**Editorial**

**Misunderstanding Prescription Labels: The Genie Is Out of the Bottle**

The U.S. health care system largely operates under the assumption that all patients have high English-language literacy skills (1). In fact, many patients do not. In this issue, Davis and coworkers (2) carefully show that a substantial proportion of users of the U.S. health care system don’t understand the instructions on prescription bottle labels and are unable to correctly execute these instructions. For those interested in improving health care quality and safety for vulnerable populations, this multisite study has important implications for practice, research, and policy. It forces us to focus on developing better “operating instructions” for medication taking. We are left wondering whether we could improve current labeling practice to communicate instructions about taking medication. I know that we can. So, who should be accountable for implementing a better system?

Briefly, in a sample of ethnically diverse primary care patients from community health centers, the investigators demonstrated a high rate of misunderstanding instructions on prescription labels for 5 common medications. Although the highest rates of misunderstanding across each of the 5 bottle labels (13% to 48%) occurred among patients with the lowest literacy levels, misunderstanding was common even among those with the highest literacy levels (5% to 27%). In multivariate analyses, lower literacy and greater number of prescription medications taken were associated with misunderstanding. Even worse, among those who seemed to understand a standard prescription label—by correctly reading and restating the instructions—far fewer correctly demonstrated how they would take the medication at home. Specifically, participants were asked to show how many pills they would take in 1 day, using candy pills from the bottle. Lower literacy was also associated with failure to correctly execute pill-taking instructions.

Does the authors’ evidence fully support their conclusion that poor reading skills were responsible for poor understanding? In fact, the evidence is incomplete because the authors did not account for patients’ cognitive function or visual acuity—each of which can impair reading comprehension and could explain poor understanding of labels. However, although this oversight may undermine the strength of the association between low literacy and poor understanding, it does not weaken the conclusion that many patients do not comprehend prescription labels and cannot act on their instructions. Some may argue that it is not surprising that doing poorly on a formal literacy “test” is associated with doing poorly on another form of literacy test: reading a prescription label. They would claim that this study confirms that poor test-taking skills beget poor test-taking and that the results of this particular test may not adequately reflect patients’ behaviors at home. Although the authors did not assess actual medication-taking behaviors, other research has found that misunderstanding one’s own warfarin prescription label, as measured by a similar test, is associated with limited literacy and unsafe anticoagulant outcomes (3), providing support for Davis and colleagues’ conclusion that low literacy can have clinical consequences.

Do the findings of Davis and coworkers apply to other populations? While study participants were recruited from sites that serve the economically disadvantaged, the prevalence of low literacy was similar to that documented in a recent national assessment of literacy. This study categorized 36% of the U.S. population as having basic or below-basic literacy skills as regards to health-related tasks (4). The nature of the study design by Davis and colleagues was somewhat artificial—the authors asked participants to read, interpret, and demonstrate how to follow instructions from hypothetical sample prescription bottles and labels for commonly prescribed medications. This approach was necessary to standardize the test of prescription label reading, but it may raise concerns that the results do not reflect a “true” understanding of a patient’s own prescription bottle labels—labels that patients arguably have learned to read and interpret correctly despite poor reading skills. However, more than one third of patients who take warfarin cannot demonstrate how to follow label instructions on their own medications (5), which suggests that the results from the study by Davis and coworkers apply to patients’ own prescription medications. Finally, the patients in the study were atypical: They took few medications regularly (mean, 1.4 medications), were relatively young, and spoke fluent English (6). Rates of misunderstanding in a typical internal medicine practice are probably even higher, because greater medication burden, older age, and limited English-language proficiency are all associated with misunderstanding prescription labels (5).

Davis and colleagues move the health literacy field forward considerably by developing improved research methods. The investigators’ rigorous method for determining agreement between patients’ and clinical investigators’ interpretations of the same instructions will be useful for future descriptive and intervention studies. In addition, the researchers were able to tease out the “understanding” component of task performance, as measured by having participants verbally interpret prescription label instructions, from the “demonstration” component, as measured by having participants actually show how many pills they would take of the medicine in 1 day.

The study has several important implications. First, for the practitioner, it confirms that detailed medication reconciliation—ensuring that the patient knows which medications have been prescribed and can demonstrate how to correctly use all of them—must be part of routine practice. Medication reconciliation is important for all patients, but may be especially so for patients taking several medications.
those taking medications that require stringent adherence, or those taking medications that cause adverse events if taken incorrectly. The best way to efficiently assess comprehension and elicit correct demonstration as part of the reconciliation process is unclear (5). The methods will probably include interactive communication strategies (7, 8) and using information from multiple sources (patient verbal report, demonstration of correct medication taking, and pharmacy records). However, in the absence of significant changes in prescription labeling and/or development of a more robust and standardized prescription communication system, medication reconciliation will usurp a substantial portion of clinical visit time, thereby infringing on the practice of a more relationship-centered type of care.

Second, from the perspective of patient safety research, the study findings challenge the fields of health communication, human cognition, and ambulatory medication safety to do better. For example, 2 related methods for assessing comprehension used in this study provided divergent results (many patients who correctly stated the instructions could not correctly demonstrate how to take the medications). This study was not designed to show which types, design, or formatting of label instructions is particularly challenging or effective, which should now be an area for intense scientific inquiry. Although the study did not examine the relationship between misunderstanding prescription labels and adverse events, research from our group has clarified this causal link. We found that providing a visual aid that shows the weekly pill regimen seems to increase comprehension of prescription labels and reduce the risk for medication-related adverse events (9).

Finally, this study has profound implications for health policy. In the United States, transmission of information on written prescriptions occurs in 4 ways (William Shrank, MD, MSHS, personal communication; 16 October 2006). The first is the label affixed to the bottle, the focus of the current study. The U.S. Food and Drug Administration (FDA) and state boards of pharmacy jointly regulate the content—but not the format—of this label. Not surprisingly, practices within and among states vary. Second, pharmacies voluntarily provide consumer medication information in the form of nonstandardized, privately developed information leaflets delivered with most filled prescriptions. Consumer medication information is entirely unregulated and is often of poor quality. Third, package inserts, which are heavily regulated by the FDA, are intended for the use of the prescribing physician, are rarely delivered with prescriptions, and offer little benefit to patients (10). It is the prescribing physician, in his or her capacity as a “learned intermediary” between the drug manufacturer and the patient, who ultimately is accountable for successfully transmitting information about prescription medications. However, physician communication of basic prescription information to patients is notoriously spotty, and physicians do not seem to make a greater effort to communicate with less educated patients (11). Finally, in the past decade, the FDA has required the development of patient-directed medication guides for particularly high-risk medications (often those with “black box warnings”). In a recent study of a representative sample of such guides, none met federal readability recommendations, and nearly all were unsuitable for the average user (12). Nonetheless, the FDA’s action to require medication guides at least provides a regulatory template within which we can operate as we develop more effective strategies to ensure effective and consistent prescription communication.

Why don’t we have a standardized system to transmit medication instructions that all patients can understand and act on? Perhaps it is because the field of health literacy is in its infancy and research findings have not yet been translated into policy changes. To date, we have invested too little in generating the scientific evidence to show that labeling practice or communication system is superior to another (5, 9). Furthermore, because the framework for regulating the content of prescription labels and accompanying materials is inadequate, patients and clinicians are suffering. With this study, the genie is out of the bottle.

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