Reducing adverse events associated with medication errors in the ambulatory care setting remains an important patient safety objective for physicians and for the health care community at large (1–7). Although much attention has been directed to medication-related errors attributed to physician or system failure (1, 8–10), patient-initiated errors in medication use have received less recognition. As the focus on health care delivery continues to shift from inpatient to outpatient settings, the practice of quality control over medication use is becoming more the responsibility of the patient and less the responsibility of the provider. Yet, patients do not always take medications as prescribed, and as a result, outpatient adverse drug events are common (4–6).

Previous studies have found that many patients are not receiving oral or written instructions from their physicians and pharmacists on how to appropriately manage prescription medications (11, 12). As a result, instructions on the prescription container label assume greater importance. The Institute of Medicine (13) estimates that 90 million adults in the United States may have trouble understanding and acting on health information. Medication container labels, in particular, may be confusing and difficult to comprehend for many patients (14–18).

The incidence of patient medication errors is likely to increase, because Americans are taking more prescription medications annually (19). The physician and the pharmacist may assume that their patients can read, understand, and act on brief instructions found on prescription medication labels, but this may not be the case (11–13). The purpose of this study was to examine whether adult primary care patients were able to read and correctly state how they would take various medicines after reviewing label instructions on actual pill bottles. We hypothesized that low literacy would be associated with higher rates of misunderstanding and incorrect demonstration.

Methods

Participants

Study participants were adult patients who attended 1 of 3 outpatient primary care clinics that predominantly serve indigent community populations in 3 distinct cities and states (Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois). Participant recruitment took place in Shreveport, Louisiana, during July 2003 and at the remaining 2 sites during July 2004. In Shreveport, the primary care clinic was situated within a public hospital, whereas the clinics in Chicago and Jackson are both federally qualified health centers that provide care to medically underserved neighborhoods.

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Conversion of tables into slides
Patients were considered eligible for the study if they were 18 years of age or older and were considered ineligible if the clinic nurse or study research assistant (during the course of the interview) identified a patient as having 1 or more of the following conditions: 1) severely impaired vision, 2) hearing problems, 3) illness too severe to participate, and 4) inability to speak English. The institutional review boards at all locations approved the study. All participants provided informed consent. A total of 458 patients were approached in the order they arrived at the clinics and before the medical encounter; 446 consented to participate in the study. Seventeen patients were excluded on the basis of self-reported impairments in hearing (n = 5) or vision (n = 12). Nine patients were excluded because they spoke English as a second language, and 25 additional patients were excluded on the basis of incomplete information. In all, 395 patients participated in the study. A response rate was determined following the American Association for Public Opinion Research standards (20), which estimated that 91.6% of approached eligible patients participated in the study.

Structured Interview and Literacy Assessment

A structured “cognitive” interview protocol was developed to assess patients’ understanding of the instructions of 5 common prescription medication container labels. Interviews were conducted with 6 primary care physicians and 1 hospital pharmacist to identify common medication prescriptions for acute and chronic health conditions. Through these interviews, a consensus was reached and 5 medications were identified for the study, including 2 antibiotics (amoxicillin [for pediatric use] and trimethoprim); an expectorant (guaifenesin); an antihypertensive, channel-blocking agent (felodipine); and a diuretic (furosemide).

After patients consented to participate in the study, a trained research assistant administered the structured interview that included self-report of sociodemographic information (age, sex, race and ethnicity, education, source of payment for medications, and number of prescription medications currently taken daily). Actual prescription pill bottle containers with labels were then shown in the same order to all of the patients for review. Once the patient provided his or her interpretation of all of the labels, the research assistant administered a brief literacy assessment, which concluded the interview.

Understanding Medication Container Label Instructions

To assess patient understanding of the instructions on each of the 5 prescription medication labels, the research assistant asked, “How would you take this medicine?” The patient’s verbatim response was then documented on a separate form. All patient responses (n = 1975) to the instructions for each of the 5 medications were then independently rated as either correct or incorrect by 3 general internal medicine attending physicians from 3 academic medical centers. Each physician-rater was blinded to all patient information and was trained to follow stringent coding guidelines previously agreed on by the research team. Specifically, correct scores were to be given only if the patient’s response included all aspects of the label’s instruction, including dosage; “timing”; and if applicable, duration. Responses were given an incorrect score if they were inaccurate or if they did not contain all aspects of the instructions.

Interrater reliability was high among the 3 physicians who coded the patient responses (κ = 0.85). The 147 responses (7.4%) that received discordant ratings among the 3 reviewers were sent to an expert panel for further review. This panel included 3 primary care physicians and 2 behavioral scientists with expertise in health literacy. Each panel member, also blinded to patient information, independently reviewed and coded the responses as correct or incorrect. For 76.2% (n = 112) of the 147 responses, a consensus ruling was achieved among the 5-member panel for a final ruling on the coding of those responses. For the remaining 35 patient responses, a majority rule was imposed and the rating by a minimum of 3 panel members was used to determine the scores.

In a final review, responses that were coded as incorrect were qualitatively reviewed by 3 research assistants, who were trained by the expert panel members to code the responses according to the nature of the misunderstanding (incorrect dosage, incorrect frequency, incomplete response, navigation difficulty as defined by stating information on the container other than the primary label instruction, and no attempt because of self-reported reading
difficulties). Interrater agreement was high among the research assistants (κ = 0.82).

**Attendance to Auxiliary Label Instructions**

We also investigated the patient’s attentiveness to the auxiliary or “secondary” warning labels on the pill bottles. These labels provide supplementary instructions, such as “Take with food” or “Do not chew or crush, swallow whole,” which support the safe administration of the medications. Research assistants were instructed to document whether patients attempted to interpret the auxiliary label along with the primary label, or whether they physically turned the bottle to inspect the color stickers on which these warning messages are placed. Patient attendance to the auxiliary label was coded as “yes” if his or her response or behavior was noted by the reviewer and “no” if the label was disregarded. Our research team has previously investigated patients’ understandings of these auxiliary labels (21).

**Understanding versus Demonstration**

A substudy was conducted among all patients to test whether those who could accurately read and state the instructions for guaifenesin (“Take two tablets by mouth twice daily”) could correctly demonstrate how many pills were to be taken daily. After patients answered the first question, “How would you take this medicine?” they were asked, “Show me how many pills you would take [of this medicine] in one day”. The medication container was filled with candy pills for patients to dispense and count out the correct amount. Responses were coded as correct if their answer was “4” and incorrect if any other response was provided.

**Literacy Assessment**

Patient literacy was assessed by using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test comprising 66 health-related words (22–24). This is the most commonly used test of patient literacy in medical settings (24). Raw scores can be converted into 1 of 3 reading levels: sixth grade or less (score, 0–46), seventh to eighth grade (score, 45–60), and ninth grade and above (score, 61–66). The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (14).

**Statistical Analysis**

All statistical analyses were performed by using SAS software, version 9.1 (SAS Institute, Inc., Cary, North Carolina). Descriptive statistics (percentage, mean, and SD) were calculated for each variable. Chi-square tests were used to evaluate the association between sociodemographic characteristics and patient understanding of primary label instructions of 5 prescription medications and attendance to the auxiliary labels. In multivariate analysis, the 5 binary repeated responses of understanding per patient were modeled by using a generalized linear model with a complementary log-log link function. A generalized estimating equation approach was used to adjust model coefficients and standard errors for within-patient correlation by using PROC GENMOD (SAS Institute). Wald 95% CIs were calculated for adjusted relative risk ratios by using the robust estimate of the standard error as detailed by Liang and Zeger (25). The final multivariate model included the potential confounding variables: age, sex, race (white vs. African American), education, and number of medications currently taken daily. Although education is associated with literacy, it was examined separately but included in the final model to present conservative estimates of the effect of literacy on rates of understanding. This issue has previously been reviewed by Wolf and colleagues (26) and the same method was used in our study. Site was also entered into the model to adjust for any potential differences across study locations. In multivariate analyses, patient literacy was classified as low (sixth grade and below), marginal (seventh to eight grade), or adequate (ninth grade and higher). For the substudy analyses, chi-square tests were used to evaluate the association between sociodemographic characteristics and correct demonstration of the specified medication instructions. A multiple logistic regression model was used to examine the relationship between literacy and comprehension of the medication labels while controlling for the previously mentioned confounding variables and study site. Model fit was assessed by using the c-statistic from the receiver-operating characteristic curves and the Hosmer–Lemeshow goodness-of-fit chi-square test.

**Role of the Funding Sources**

The study was internally funded by the Health Education and Literacy program at Louisiana State University Health Sciences Center and by a career development award from the Centers for Disease Control and Prevention.

**RESULTS**

The mean age for all respondents (n = 395) was 44.8 years (SD, 13.7; range, 19 to 85 years). Fifty-seven percent of patients were recruited from Shreveport, Louisiana; 25% from Jackson, Michigan; and 18% from Chicago, Illinois. Two thirds (67.8%) were women, approximately half were African American (47.4%) and half were white (48.4%), and 28.4% reported less than a high school level of education. Patient literacy was limited; 19.0% read at or below a sixth-grade level (low literacy), and 28.6% read at the seventh- to eighth-grade level (marginal literacy).

Patients were taking an average of 1.4 prescription medications, and 22.8% lacked insurance for these medications. Low literacy was associated with older age (P < 0.001), African-American race (P < 0.001), and less education (P < 0.001) (Table 1). No statistically significant differences were reported between literacy level, sex, source of payment for medications, or number of prescription medications taken daily.

Overall, the 395 patients gave a total of 1975 responses for the 5 medication labels. Of these responses,
374 (18.9%) were coded as incorrect. Almost half (46.3%) of patients misunderstood 1 or more of the prescription label instructions, and the prevalence among patients with adequate, marginal, and low literacy was 37.7%, 51.3%, and 62.7%, respectively (P<0.001). The rates of understanding individual labels ranged from 67.1% for the instructions for trimethoprim (“Take one tablet by mouth twice daily for seven days”) to 91.1% for the instructions on the label for felodipine (“Take one tablet by mouth once each day”). Patients with low literacy were less able to understand the meaning of all 5 medication labels than those with adequate literacy (Table 2). No statistically significant differences in rates of understanding the medication labels were noted by either age or number of prescription medications currently taken.

The majority (51.8%) of incorrect patient responses reflected an error in dosage (that is, tablespoon vs. teaspoon), and 28.2% stated the wrong dose frequency (that is, “one tablet each day for seven days” instead of “Take one tablet by mouth twice daily for seven days”). For the instruction, “Take one tablet by mouth twice daily for seven days”, 11.1% of responses omitted the duration of use. In 5.8% of the incorrect responses, patients had difficulty finding the instructions on the prescription label, and in 3.2% of incorrect responses, the patient acknowledged to the interviewer that he or she was unable to read.

Multivariate analyses identified low and marginal literacy as statistically significant independent predictors of misunderstanding the primary medication label instructions (adjusted relative risk, 2.32 [CI, 1.26 to 4.28] for low literacy and adjusted relative risk, 1.94 [CI, 1.14 to 3.27] for marginal literacy) (Table 3). Patients who took more prescription medications were also independently found to be more likely to misunderstand the labels (adjusted relative risk, 2.29 [CI, 1.16 to 4.54] for 1 to 2 medications; adjusted relative risk, 3.22 [CI, 1.53 to 6.77] for 3 to 4 medications; and adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for ≥5 medications) (Table 3). No statistically significant interactions were found between literacy, age, number of medications taken, sex, and race.

One-way sensitivity analyses were conducted to account for responses that were coded as incorrect because of incomplete information on duration of use (n=41 [11.1% of incorrect responses]). When these responses were recoded as correct, no substantial differences were noted for the association between misunderstanding and low literacy (adjusted relative risk, 2.29 [CI, 1.16 to 4.54]) for 1 to 2 medications; adjusted relative risk, 3.22 [CI, 1.53 to 6.77] for 3 to 4 medications; and adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for ≥5 medications) (Table 3). No statistically significant interactions were found between literacy, age, number of medications taken, sex, and race.

Substudy Analyses
A substudy analysis compared the percentage of patients who accurately read and correctly stated the label instructions for guaifenesin (“Take two tablets by mouth...
twice daily”) compared with the percentage of patients who correctly demonstrated the number of pills to be taken. Patients at all literacy levels were more able to read label instructions than to demonstrate the correct number of pills to be taken. Among patients with adequate literacy, 89.4% were able to read the instructions, whereas 80.2% properly demonstrated the correct number of pills to be taken. Differences in the ability to read versus the ability to demonstrate use were larger among patients with marginal (84.1% vs. 62.8%) and low literacy (70.7% vs. 34.7%). In multivariate analysis, low literacy was the only statistically significant independent predictor of correct demonstration of the label instructions (adjusted relative risk, 3.02 [CI, 1.70 to 4.89]). The model was tested for interactions; none were found to be statistically significant.

**DISCUSSION**

Physicians may assume that patients can understand instructions on prescription medication containers, because their appearance suggests that they are simple and clear. However, in this multisite study of primary care patients, approximately half (46.3%) were unable to read and correctly state 1 or more of the label instructions on 5 common prescriptions. Rates of misunderstanding were higher among patients with marginal and low literacy, yet more than one third (37.7%) of patients with adequate literacy skills misunderstood at least 1 of the label instructions. This is cause for concern, because patient misunderstanding could be a potential source of medication error.

The instructions on the 5 prescription labels were typical in that they were short and used seemingly simple words. Nonetheless, the information was not clear for many patients. Mistakes were more common when the instructions had several components with varying numerical information (for example, “Take one tablet by mouth twice daily for seven days” vs. “Take one tablet by mouth once each day”). Misunderstanding was less frequent for the label with the most explicit dosing instructions (“Take one tablet in the morning and one at 5 p.m.”), and differences by literacy did not reach statistical significance. However, this is probably the result of a higher rate of comprehension among patients with marginal literacy, because the difference between patients with adequate and low literacy skills was still similar to that found for other labels with less explicit instructions. Beyond the clarity of the instructions, patients may misread labels as a result of haste or limited literacy. Twenty-two percent (n = 23) of the patients with incorrect responses to the instructions, “Take one teaspoonful by mouth three times daily,” misinterpreted the dose as “tablespoon” rather than “teaspoon.”

Among the patients correctly stating the instruction, “Take two tablets by mouth twice daily” (n = 333 [84.3%]), one third were unable to demonstrate the correct number of pills to take per day. This was most pronounced

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Instruction</th>
<th>Correctly interpreted primary label</th>
<th>Attended to auxiliary labels</th>
<th>Literacy Level</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Adequate (n = 207)</td>
<td>Marginal (n = 113)</td>
<td>Low (n = 75)</td>
<td></td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Correctly interpreted primary label</td>
<td>Take one teaspoonful by mouth three times daily</td>
<td>82.6</td>
<td>65.5</td>
<td>58.7</td>
</tr>
<tr>
<td></td>
<td>Attended to auxiliary labels</td>
<td>5.3</td>
<td>4.4</td>
<td>0.0</td>
<td>0.130</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Correctly interpreted primary label</td>
<td>Take one tablet by mouth twice daily for seven days</td>
<td>73.0</td>
<td>66.4</td>
<td>52.0</td>
</tr>
<tr>
<td></td>
<td>Attended to auxiliary labels</td>
<td>7.8</td>
<td>7.1</td>
<td>1.3</td>
<td>0.144</td>
</tr>
<tr>
<td>Guaifenesin</td>
<td>Correctly interpreted primary label</td>
<td>Take two tablets by mouth twice daily</td>
<td>89.4</td>
<td>84.1</td>
<td>70.7</td>
</tr>
<tr>
<td></td>
<td>Attended to auxiliary labels</td>
<td>14.1</td>
<td>7.1</td>
<td>0.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Felodipine</td>
<td>Correctly interpreted primary label</td>
<td>Take one tablet by mouth once each day</td>
<td>94.7</td>
<td>87.6</td>
<td>86.7</td>
</tr>
<tr>
<td></td>
<td>Attended to auxiliary labels</td>
<td>12.6</td>
<td>10.6</td>
<td>4.0</td>
<td>0.115</td>
</tr>
<tr>
<td>Furosemide</td>
<td>Correctly interpreted primary label</td>
<td>Take one tablet in the morning and one at 5 p.m.</td>
<td>91.3</td>
<td>91.2</td>
<td>82.7</td>
</tr>
<tr>
<td></td>
<td>Attended to auxiliary labels</td>
<td>14.5</td>
<td>8.9</td>
<td>2.7</td>
<td>0.011</td>
</tr>
</tbody>
</table>

* The multicolored labels that provide auxiliary instructions, such as “Take with food” and “Do not chew or crush, swallow whole.”
among patients with low literacy—fewer than half—who correctly stated the instruction were then able to count the right number of pills. This may reflect more of a patient’s numeracy skills than reading proficiency; however, numeracy is an aspect of functional literacy. According to the National Adult Literacy Act of 1991 (27), functional literacy is defined as “the ability to read, write, and speak in English, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one’s goals, and develop one’s knowledge and potential.” Our finding that patients may be able to read label instructions but not correctly demonstrate the number of pills to be taken suggests that numeracy may be a more difficult literacy task than decoding relatively simple words (28).

Currently recommended methods for confirming patient understanding include the “teach-back” technique in which patients are asked to repeat instructions to demonstrate their understanding (29). This may be inadequate for identifying potential errors in medication administration, because study results documented a gap between a patient’s ability to correctly state instructions and his or her ability to correctly demonstrate the correct number of pills to be taken daily. A system approach in which someone (pharmacist, nurse, clinic assistant, or physician) verifies that patients can accurately demonstrate or articulate specific correct medication taking behaviors is important to ensure quality care. A recent report from the Institute of Medicine (7) notes the importance of providers having enhanced discussions with patients as a means of improving medication safety. This study suggests that medication review needs to verify that patients, or their surrogates, can accurately describe and demonstrate how to take medications safely.

Most patients did not pay attention to the auxiliary (warning) labels, and those with low literacy were more likely to ignore them. Lack of attention to the warning labels has been recognized as a problem (21). In a previous study, patients reported that they rarely attended to warning labels. This may be attributed to a limited effort by physicians or pharmacists to counsel patients about the importance of these labels. Nonetheless, failure to heed the special instructions on these labels could potentially lead to a loss of drug potency; change in the rate of absorption of the medication; or in certain formulations, cause such adverse events as gastrointestinal bleeding (30).

Table 3. Risk Factors for Misunderstanding Prescription Medication Label Instructions*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Relative Risk (95% CI)</th>
<th>P Value</th>
<th>Adjusted Relative Risk† (CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Literacy level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Marginal</td>
<td>1.59 (1.12–2.26)</td>
<td>&lt;0.001</td>
<td>1.94 (1.14–3.27)</td>
<td>0.014</td>
</tr>
<tr>
<td>Low</td>
<td>2.38 (1.64–3.45)</td>
<td>&lt;0.001</td>
<td>2.32 (1.26–4.28)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Age, y</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;40</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>40–49</td>
<td>1.18 (0.81–1.74)</td>
<td>0.39</td>
<td>1.18 (0.70–2.03)</td>
<td>0.53</td>
</tr>
<tr>
<td>50–59</td>
<td>1.26 (0.84–1.89)</td>
<td>0.26</td>
<td>0.63 (0.33–1.19)</td>
<td>0.155</td>
</tr>
<tr>
<td>≥60</td>
<td>1.42 (0.89–2.27)</td>
<td>0.146</td>
<td>1.09 (0.58–2.08)</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.65 (1.21–2.23)</td>
<td>&lt;0.005</td>
<td>1.43 (0.95–2.14)</td>
<td>0.083</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>1.46 (1.08–1.98)</td>
<td>0.016</td>
<td>0.99 (0.63–1.55)</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;High school</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Completed high school or GED degree</td>
<td>1.09 (0.76–1.58)</td>
<td>0.63</td>
<td>1.07 (0.64–1.80)</td>
<td>0.79</td>
</tr>
<tr>
<td>Grades 9–11</td>
<td>1.46 (0.97–2.19)</td>
<td>0.075</td>
<td>0.89 (0.48–1.65)</td>
<td>0.70</td>
</tr>
<tr>
<td>Grades 1–8</td>
<td>2.53 (1.31–4.87)</td>
<td>&lt;0.001</td>
<td>1.83 (0.85–3.99)</td>
<td>0.121</td>
</tr>
<tr>
<td><strong>Medications taken daily, n</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>1–2</td>
<td>1.60 (1.05–2.44)</td>
<td>0.032</td>
<td>2.29 (1.16–4.54)</td>
<td>0.022</td>
</tr>
<tr>
<td>3–4</td>
<td>1.77 (1.13–2.76)</td>
<td>0.012</td>
<td>3.22 (1.53–6.77)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>≥5</td>
<td>1.63 (1.01–2.62)</td>
<td>0.054</td>
<td>2.98 (1.40–6.34)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* GED = general educational development.
† Multivariate adjusted relative risks derived from generalized estimating equation regression models, adjusting for site in addition to all variables shown.
taken is a proxy for a greater number of comorbid conditions. Previous studies have shown that poorer health status is not only associated with more prescription medications in one's regimen but also with low literacy skills (26). This is noteworthy in light of recently reported trends. According to the Medical Expenditures Panel Survey (19), the average number of prescription medications filled annually by adults in the United States increased from 7 to 10 prescriptions between 1996 and 2003. An earlier study reported parallel trends in the increase of hospitalizations and deaths associated with medication errors (31).

Few studies have assessed actual patient understanding of medication instructions, and those that have more often focused solely on the elderly, a population especially vulnerable to misunderstanding prescription labels and instructions (17, 18, 32, 33). Senior citizens consume 2 to 3 times more medicine than does the general public, are more likely to have lower literacy skills, and have repeatedly been found to have poorer comprehension and recall of information on medication labels (28, 33). Although these studies have identified problems among elderly patients, our findings show that patients of all ages would benefit from additional efforts to improve the clarity and comprehensibility of labeling on prescription drugs.

Our study has limitations. We investigated patient understanding only of the primary label on prescription medications. The association between misunderstanding of label instructions and medication error was not examined. We also did not study the patients’ actual prescription drug-taking behaviors. Motivation, concentration, and comprehension might have been greater if the patients were reporting on their own medication given by their physician for conditions they or their children actually had. Because the study design did not include a chart review, we could not identify whether patients had actual experience with the study medications.

Patients in our study were socioeconomically disadvantaged persons from 3 primary care clinics in diverse areas of the United States. Recruitment solely at clinics mandated to serve indigent populations was intentional. Our sample addresses those persons who are disproportionately affected by poor health outcomes and whose health and health care are targeted for improvement by Healthy People 2010 (34). The generalizability of our findings is further limited because the participants in our study were predominantly women (an accurate depiction of the clinic patient populations) and participation was limited to those who were proficient only in English. This was due in part to criteria for using the REALM as our literacy assessment. Additional research is needed to examine the language barrier to understanding instructions on prescription drug labels.

Our estimated prevalence of misunderstanding 1 or more prescription container labels (46.3%) was very similar to the estimates published by the National Assessment of Adult Literacy of 2003 (28), which reported that 43% of adults in the United States read at the lowest levels of reading proficiency. Previous studies suggest that misunderstanding instructions on prescription medication labels is more common among elderly persons (17, 18, 33). Only 12% of patients in our sample were older than 60 years, and it is possible that we underestimated this relationship.

The Institute of Medicine Patient Safety Report (1) and a more recent report (7) stress the importance of addressing patient safety as a critical first step in improving quality of care. Our study found hidden health literacy problems with seemingly simple prescription medication labels. Although the prescriptions we examined have a relatively wide therapeutic margin, errors in their use have clinical importance. Moreover, it is probable that the rates of misunderstanding would be similar among medications with a more narrow range for clinical efficacy and safety. These medications may have similar dosing instructions to those we studied but possess greater risks for serious treatment failure or adverse events if taken incorrectly.

In summary, patients of all ages would benefit from additional efforts to improve the clarity and comprehensibility of labeling on prescription drugs (35–37). The text and format of existing primary and auxiliary labels on prescription medication containers should be redesigned and standardized. Less complex and more explicit dosing instructions may improve patient understanding; however, more research is needed to properly evaluate different instructional formats.

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Note: Drs. Davis and Wolf contributed equally to the creation of this manuscript.

Acknowledgments: The authors thank Jian Huang, MD, Robert Jackson, MD, Paul Cooper, MD, Jennifer Singh, MD, and Mark Middlebrooks, PharmD, for their aid in selecting the medication prescriptions. They also thank Connie Manning, Anna Bocchini, Stephanie Savory, and Silvia Striplakauskas for their help in data collection; Mickey Eder, PhD, and Molly Kaser for supporting recruitment efforts at the study locations; Ed Vonesh, PhD, and Fred Rademaker, PhD, for their guidance on statistical matters; and Mary Bocchini, Kat Davis, Jenney Palmer, and Courtney Noble, MD, for their assistance in coding patient responses.

Grant Support: Dr. Wolf is supported by a career development award through the Centers for Disease Control and Prevention (1 K01 EH000067-01).

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