



**Recommendations to the Safe Medication Use Expert Committee
by the Health Literacy and
Prescription Container Labeling Advisory Panel
May and November 2009**

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Background

Inadequate understanding of prescription medication directions for use and auxiliary information on dispensed containers is widespread among patients and is a major concern affecting safe and effective use. Lack of universal standards and formal oversight for dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and even medication errors. On May 18, 2007 the Safe Medication Use Expert Committee established the Health Literacy and Prescription Container Labeling Advisory Panel (HL AP) to examine ways to improve prescription drug container labeling and, if possible, to recommend ways to standardize this labeling. In December 2008 the HL AP held its first meeting. During 2009 the HL AP wrote a series of recommendations for standards development and requested that USP develop patient-centered label standards for the format, appearance content, and language of prescription medication instructions to promote patient understanding.

The following recommendations for patient-centered prescription label standards are for the format, appearance, content, and language of prescription medication containers to promote patient understanding. These recommendations are evidence-based and address optimal understanding, adherence, and safe and effective use of medications by patients. These recommendations emanated from the May 16, 2009 and November 4, 2009 meetings of the HL AP. Pursuant to these recommendations, the HL AP is developing a proposed General Chapter <17> *Prescription Container Labeling* that will be forwarded into the *Pharmacopeial Forum* public review and comment process. The General Chapter also will be pre-posted on the USP Web site to enable broad public comment.

Recommendations

Organize the Prescription Label in a Patient-centered Manner

Patient-directed information 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.

Patient-directed instructional content will be at the top of the label, and other less critical content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, product description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information can be placed e.g., at the bottom of the label or another less prominent location. Drug name and directions for use (e.g., specific dosage/usage/administration instructions) should be displayed with greatest prominence.

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; see below) and unclear medical jargon should be avoided.

Whenever available and appropriate to the patient context, standardized patient-centered translations of common prescribing directions to patients (SIG) should be used. Ambiguous directions such as “take as directed” should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be stated on the container label.

Readability formulas and software are not recommended for short excerpts of text like that on prescription labels. The principles established by Doak, Doak, and Root for maintaining simple language can facilitate the simplification process.¹ Consumer feedback should also be sought.

Use Explicit Text to Describe Dosage/Interval Instructions

Dosage/usage/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 vs 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 medication label whenever possible and should be stated in clear, simple, patient-centered language. When such use conflicts with unit-of-use commercial packaging information, the patient should receive appropriate counseling to clarify the intended purpose of the medication vs. what is stated in commercial labeling.

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 and font size may be increased in the best interest of patient care. Critical information should never be truncated.

The following several general rules can improve readability:

- Optimize typography
- Optimize white space (use adequate space between lines of text; use wide letter spacing; and use white space to distinguish sections on the label such as directions for use vs pharmacy information)
- Use numeric rather than alpha representation (e.g., for dose information)
- Use horizontal text only
- If possible, minimize need to turn the container in order to read lines of text.

Highlighting, bolding, and other typographical cues should preserve readability (e.g., contrast, light color for highlighting), and should emphasize patient-centric information or information that facilitates patient adherence.

Provide Labeling in Patient’s Preferred Language Whenever possible, prescription container labeling should be provided in a patient’s preferred language. Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process includes the following four elements:

¹ by the Suitability Assessment of Materials by Doak, Doak, and Root

- Initial translation by a trained and competent translator (e.g., a translator with documented proficiency in both English and the other language and knowledge in both languages of terminology and concepts relevant to prescription medication)
- Review of the translation by another trained and competent translator and reconciliation of differences
- Review of the translation by a pharmacist or other medical professional who is a native speaker of the target language and reconciliation of differences
- Testing of comprehension with target audiences.

If a high-quality translation process cannot be provided, labels should be printed in English.

Include Supplemental Information

Auxiliary information on the prescription container should be minimized and should be limited to evidence-based critical information regarding safe. The information should be presented in a standardized manner and should be necessary for patient understanding. This is necessary because of the extensive variability in the content and application of supplemental information, the lack of scientific evidence for these labels, and potential ambiguity and failure to address specific patient needs.

Auxiliary information should be critical to the medicine's safe and appropriate use and should be evidence-based, should clarify instructions for use, and should enhance understanding. Use of icons should be limited to those for which evidence demonstrates enhancement of interpretation and clarity about use. The inclusion of auxiliary information on the patient prescription medication label (e.g., warnings and critical administration alerts) should be minimized and limited to critical information that is evidence based, standardized, and complementary to the patient prescription medication label.

Standardize Directions to Patients

In recognition of the nation's move toward e-prescribing, the HL AP recommends that standards should be developed for prescribing directions to patients (SIGs). 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 (BID, QID, PRN, etc.), which are often misunderstood and susceptible to variation in translation.

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