



# Evidence-Based Approach to Improved Medication Labeling

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The main objectives of the ACP Foundation's Medication Labeling Advisory Committee have been to consolidate the understanding of the problem of inadequate patient medication information and to identify a specific course of action to improve drug labeling in the United States. Medication labeling is an issue of both health literacy and patient safety. Not only are patients having difficulty understanding and acting on health information, the resulting medication errors are burdening U.S. healthcare systems. As a result, an integrated, standardized system is needed to convey prescription drug information to patients. The following are the key findings of the Medication Labeling Advisory Committee regarding an evidence-based approach to improving medication labels.

## Key findings of the Medication Labeling Advisory Committee

Reports show that the lack of universal standards for medication labeling is a root cause for medication error. Patients have trouble navigating the medication labels, which vary by pharmacy and by state. Over half a million adverse drug events occur each year in outpatient settings. In addition, there is a need for evidence-based practices to guide label content and format. Format and content should be



minimized to what is truly needed on the label. Research is needed to determine what information is necessary, how it should be organized, and how can it be as clear as possible to the patient.

As a first step in medication label improvement, the standardization of dosage/usage instructions on the container label is necessary. The involvement of patients, physicians, pharmacists, and pharmacologists is critical in this process, and the process should be guided by evidence. Dosage/usage instructions potentially vary by physician, by pharmacy, and by state and research shows

**Recent IOM Reports**

**Preventing Medication Error** (July 2006)

- Labeling leads to medication errors
- Improve consumer-directed information
- Importance of the provider-patient relationship
- Electronic prescribing as the new environment

**The Future of Drug Safety** (September 2006)

- New advisory committee on communication with patients and consumers (drug safety concerns)
- Improve information dissemination efforts
- Assure FDA role in regulating/disseminating communications

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that patients don't understand dosage/usage instructions as they are currently written.

In addition to medication labeling improvements, communication between patients and healthcare providers must also be enhanced. Providers are missing opportunities to counsel patients on taking

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medications. The 2006 IOM report, *Preventing Medication Error*, finds that the quality of information patients receive from medication labels and from healthcare providers is directly related to the occurrence of medication error. In 2006, the FDA implemented a regulation adding a patient-counseling table to the prescription drug package insert in order to assist physicians with

delivering medication information to patients. This regulation is an excellent first step, but it is necessary to continue to educate providers on how to help patients understand how to take their medicines.

Finally, research support is needed to advance labeling efforts toward an integrated, enhanced approach. Evidence is needed to inform the inclusion of relevant information on medication container labels and to provide explicit guidance to changes in label structure. Lastly, evidence is needed regarding whether medicine label modifications translate to improved patient knowledge and behaviors, and reduction in medication errors and adverse drug events.