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PROFESSION

Prescription drug containers may get simpler labels

The U.S. Pharmacopeial Convention calls for new standards, including bigger font sizes and more explicit instructions to improve patient comprehension.

By KEVIN B. O'REILLY, *amednews* staff. Posted Jan. 17, 2011.

Nearly half of patients misunderstand dosage instructions on prescription container labels, and more than half do not comprehend the warnings on those labels, according to different studies. For years, medical experts have advocated for simpler labels to help patients take their medications as intended.

Labeling standards proposed in January by the influential U.S. Pharmacopeial Convention could make those recommendations a reality.

USP's proposal says that, when creating prescription labels, pharmacies should:

- Emphasize the most important information at the top, such as the patient's name, drug name, drug strength and instructions.
- Steer clear of Latin terms; use simple, concise language; and make instructions more explicit. For example, labels should say "Take 2 tablets in the morning and in the evening," instead of "Take two tablets twice daily."
- Format labels with a large font size, the equivalent of 12-point Times New Roman or bigger, and use black print on a white background.
- Use normal punctuation, provide enough white space between lines of text and have text run only horizontally on the label.

In addition, the proposed standards say pharmacies should include the medication's purpose, with patient permission, using familiar terms -- "for high blood pressure," not "for hypertension." Labeling should be provided in the patient's preferred language when possible, using high-quality translation tools.

Multiple recommendations

The USP proposal, open for comments through March 31, builds upon recommendations made by the Institute of Medicine in 2006 and the American College of Physicians Foundation in 2007.

Officials at USP said their proposed standards -- developed by a panel including expert doctors and pharmacists as well as representatives from drug database software companies and retail drugstores -- have a good chance of being enacted as regulations by state pharmacy boards. For example, USP standards on pharmaceutical compounding have been adopted at the state level.

New USP recommendations on drug labels call for all information to be in at least 12-point black type.

More aggressive action to improve prescription labeling is overdue, said Albert Wu, MD, MPH, a member of the IOM and ACP Foundation panels.

"It's about time," said Dr. Wu, professor of health policy and management at the Johns Hopkins Bloomberg School of Public Health in Maryland. "The new standards that are proposed make good common sense."

The proposed changes may seem minor, but they would address a big problem, Dr. Wu said.

"Those are two very important square inches," he said, referring to the prescription container label. "The physician can make the right diagnosis, choose the appropriate medication for the patient, get the appropriate prescription dispensed and have it go completely to waste, since the patient doesn't know clearly what to do with it because what is present on the current labels may not be understandable to them."

Dr. Wu has had personal experience with patients' misunderstanding labels. The instruction to "take two tablets twice daily," for example, is a recipe for trouble.

"I've had cases where people take only two pills, or sometimes they take it for two days and then stop," he said.

Current labeling practices

The status quo is unacceptable, said William H. Shrank, MD, a leading researcher on prescription container labeling who served on the USP panel.

"The state of prescription drug labeling is not only poor, it is highly variable," said Dr. Shrank, associate physician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital in Boston. "The largest items on labels are generally the pharmacy name, while warnings are written in a font too small for many elderly patients to read. ... Some of the large chains have attempted to improve their labels. Nonetheless, the variability between pharmacies is unchanged."

The retailer Target, for example, launched its Clear Rx label to much praise from medical experts in 2005. However, a study by Dr. Shrank and his colleagues in the May 24, 2009, issue of *The Journal of General Internal Medicine* found that the label did little to improve medication adherence. They said the finding was unsurprising, because noncompliance can have many causes other than labeling. Dr. Shrank also is collaborating on a randomized clinical trial testing the effect of newly formatted labels on patient comprehension, adherence and health outcomes.

If no substantive changes to the USP proposal are made, a final standard would be published in November 2011 and become official in May 2012, said Shawn C. Becker, director of health care quality standards at USP.

The proposed standards could especially help older patients, who take more medications and have greater difficulty reading small print on prescription container labels, said Joanne Schwartzberg, MD, director of aging and community health at the American Medical Association.

"This is such a significant problem," said Dr. Schwartzberg, who also served on USP's expert panel. "I can't even guess how many lives could be saved by it."

This content was published online only.

ADDITIONAL INFORMATION:

Working around prescription labels

Many patients have trouble understanding the information presented on their prescription labels. To help ensure that patients are taking medications as directed, medical experts said physicians and other health care professionals should:

- Ask patients to bring each of their medications to their next appointment or any appointment after a medication change.
- Have patients read each label and express in their own words what they believe it says about how and when to take the medication and what the drug's purpose is.
- Correct any misunderstandings and have patients or family write out, in the patient's own words, instructions for taking the medicines.
- Use the "teach-back" method when prescribing a new medicine to ensure that patients understand how they are supposed to administer the drug.

WEBLINK

U.S. Pharmacopeial Convention's proposed standard on prescription container labeling, Jan. 3 (www.usp.org/USPNF/notices/generalChapter17.html)

"Can improved prescription medication labeling influence adherence to chronic medications? An evaluation of the Target pharmacy label," *The Journal of General Internal Medicine*, May 24, 2009 (www.ncbi.nlm.nih.gov/pubmed/19247719)

"Improving Prescription Drug Container Labeling in the United States: A Health Literacy and Medication Safety Initiative," American College of Physicians Foundation white paper, Oct. 12, 2007 (www.acpfoundation.org/medlabel/medlabel_acpf.htm)

Preventing Medication Errors, *Institute of Medicine, 2007* (www.nap.edu/catalog.php?record_id=11623)

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