sunlight, but a cool place

[a]BR = beginning reading, the term used in the Lexile Framework to convey a reading level below the first grade.

Table 3.
Literacy Level of Respondents Who Correctly Interpreted Prescription Drug Warning Labels

Label	No. (%) Participants		
	Third Grade or Below (*n* = 28)	Fourth to Sixth Grade (*n* = 46)	*p*
Take with food	17 (61)	41 (89)	0.003
For external use only	0	7 (15)	0.032
Medication should be taken with plenty of water	4 (14)	24 (52)	0.001
Do not chew or crush, swallow whole	5 (18)	30 (65)	<0.001
Refrigerate, shake well, discard after (date)	0	6 (13)	0.049
Do not drink alcoholic beverages when taking this medication	6 (21)	24 (54)	0.004
Do not take dairy products, antacids, or iron preparations within one hour of this medication	0	0	NS[a]
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication	1 (4)	2 (4)	NS

[a]NS = not significant.

swallowed a nickel," "indigestion," and "a bladder." For PWLs that conveyed multiple steps for proper compliance, such as "Refrigerate, shake well, discard after (date)," icons were not able to convey all aspects of the text. The icon (a refrigerator) used on this label addressed only the first step of the instruction, and common incomplete responses to the PWL were subsequently limited: "keep medicine chilled" and "put in refrigerator."

Use of label color. Many patients attributed the use of color to the severity of the label's message. Patients reported that red meant danger; yellow translated to caution; and blue, white, and green labels were viewed as "recommendations" that were not as severe or important as the instructions on red labels. Thirty-one patients (41.9%) applied this cognitive valuation of color to the PWLs.

Message clarity. Text messages on certain PWLs, regardless of Lexile score, were not understood by most patients. For example, "For external use only" had a very low Lexile score (approximately first-grade level) but proved difficult for 90.7% of respondents. For other labels, it was apparent that only a part of the message could be interpreted. For the PWL "Do not chew or crush, swallow whole," some patients provided interpretations that suggested they had read some but not all of the words on the label (e.g., "do not swallow whole," "chew it up so it will dissolve"). Often, patient interpretations of several PWLs were reliant on the pictogram, which led to discordance between the text and icon messages. For instance, many patients derived opposing meanings for the PWL "Do not chew or crush, swallow whole," such as "Don't swallow whole or you might choke."

Discussion

Adhesive PWLs were originally developed to highlight important instructions for the safe use of a medication that were contained within the longer package insert and to be visible every time the patient picked up the medication bottle. These labels are important, considering that many consumers report not reading the longer and more complicated package insert.[31,32] Among our sample of patients with low literacy skills, less than a third (28.7%) reported reading the package inserts that are routinely distributed with prescription medications.

Overall, the eight PWLs in this study were not helpful to patients with low literacy skills. The majority of patients misinterpreted all labels with the exception of "Take with food." The causes for misunderstanding were attributed to one or a combination of problems associated with label text (word choice, message length, and number of steps for action), icons, and color. In fact, our findings indicated that some PWLs may inadvertently promote a misunderstanding of safety information that could potentially lead to hazardous administration of the drug and an adverse reaction. This scenario was most notable on the label "Do not chew or crush, swallow whole," which was interpreted as "do not swallow whole" and "chew it up so it will dissolve."

The example above also highlights a cognitive process that is common among individuals with low literacy skills. These patients may seek out and identify one or two words in print materials that they tentatively recognize and induce meaning from these words.[33] This often leads to an improper placement of the message context, as "swallow" or "chew" was recognized but the opposite action was interpreted. Similarly, adults with low literacy may misread a central word in the message, such as the word "external" in "For external use only." Several patients interpreted the message as "use extreme caution." In this scenario, these adults recognize the first few letters of the word and make an educated guess to decipher the whole word. These individuals lack the vocabulary and reading skills to further grasp the entire content of the message. Adults with low literacy skills may therefore rely more heavily on icons and colors to interpret the meaning of labels, but

these may also mislead or confuse patients.

Though all of the text on the PWLs was brief, some was unnecessarily complex ("You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication") or vague ("medication should be taken with plenty of water"). Some terms reflect lay or professional jargon and may not be universally understood ("iron preparations," "dairy products," "antacids"). Consumers with low literacy need more concrete and specific instructions to respond accordingly.[33-35] In addition, the font size and boldfacing of words varied widely, and often the words emphasized were not central to the action requested. This may cause patients with reading difficulties to take these messages out of context. Finally, all letters in these PWLs were capitalized, despite recommendations that uppercase and lowercase text be used to improve accessibility among beginning readers.[33-35]

Limitations. This study had several limitations. First, participation was limited to English-speaking patients. However, the majority of PWLs currently used in the United States are only available in English. Second, patients were sampled from one public hospital, which may limit the generalizability of findings. However, patients in the sample reflected a group disproportionately affected by poor health outcomes and whose health and health care are targeted for improvement by Healthy People 2010.[36] Finally, the sample size limited the ability to detect significant and clinically meaningful relationships within subgroups, such as differences across age groups. Previous studies found that older adults were less able to comprehend prescription labels compared with younger adults.[37,38] Another study found that 67% of elderly persons did not fully understand the information on the drug labels.[9] Less than 5% of patients in our sample were 75 years of age or older.

Opportunities for improvement. Over the past decade, improvements have been sought to make the general prescription drug label and any patient information included in package inserts more accessible to all consumers.[1,10,39] We offer the following steps as a road map to move from policy to practice, providing direction for the development of new messages, icons, and labels to better convey these important warnings and dosage instructions.

Develop standards, regulations, and guidelines. The Federal Food, Drug, and Cosmetic Act of 1938 provides FDA with regulatory oversight to mandate reform for the general drug label and package inserts.[40] However, these adhesive warning labels have not been viewed within the scope of this act, were not included in the Keystone Dialogue, and have largely been ignored by FDA, manufacturers, and other organizations. The development and use of PWLs should become an essential component of package labeling and should receive regulatory oversight to ensure that standards are in place for their continued development and use. Recognizing that such national regulation will take time, and realizing the urgency posed by the clear evidence of misunderstanding and the potential for harm, concerted voluntary action is needed. NABP and the Pharmaceutical Research and Manufacturers of America should develop consensus guidelines to ensure safe and consistent messages through PWLs.

Involve consumers. Consumers need to be actively involved in the development of new PWLs to ensure that the icon design, words, and formatting are useful to all individuals, including those with low literacy. Intensive cognitive testing of patients of all literacy levels should be conducted to confirm the appropriate meaning of text, icons, and color. Feedback from pharmacists and physicians, who may counsel patients on the safe administration of prescription medications and eventually distribute and explain the revised labels, should also be sought.

Seek universal acceptance and consistent use of label icons. Several companies currently produce PWL stickers for U.S. pharmacies. As a result, different icons have been developed to convey similar messages regarding medication administration. Therefore, patients may be exposed to multiple PWLs and icons for the same medication if they fill prescriptions at more than one pharmacy or if their pharmacy changes label vendors. Icons should be consistent and universal acceptance of their meaning sought.

Train professionals in literacy issues and communication. Pharmacists, physicians, and other health care professionals should be oriented to this approach to supplemental labels to ensure that they, too, are communicating a consistent message. Specifically, the pharmacist may be the first to recognize problems with patient literacy and proper understanding of how to safely use prescription medications. However, pharmacists should be educated to the larger problem of health literacy and learn simple ways for both recognizing patients at risk and responding accordingly.[41] Low literacy communications training modules currently exist that could provide pharmacists with useful skills, such as the "teach back" technique to confirm patients' understanding of medication instructions, including those listed on warning labels.[42]

Simplify text used on labels. Reading difficulty formulas, such as the Lexile Framework, should be used as a starting point to gauge the complexity of the print message on PWLs. However, these formulas should be used with more comprehensive assessments[33-35] that focus on other contributing factors to reading

ease, such as organization, complexity, and clarity.[33]

Minimize the action sought per label. Our findings suggest that multiple-step instructions on PWLs should be avoided when possible. For instance, the PWL "Do not take dairy products, antacids, or iron preparations within one hour of this medication" might be divided into three separate messages. For the label "Refrigerate, shake well, discard after (date)," it may be important to include multiple icons rather than one that only addresses the first action.

Give meaning to color and standardize its use. Consumers, like those in our study, may impose a "traffic light" color scheme to a label and its message. We recommend limiting the number of colors used and applying a consistent color scheme to different messages. For instance, messages conveying a warning or restriction might use red and yellow colors, and PWLs that provide instructions could be printed on white labels.

Aim for message concordance across languages. While some PWLs have translations in Spanish, many do not, and it is not clear how message concordance was achieved across languages for these labels. A systematic approach to the development and translation of PWLs across languages needs to be established. Existing resources are available to guide the translation process.[43] Cultural considerations should specifically be addressed, including semantic differences associated with both text and icons within a language.

Conclusion

Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.

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