Patient counseling practices in U.S. pharmacies: Effects of having pharmacists hand the medication to the patient and state regulations on pharmacist counseling

Carole L. Kimberlin, Allison Newland Jamison, Stephan Linden, and Almut G. Winterstein

Abstract

Objectives: To determine the amount and type of oral counseling given to shoppers posing as new patients with new prescriptions and to determine how state regulations, pharmacy and pharmacist characteristics, and environmental factors affect oral counseling practices.

Design: Cross-sectional, observational, correlational study.

Setting: 41 states and the District of Columbia between January 28 and March 31, 2008.

Participants: 365 community pharmacy staff members had interactions with shopper-patients.

Intervention: Shoppers presented new prescriptions in community pharmacies and recorded observations related to oral communication with pharmacy staff.

Main outcome measures: Oral provision of medication information and risk information to shoppers by pharmacy staff, as well as questions asked of shoppers by pharmacy staff.

Results: Some form of oral communication related to a medication was reported in 68% of encounters. At least one informational item for either medication was provided for approximately 42% of encounters. At least one risk information item was provided in 22% of encounters. Logistic regression findings indicated that the strongest predictor of oral counseling, either providing information or asking questions, was the pharmacist being the pharmacy staff member who handed the medication to the patient, controlling for all other variables in the models. In addition, having strict state regulations specifying that pharmacists must counsel all patients receiving new prescriptions predicted whether patients received counseling. A more private area for prescription pick up also was a significant predictor.

Conclusion: The importance of the direct encounter between the pharmacist and patient and strict state regulations mandating that pharmacists counsel patients with new prescriptions were highlighted by these findings.

Keywords: Patient counseling, pharmacist–patient communication, community pharmacy, medication information.

J Am Pharm Assoc. 2011;51:527–534.
doi: 10.1331/JAPhA.2011.10012

Received February 12, 2010, and in revised form September 24, 2010. Accepted for publication October 18, 2010.

Carole L. Kimberlin, PhD, is Professor; **Allison Newland Jamison** is a student pharmacist; and **Stephan Linden** is a graduate student, Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville. **Almut G. Winterstein, PhD,** is Associate Professor, Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, and Department of Epidemiology and Biostatistics, College of Public Health and Health Professions, University of Florida, Gainesville.

Correspondence: Carole Kimberlin, PhD, College of Pharmacy, University of Florida, PO Box 100496, Gainesville, FL 32610. Fax: 352-273-6270. E-mail: kimber@cop.ufl.edu

Disclosure: The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

Funding: A companion study analyzing consumer medication information was funded by the Food and Drug Administration. Funding for oral counseling research was provided by the Department of Pharmaceutical Outcomes and Policy, University of Florida.

Pharmacy practice regulations have evolved from restricting pharmacists in their provision of medication information to patients[1] to mandating that pharmacists counsel or offer to counsel patients on drug therapy.[2,3] The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) required that states, as a condition of participation in Medicaid, establish requirements that "[t]he pharmacist must offer to discuss with each individual receiving benefits" or the individual's caregiver matters that in the exercise of the pharmacist's professional judgment "are deemed significant."[2,3] State legislatures acted to extend this mandate so that all patients would receive the same level of service.[3] In addition, a number of states enacted regulations requiring that pharmacists personally provide face-to-face counseling on prescribed medications and not simply "offer to discuss" medications with patients.[4] A legal analysis of state pharmacy laws by the National Health Law Program[4] found that, at present, 19 states require pharmacist provision of oral counseling to patients in certain circumstances, typically when new prescriptions are dispensed. These states are identified in Table 1. In 29 states, the only requirement is that an offer to counsel or discuss is proffered. Three states are identified as not having clear legal requirements to counsel or offer to counsel (Table 1).

Despite evidence of the benefits of pharmacist–patient counseling,[5,6] studies have shown wide variability in counseling rates, with ranges from 19% to 74% in studies using direct observations[7–12] to 43% to 69% for reports from shopper studies.[13–16] Comparison among these studies is difficult as a result of different definitions of counseling. Examples of different criteria that meet definitions of counseling include the "offer to discuss,"[7] inclusion of administrative items (e.g., drug price, generic substitution availability, number of refills available),[8] and definitions that are limited to strictly medication-related information items (e.g., name, directions, purpose, adverse effects).[14]

Observer effects may create biased results, especially when the pharmacist must agree to participate in the study beforehand. In past shopper studies, protocols have requested that shoppers, if provided with an offer to discuss, ask to speak with the pharmacist or prompt counseling by asking questions about their new prescriptions.[13–16] This "active patient" approach may not reflect the response of most patients to a perfunctory "offer to discuss." Sleath[11] noted that a difference exists between asking whether a patient has a question and offering a genuine invitation to discuss therapy. Evidence suggests that patients may not perceive a closed-ended question, such as "Do you have any questions?," to be an actual question posed to them by a pharmacist.[17] Patients may be likely to decline the offer to discuss as it is often provided, especially when they are unaware of their needs for additional information. For

At a Glance

Synopsis: Investigators in the current work sent trained shopper-patients to community pharmacies throughout the United States to obtain data on the amount and type of oral counseling given to patients with new prescriptions and to determine how state regulations, pharmacy and pharmacist characteristics, and environmental factors affect oral counseling practices. Oral communication related to a medication was reported in 68% of encounters. At least one medication information item was provided in about 42% of encounters, and at least one risk information item was provided in 22% of encounters. The pharmacist handing the medication to the patient was the strongest predictor of oral counseling. Having strict state regulations specifying that pharmacists must counsel all patients receiving new prescriptions and having a private area for prescription pick up also were significant predictors of counseling provision.

Analysis: *These findings highlight the importance of the direct pharmacist–patient encounter and of state regulations mandating that pharmacists counsel patients orally. Although shoppers receiving prescriptions in states with stricter counseling regulations were more likely to receive information through oral communication, 43% reported that they did not receive medication information from anyone in the pharmacy. The failure of the majority of states to require actual counseling appears to be a significant factor in low counseling rates, as 67% of shoppers reported receiving no oral medication information from pharmacy personnel in states with weaker counseling regulations. Organizational research is needed on factors influencing weak patient counseling regulations being maintained by state boards of pharmacy. Research also is needed to better understand enforcement activities and factors affecting the level of enforcement of stricter counseling regulations.*

Table 1. State pharmacy laws regarding patient counseling[a]

States requiring face-to-face counseling by pharmacists	States requiring offer to counsel only
Alaska, Arizona, Arkansas, California, Delaware, Iowa, Maine, Michigan, Minnesota, Nevada, New York, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Utah, Washington, Wisconsin	Alabama, Colorado, Connecticut, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Virginia, West Virginia, Wyoming

[a]Hawaii and Vermont do not have explicit language requiring counseling or an offer to counsel; Louisiana law states that counseling should be done "when possible and appropriate."
Source: Reference 4.