Low Literacy Limits Label Comprehension

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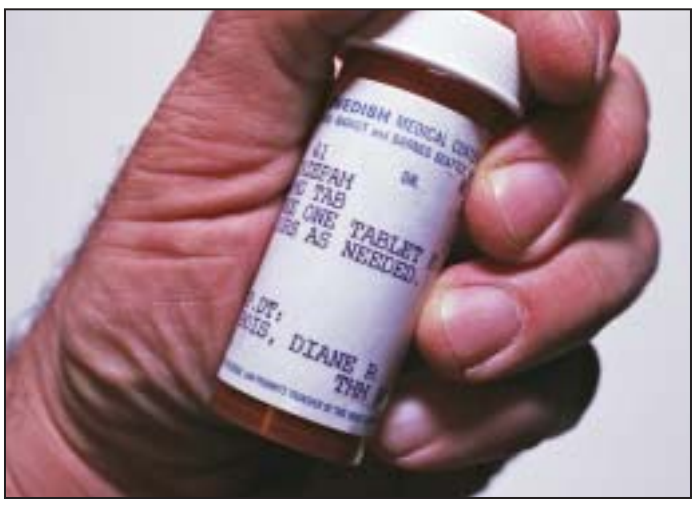
WASHINGTON — Patients who read at or below the 6th-grade level had a low level of comprehension of instructions on the labels of five commonly used medications, according to a study led by Terry Davis, Ph.D., of the Louisiana State University.

Even though labels seem short and to the point, "many patients need more specific, concrete information," including instructions on exactly what time of day to take a medication, Dr. Davis said in presenting the findings at a conference on health literacy sponsored by the American College of Physicians.

Along with colleagues at Northwestern University, the University of North Carolina, Western Michigan Area Health Education Center, and Emory University, she queried 395 patients at three clinics that primarily serve the indigent about their understanding of labels for the following drugs: amoxicillin for pediatric use, trimethoprim, guaifenesin, felodipine, and furosemide (Ann. Intern. Med. 2006;145:887-94).



The study found that "many patients need more specific, concrete information" about prescribed medications.

The goal was to determine whether primary care patients could read and correctly state how to take medicines after reading the labels on actual pill bottles, Dr. Davis said. The researchers hypothesized that patients with low literacy were more likely to misunderstand instructions. They also believed that the increasing number of medications taken by Americans is leading to growing confusion and medication errors.

Participants spoke English as a primary language and were not hearing or vision impaired. Half were African American and half were white. The mean age was 45 years, and 29% had a less than high school education. Literacy was assessed with the Rapid Estimate of Adult Literacy in Medicine (REALM) test. Of the 395 patients, 19% (75) were deemed to have low literacy, reading at or below a 6th-grade level, and 29% (114) had marginal literacy, reading at the 7th- to 8th-grade level.

All patients were asked how they would take the medicine. A "correct" answer was given if they included all aspects of the label instruction, including dosage, timing, and duration. Overall, 47% (185) of patients misunderstood at least one of the instructions. For marginal literacy patients, 51% (201) misunderstood one or more instructions, and for low literacy patients, 63% (249) misunderstood.

The majority—91%, or 359 patients—understood the felodipine instructions, which were, "Take one tablet by mouth once each day." The lowest level of comprehension was for trimethoprim, which had a label instructing to "take one tablet by mouth twice daily for seven days."

Higher literacy patients routinely understood instructions better than those with lower literacy, Dr. Davis said. The adjusted odds ratio of misunderstanding for low literacy was 2.32, and for marginal literacy, 1.94. Most misunderstandings had to do with dosage. For instance, patients commonly believed they should give children a tablespoon instead of a teaspoon of amoxicillin.

Patients who took more medications were also more likely to misunderstand labels, with the adjusted relative risk rising from 2.29 for 1-2 medications to 2.98 for 5 or more medications.

Study limitations included the fact that the authors only examined understanding of the primary label. They did not assess patients' actual compliance or drug-taking behavior, whether medication errors occurred, or if any of the patients had experience with any of the five medications.

In an editorial accompanying Dr. Davis' study (Ann. Intern. Med. 2006;145:926-8), Dr. Dean Schillinger wrote that the authors did not fully prove out their conclusion that low literacy is correlated with poor comprehension because they did not "account for patients' cognitive function or visual acuity—each of which can impair reading comprehension and could explain poor understanding of labels."

But, he added, that "does not weaken the conclusion that many patients do not comprehend prescription labels and cannot act on their instructions."

In fact, misunderstanding among patients at a typical internal medicine practice might be higher because patients are likely to be older, take more medications and have less English proficiency than those in the study, said Dr. Schillinger, of the University of California, San Francisco.

He said the study should prod physicians to routinely ask patients if they understand what medications they have been prescribed and how to correctly take them. ■

POLICY & PRACTICE

Off-Label Use of Atypicals

Evidence is limited in many cases to support the off-label use of atypical antipsychotics, according to an analysis from the Agency for Healthcare Research and Quality (AHRQ). However, these drugs may pose an increased risk of adverse events, such as stroke, tremors, and weight gain, the report said. Currently, atypical antipsychotics are approved only for use in treating schizophrenia and bipolar disorder. The AHRQ report examines the evidence for the off-label use of aripiprazole, olanzapine, quetiapine, risperidone, and ziprasidone in treating dementia and severe geriatric agitation, depression, obsessive-compulsive disorder, posttraumatic stress disorder, and personality disorders. Researchers found, for example, that the strength of evidence for using atypical antipsychotics in treating personality disorders was considered very low because of small effects, small study sizes, and limitations in trial quality. "Caution is necessary in the off-label use of atypical antipsychotics, especially when used in the elderly and when the evidence for effectiveness is not good," Dr. Carolyn M. Clancy, AHRQ director, said in a statement.

More States Pass Parity Laws

New York and Ohio recently became the latest two states to enact mental health parity laws. Forty-two states now have enacted some form of mental health parity law, according to the National Alliance on Mental Illness. At the end of last year, former New York Gov. George E. Pataki (R) signed Timothy's Law, which requires insurance companies to provide coverage for individuals with mental illness that is comparable with the policies for other medical care. The law also sets additional requirements, including coverage of at least 30 days of active inpatient care in a calendar year. In Ohio, insurers who offer basic health care services also must offer diagnostic and treatment services for biologically based mental illnesses. However, insurers do not have to provide this coverage if they can prove that it independently caused their expenses to increase by more than 1% per year. Former Ohio Gov. Bob Taft (R) signed this legislation into law at the end of 2006.

Alcohol, Drug Screening Coverage

Physicians may have an easier time getting paid for screening and treating patients for alcohol and drug abuse thanks to a new Medicaid coverage policy. Starting Jan. 1, officials at the Centers for Medicare and Medicaid Services have added two new codes to the Healthcare Service Procedures Coding System (HCPCS) Level II coding system—one for use for alcohol and drug screening (H0049) and another for brief intervention (H0050). "Fewer than 10% of adults with alcohol and drug disorders are identified and treated," said Eric Goplerud, Ph.D., project director of the alcohol treatment program at George Washington University, Washington. "The new codes will encourage doctors to address alcohol and drug problems, leading to a reduction in the tremendous social and medical costs associated with addiction."

Lilly Reaches Zyprexa Settlement

The drugmaker Eli Lilly & Co. has agreed to pay up to $500 million to settle approximately 18,000 claims related to its atypical antipsychotic Zyprexa (olanzapine). Most of the claims stated that, before September 2003, the Zyprexa package insert did not adequately display the risk of hyperglycemia and diabetes. In September 2003, the Food and Drug Administration required a label change for all atypical antipsychotics that added information about a relationship between diabetes and this type of medication. Zyprexa has been approved for the treatment of schizophrenia and bipolar disorder. "While we remain confident that these claims are without merit, we took this difficult step because we believe it is in the best interest of the company, the patients who depend on this medication, and their physicians," Sidney Taurel, CEO of Eli Lilly, said in a statement. The settlement also means that any claims in which physicians are named as codefendants will be dismissed, according to Eli Lilly. Approximately 1,200 Zyprexa claims were not included in the settlement.

Rules Slow Medicaid Enrollment

New requirements that Medicaid beneficiaries show proof of citizenship is contributing to decreases in enrollment and backlogs in processing applications in several states, according to a new report from the Kaiser Commission on Medicaid and the Uninsured. Beginning on July 1, 2006, individuals applying for Medicaid or seeking to renew their coverage must present proof of citizenship and identity under a provision of the Deficit Reduction Act of 2005. The law exempts certain groups from the requirement, including children in state foster care systems. In Iowa, state Medicaid officials reported that in the months immediately following implementation of the new documentation requirement, the state experienced the largest drop in Medicaid enrollment in the past 5 years. State officials attributed the decline to the documentation requirements and told researchers that they believed the decline was caused by eligible citizens being unable to produce documentation, not undocumented individuals leaving the program. Similar trends were reported in Louisiana, New Hampshire, Virginia, and Wisconsin. "The requirement appears to be obstructing access to health coverage by eligible U.S. citizens, and could place a considerable burden on working families in particular," the researchers wrote in the report.

—Mary Ellen Schneider