

Panel Recommends Standardizing Prescription Container Labeling

EurekaAlert

Rockville, Md., May 10, 2010 - To promote the establishment of universal standards for prescription medication labels-and to address the widespread problem of patient misinterpretation of medication instructions-an advisory panel formed by the U.S. Pharmacopeial Convention (USP) recently issued a set of recommendations to bring consistency to labeling on dispensed prescription packaging. The recommendations are patient-centered, and were developed following a call for such standards by the Institute of Medicine (IOM) on the issue of health literacy. The recommendations were presented to the IOM Health Literacy Roundtable.

Limited health literacy has been cited as a major problem by IOM, which states that 90 million adults are affected. Those with limited health literacy cannot fully benefit from much that the health and health care system have to offer, according to IOM. One critical component to health literacy is the ability to properly understand medication instructions and important supplemental information (such as drug interactions). Poor health literacy can lead to non-adherence and medication errors, which may pose significant health risks to patients. Medication misuse results in over 1 million adverse drug events per year.

USP, a nonprofit scientific organization that sets legally enforceable standards for the identity, as well as the strength, quality and purity of medicines in the United States, formed a Health Literacy and Prescription Container Labeling Advisory Panel in 2007 to examine ways to improve prescription drug container labeling. USP recently released the panel's recommendations, which cover format, appearance, content and language of prescription labels-all of which contribute to optimal patient understanding, which leads to safe and effective use of medications.

"Patients have the right to understand health information that is necessary to safely care for themselves and their families," said Joanne G. Schwartzberg, M.D., co-chair of the USP Health Literacy and Prescription Container Labeling Advisory Panel. "Confusing medication labels is one area that can be improved considerably. As most of us who have ever received a prescription drug know, the content and appearance of medication labels can vary widely. Sometimes, there is so much information included that it can be difficult to find the most essential information-the directions for use. By standardizing labels of medications so that they provide reliable, simple and concise information, I think we can significantly advance patient health and safety."

The recommendations by the advisory panel include:

- Organize the Prescription Label in a Patient-Centered Manner. Information

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must be organized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container labeling should feature only the most critical patient information needed for safe and effective understanding and use.

- **Simplify Language.** To improve patient understanding and safe and effective prescription medication use, language on the label should be clear, simplified, concise and standardized. Only common terms and sentences should be used. Use of unfamiliar words (including Latin terms) and unclear medical jargon should be avoided. Ambiguous directions such as "take as directed" should be avoided unless clear and unambiguous supplemental instructions and counseling are provided.
- **Use Explicit Text to Describe Dosage/Interval Instructions.** Dosage, usage and administration instructions must clearly separate dose from interval and must provide the explicit frequency of drug administration (e.g., "Take 4 tablets each day. Take 2 tablets in the morning and 2 tablets in the evening" is better than "Take two tablets by mouth twice daily"). Use numeric rather than alphabetic characters for numbers.
- **Include Purpose for Use.** Confidentiality and FDA approval for intended use (e.g., labeled versus off-label use) may limit inclusion of indications on drug product labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms. Therefore, the prescriber's intended purpose of use/indication should be included on the prescription whenever possible and should be stated in clear, simple language (e.g., for high blood pressure, for rash or for stomach cramps).
- **Improve Readability.** Critical information for patients must appear on the prescription label in an uncondensed, simple, familiar, minimum 12-point, sans serif font (e.g., Arial) that is in sentence case (i.e., punctuated like a normal sentence in English: initial capital followed by lower-case letters except for proper nouns, acronyms, etc.). Field size (examples of "fields" include patient name and directions for use) and font size may be increased in the best interest of patient care. Critical information should never be truncated.
- **Provide Labeling in Patient's Preferred Language.** Whenever possible, prescription container labeling should be provided in a patient's preferred language. Translations of labels should be produced using a high-quality translation process.
- **Include Supplemental Information.** Auxiliary information on the prescription container should be minimized and should be limited to evidence-based critical information. The information should be presented in a standardized manner and should be necessary for patient understanding. This is important because of the extensive variability in the content and application of supplemental information, the lack of scientific evidence for these labels, and the potential ambiguity and failure to address specific patient needs.
- **Standardize Directions to Patients.** In recognition of the nation's move toward e-prescribing, standards should be developed for prescribing directions to patients. This would lead to consistency of language and use across all health care professionals and systems. An important element is the elimination of Latin abbreviations, which are often misunderstood and susceptible to variation in translation.

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The USP panel, which is co-chaired by Dr. Schwartzberg and Gerald McEvoy, Pharm.D., is composed of a group of experts in the fields of health literacy, health policy and medication safety. The panel members are: Cynthia Brach; Sandra Leal, Pharm.D., CDE; Linda Lloyd, M.Ed.; Melissa Madigan, Pharm.D., J.D.; Dan Morrow, Ph.D.; Ruth Parker, M.D.; Cynthia Raehl, Pharm.D., FASHP, FCCP; William Shrank, M.D., MSHS; Patricia Sokol, R.N., J.D.; Darren Townzen, R.Ph., MBA; Jeanne Tuttle, R.Ph.; Joan E. Kapusnik-Uner, Pharm.D., FCSHP; Michelle Weist, Pharm.D., BCPS; and Michael Wolf, Ph.D., MPH.

Their recommendations will form the basis for consideration of a new USP general chapter on prescription container labeling, which is being developed by USP's Safe Medication Use Expert Committee. A proposed General Chapter Prescription Container Labeling is expected to be completed within the next few months. USP then will seek input from the public, including consumer and health care organizations, on its content.

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