

SELF-REPORTED CONSUMER MEDICATION TAKING BEHAVIOR IN THE UNITED STATES: EVIDENCE FOR A MEDICATION EDUCATION GAP

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ABSTRACT

BACKGROUND: Effective health communication is essential for safe and effective self-care by consumers and patients. Despite successes on content and format improvements of drug labeling by the Food and Drug Administration, significant gaps remain in medication education by practitioners and self-education by consumers and patients.

OBJECTIVES: Assess consumer-reported use of Retail Drug Monographs (RDMs) provided at the time of dispensing prescription medicines, attitudes and behaviors of Low English Proficiency (LEP) consumers to RDMs printed in their foreign language, and consumer use of the OTC Drug Facts label in relation to allergy alerts, as a means to add to the body of literature characterizing the medication education gap in the U.S.

METHODS: Using standard label comprehension survey techniques, previously unpublished data was analyzed in relation to participants' intent to read and keep RDMs for Rx medicines and the allergy alert in OTC Drug Facts labels, as well as LEP participants' attitudes on access to, use and desire to have RDMs in their native language.

RESULTS: Across all studies, a substantial number of consumers do not read or keep RDMs or the OTC drug allergy alert when using a medicine the first time, and LEP consumers want but are not receiving essential medication education at the time of Rx dispensing.

CONCLUSIONS: Many consumers and patients do not get or use essential medication education placing them at risk for injury. Higher priorities for research and education outreach are needed to enhance behavior changes by consumers, patients and practitioners in order to fill the medication education gap.

Key words: Consumer behavior, medication information, drug labeling.

INTRODUCTION

Key stakeholders in patient and medication safety advocate communication of essential medication information (EMI) so patients and consumers can make better informed decisions about benefits and risks of medication therapy¹. U.S. regulations require prescription drug

labeling to contain EMI derived from “the essential scientific information needed for the safe and effective use of the drug”. This is comprised of indications, dosage, dosage forms and strengths, directions for use, contraindications and other warnings, side effects and drug interactions, among other information². EMI is provided in the Full Prescribing Information (i.e., package insert) for prescription medicines and under State laws in the Retail Drug Monograph (RDM) that must be provided with every dispensed prescription medicine. U.S. nonprescription drug labeling found on immediate containers and outer packaging must also conform to regulations that specify the content and format of EMI, which is termed the OTC Drug Facts Label³.

For more than a score of years, efforts have been underway in the U.S. to make essential information easier to read and more useful to patients and consumers under a key assumption: that patients and consumers will read and act on medication education in order to help them appropriately self-care with medication therapies, including self-selection of nonprescription medicines and decisions about dosage, adherence, and management of emergent side effects^{1,4}. Yet, there is evidence indicating that a significant medication education gap exists, potentially reducing the full benefit that can be achieved with safe and effective self-care with medicines. The gap appears to relate to a communication breakdown in medication education by health professionals, as well as patient and consumer inertia about being active participants in the receipt of EMI⁵⁻¹¹.

In the case of nonprescription medicines, consumers are expected to read the label as an essential step in responsible self-selection and self-care. Nationally representative surveys on self-mediating behaviors of the American public by Harris Interactive for the National Council on Patient Information and Education (NCPPIE) show that a minority of adults report consulting the OTC Drug Facts Label for active ingredients (44%), side effects (20%), or dosage instructions (34%); and 8% percent do not consult the label at all⁵. The implications of this relate potentially to safety concerns, as the study showed a substantial number of consumers report that there are times when they take more than the recommended doses (i.e., 48%, of which 35% report taking their next dose sooner than directed, 32% taking more than what is recommended in labeling, and 18% taking their medications more times during the day than recommended).

For prescription medicines, health professionals are expected to be intermediaries in providing EMI to their patients. Yet this critical communication process appears to be a vulnerable area in relation to EMI. For example, in most U.S. states, community pharmacists are required to counsel patients for first prescriptions, yet Feifer *et al.* showed that 58% of patients did not recall the offer of information⁶. These investigators used telephone outreach for health plan members who had enrolled in a self-care plan for chronic conditions and had a new prescription within the past several weeks. The study showed that among the 31% who received counseling, 39% were not satisfied with the information they received.

It also appears that the requirement for communication of EMI is not being met during physician office visits. For example, Tarn *et al.*, assessed the nature of physician-patient counseling on first-prescribed medication using audio-taped and transcribed office visits for 185 patients seen by 45 family physicians, internists and cardiologists in the medical groups

in Sacramento, California⁷. Of the 243 new medications prescribed for pain, infections, skin conditions, pulmonary conditions and mental health, Tarn *et al.* rated the overall quality of physician communication as poor with, on average, only three of five essential elements (i.e., medication name, purpose, duration of use, adverse effects, dosage and frequency of use) provided for each new prescription. These findings are underscored by a health professional survey commissioned by the NCPIE, in which physicians reported spending “more than a minute” offering special counseling (65%) of which most was spent on: how to take a product (62%); what OTC drug to use (56%); how well the product works (54%); drug interactions (50%); taking more than one OTC drug at a time (49%); cautions prior to or following surgery (43%); and taking more than the recommended dose of an OTC medicine (42%)⁸. Another study on recorded time spent prescribing medicines indicates physicians spend a mean time of about a minute and a half (range 21 seconds to about 4 minutes) discussing the five elements cited above for the study by Tarn *et al.*⁸. Yet much may transpire for a patient during an office visit, including receipt of a fearful diagnosis, uncertain decision making, and sorting through complex medical information. It’s not surprising that studies show 40-80% of medical information provided by healthcare practitioners is forgotten immediately^{8,9}.

Consumer and patient inertia in reading and using medication education on OTC and Rx medicines may relate to a variety of factors, including lack of motivation, a preference for just-in-time medication information (i.e., “I’ll use it when/if I need it”), low health literacy, cognitive problems (e.g., from underlying conditions and/or medications), and low proficiency in English (i.e., LEP, or those whose native language is not English and those who come from an environment where a language other than English is dominant)¹². LEP consumers include 11 million U.S. residents, 27% of whom do not speak English at all, which represents a challenge in disseminating oral and written medication education¹³. Counseling and translation requirements for pharmacies vary by U.S. state, although virtually all require community pharmacists to provide some form of oral counseling and distribution of written materials¹⁴. As of 2010, a few U.S. states require pharmacists to supply translated medication education for LEP patients (e.g., California, requires four languages as part of the AIDS drug program; Texas, requires Spanish and English when generic substitution occurs). This situation is changing with regular availability of foreign language information in pharmacies through legal avenues and voluntary services (e.g., telephone-based translators). However, there is no information to indicate the extent to which this communication of medication education by these services is useful and/or wanted by LEP persons.

On this background, we report results from a series of labeling comprehension studies we conducted over the past several years. We asked U.S. residents to answer questions as to whether they read and keep written information obtained at the time of Rx dispensing and OTC self-selection, and whether LEP consumers receive and want essential medication education in their native language at the time of Rx dispensing.

Our work on the RDM and OTC Drug Facts label represents a unique compilation of data on consumer-reported behavior in relation to essential elements of medication communication.

As noted previously, the RDM represents EMI required to be given to patients at the time of dispensing every prescription medicine, and thereby constitutes a suitable topic for inquiry. We chose the OTC drug allergy alert because it is an essential element of the OTC Drug Facts label, since it lists symptoms that may progress to be life threatening and provides instructions to seek medical help right away based emergent symptoms. Drug Induced Allergies (DIAs) such as Stevens Johnson Syndrome are rare and virtually impossible to prevent, since they are unpredictable, and may occur even after the product has been used before safely. Thus, allergy alerts are a key content element of medication labels and a suitable topic of study to ensure this information is complete, clear and understandable.

MATERIALS AND METHODS

Five labeling comprehension studies have been completed recently by researchers in the UCSF Center for Self Care relating to prescription drug labels on the dispensed bottle and the accompanying RDMs. The methods used in the first two studies assessing prescription bottle labels and RDMs have been published elsewhere¹⁵. The information pertaining to consumer use and retention of the retail drug monograph has been compiled uniquely for this report. In brief, these studies were prospective, hands-on comparisons of packaging and labeling formats by volunteers who were recruited with incentives (\$10 gift card) in 2006 and 2008 at two large Northern California shopping malls. Participants were asked to compare Target Pharmacy's ClearRx bottles and conventional cylindrical prescription bottles labeled as containing fluoxetine, albuterol, amoxicillin, or atenolol. Inclusion criteria were: 18-75 years of age, natural or corrected visual acuity to be able to read black-on-white English language print in 5.5-point type, and fulfillment of informed consent. The two common questions included in the pretested questionnaires in both studies were: 1, before taking a prescription medicine for the first time, do you read all of the drug monograph page?; and 2, after you start taking a prescription medicine, do you keep the drug monograph page handy as a reference? Participants were presented with the RDM and accompanying prescription bottle in a dispensing bag and asked to read the RDM prior to answering the questions. Answers were given on a 5-point Likert scale as never, seldom, half of the time, most of the time, always.

Two other labeling comprehension studies were undertaken in 2008 and 2011 with U.S. residents in the San Francisco Bay area with individuals from local community centers and churches. Chinese and Vietnamese participants who self-reported English as a second language demonstrated their level of proficiency in reading English to a researcher who was proficient in their native language. Test materials were in 8-point type and taken from a commonly read children's book written in their respective native languages. Subjects were allowed to use corrective lenses. If they reported that they could not read a sample English language paragraph taken from such a book (i.e., 6th grade reading level), or if they incorrectly pronounced more than two words in the text and incorrectly translated the meaning of the sentence with which they had difficulty, they were included in the study as low English proficiency participants. In addition they had to demonstrate fluent oral reading skills. This was done by ensuring no

more than one incorrect pronunciation, or if more than one incorrect pronunciation, then a correct unaided description of the meaning of the text. During the survey, participants also had to correctly find the potassium warning in the RDM for hydrochlorothiazide to demonstrate proficiency in reading and using the RDM in their native language. In this way we were assured that we had enrolled LEP persons in our surveys. Other inclusion criteria were: 18-86 years of age and completed informed consents. Chinese-speaking participants were given an incentive in the form of a donation to the church at which the study was fielded. Vietnamese residents were given a \$10 incentive through their community center. Participants were asked, among other questions relating to content and format utility and preferences (not reported here), whether they had ever received medication education in the form of the required written RDM when getting a prescription medicine at a pharmacy, and whether they wanted that information. These questions were asked after participants were presented with, and asked to read, different formats of a current retail drug monograph for hydrochlorothiazide to demonstrate the usefulness of and their preferences for the labeling (not presented here).

The fifth label comprehension study assessed the attitudes of consumers to the format and content of drug allergy alerts that appear in the U.S. OTC Drug Facts Label. The study was undertaken with volunteers who were 18-75 years of age, were proficient in English, able to read 6-point type with uncorrected vision or with corrective lenses, reported never having had a physician diagnosed drug induced allergy, signed informed consent, and attended a local San Francisco community center. As part of the scenario-based questionnaire, participants were asked several questions relating to whether they read the drug allergy alert prior to use and/or keep the OTC carton for future reference during use.

Survey questionnaires for all studies were developed in an iterative fashion and pretested prior to fielding. Questionnaires and labeling used in the foreign language studies were written in the participants' foreign languages (i.e., Vietnamese or Chinese). All studies were conducted under approved IRB submissions.

While the main outcomes of these studies related to usability and preferences for different content and formats, the questions assessing whether consumers want, use, or retain OTC and Rx drug labeling are reported here. Respondents rated their survey answers using 5-point Likert scales and categorical responses of yes/no/uncertain. Standard statistical approaches were used to analyze Likert responses using confidence intervals for proportions and two sided one sample z-test with Bonferroni adjustment for selected observations.

RESULTS

An overview of the demographics of the consumers in the five label comprehension studies is shown in Table 1. Generally speaking, the majority of the participants were middle-age or older, had obtained a prescription medicine from a U.S. pharmacy in the last 6 months, and either had English as a first language (i.e., in the Prescription Bottle Label and RDM studies and OTC Drug Allergy Study) or had a primary foreign language and LEP (i.e., the Vietnamese and Chinese RDM studies). Most had attained higher levels of education than the general public.

Overall, Asians, Hispanics and African-Americans were over-represented in these studies, which were designed to test labeling in literate populations unrelated to ethnicities or special LEP populations.

Table 1

Demographics of Consumers in the Five Label Comprehension Studies (n=1,346)				
Parameter	Prescription Bottle Label and RDM * Studies	Vietnamese RDM Study	Chinese RDM Study	OTC Drug Allergy Alert Study
Study n	1000	133	100	113
Mean Age (Years)	37 (18-75)	48 (18-86)	56 (29-84)	47
Gender (M/F)	33%/67%	51%/49%	61%/39%	50%/50%
Gender Male	33% (330)	51% (68)	61% (61)	49% (56)
Female	67% (670)	49% (49)	39% (39)	51% (57)
English as a First Language	80% (800)	0% (0)	0% (0)	100% (113)
Had a Rx Filled in Last 6 Months	62% (620)	88% (78)	86% (86)	NA
Education < High School Graduate	39% (390)	12% (11)	26% (26)	1%
>High School	58% (580)	88% (78)	68% (68)	97%
Other (Tech. School)	3% (30)	0% (0)	6% (6)	2%
Ethnicity African American	22% (220)	0% (0)	0% (0)	1%
Asian	23% (230)	100%^	100%^	9%
Caucasian	32% (320)	0% (0)	0% (0)	75%
Hispanic	14% (140)	0% (0)	0% (0)	6%
Other	9% (90)	0% (0)	0% (0)	9%
* RDM = retail drug monograph, which is disseminated with each dispensed prescription at community pharmacies in the United States ^ All participants were Vietnamese ethnicity. ^^ All participants were Chinese ethnicity. NA Not assessed as this was an OTC label comprehension study				

In the prescription bottle label and RDM studies on 1,000 English-speaking consumers (Figure 1), 43% reported never or seldom (27%) reading or being uncertain (16%) they read the RDM before taking a prescription medicine the first time. Almost half reported they never/seldom (37%) or half the time (11%) keep the RDM for reference purposes when taking a prescription medicine the first time. RDMs are supplied by chain and independent pharmacies in fulfilling requirements for providing essential medication education to patients. Figure 1 also summarizes selected findings from one of a series of studies on improving drug allergy alerts for OTC and Rx medicines¹⁶. As part of those surveys, 51% of consumers with no self-reported history of physician-diagnosed drug-induced allergies reported they are not likely to read (40%) or uncertain if they might read (11%) the allergy alert before first using a medicine product the first time, and a higher percentage (80%) reported they would not be likely to keep the carton (70%), or were uncertain (10%) if they would keep the carton, for reference when using the medicine the first time.

Figure 1

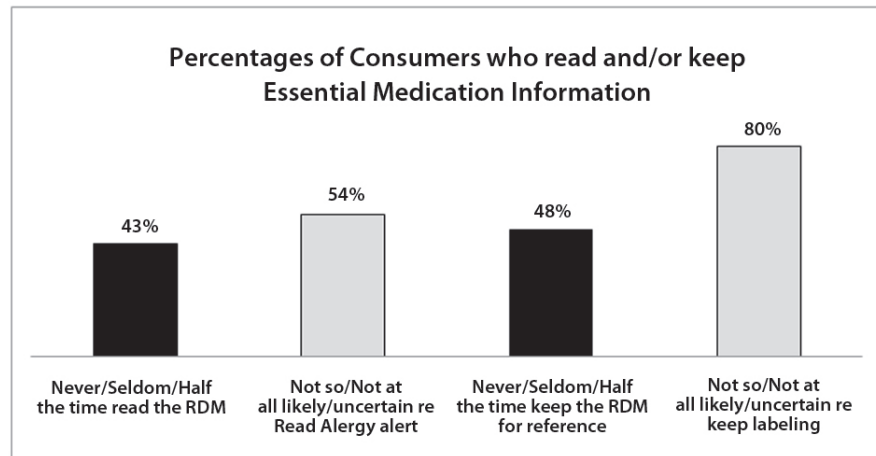


Table 2 shows the pooled results of self-reported medication-taking behaviors of Vietnamese and Chinese LEP consumers from the two label comprehension studies of foreign language RDMs. The individual results from the two studies are comparable within similar confidence limits (not shown). Generally speaking, the large majority of the pooled population had used Western pharmacies for prescription medicines, had used prescription medicines with English only bottle labels and RDMs, and had never gotten or asked for a prescription medicine in their native language, yet both populations considered it important to have RDMs in their native language or wanted a RDM with their next prescription (Vietnamese U.S. residents). Among the Vietnamese surveyed, 80% indicated that they did not ask for medication education in Vietnamese because they either did not think to do so or did not know it was available (not shown).

Table 2

Pooled Self-reported Behaviors Relating to Medication Education of San Francisco Bay Area Vietnamese- and Chinese-speaking Residents [^]				
	Yes	No	Uncertain	P*
Ever used a prescription medicine obtained from a pharmacy (n=228) ^{^^}	86% (197)	9% (20)	4% (11)	<0.001
Had used a prescription medicine with bottle label and RDM in English Only (n=230)	86% (197)	10% (22)	5% (11)	<0.001
Ever gotten a prescription medicine in their native language label (n=231)	22% (50)	70% (162)	8% (19)	<.001
Ever asked for native language RDM (n=230)	20% (43)	77% (170)	3% (7)	<0.001
Is it important to have a RDM in Native Language [^] (n=220)	92% (202)	6% (14)	2% (4)	<0.001
Want RDM in native language with next Rx medicine (n=233)	91% (233)	6% (15)	3% (6)	<0.001
[^] Questionnaires were written in native language (i.e., Vietnamese or Chinese) ^{^^} If less than n=233, then some participants left answer blank * Using a 1-proportion Z-test, p-value = 0.000; Bonferroni Adj: $\alpha = 0.016667$, Holm's Test: $\alpha = 0.05$				

DISCUSSION

The concept that consumers read, understand and use oral and written medication information is fundamental to the U.S. government's mission, the growth of self-care through responsible self-medication, and ultimately the containment of health care costs through better medication safety. However, the results drawn from our five labeling comprehension studies are consistent with published findings on gaps in EMI communications between health professionals and patients and to consumers, and thus add to a concern about the potential magnitude and implications of this gap in the United States and other countries. Our results show substantial numbers of patients and consumers are not reading, or keeping for reference during use, essential medication education provided at community pharmacies in the form of RDMs and OTC medication labels.

However, some caution is warranted in interpreting the results of our studies and related work in the literature. Most of the studies on this topic are limited in size and omit certain key populations (e.g., pregnant and nursing women, caretakers of young children, those with low health literacy, elderly individuals with cognitive difficulties, etc.). Hence it is difficult to derive a general population estimate and/or subpopulation estimates of the true magnitude of a medication education gap in the U.S. Nevertheless, the consistency of the findings across the cited studies in the literature and our results suggests that many people do not read or receive EMI. Incorporating this issue into a large government-based survey as was done by the Centers for Disease Control and Prevention for the National Health and Nutrition Examination Survey (NHANES) for consumer use and reading of the food label, would be one approach to further articulate this issue¹⁷.

With our observations about consumer inertia in reading EMI (i.e., as indicated by self-reports of not reading the label) and observations by others relating to consumer risk taking (e.g., knowingly using more than is directed on the label)⁵, we also recommend research into the attitudes, beliefs, and motivational constructs of medication taking behavior across disease types and medication classes. This information could be understood as a basis for social marketing of responsible self care with the aim of creating positive changes in practitioner, patient and consumer attitudes about EMI. In this regard, it seems ironic that one of the messages from our work is: when people have something, they do not always use it (i.e., as in the case of English-speaking participants in our studies reporting they do not read EMI). So too, when people do not have something, they want it, as in the case of our LEP participants who are Chinese and Vietnamese. Understanding determinants of this attitudinal construct is likely to be one of the core issues in identifying ways to overcome the medication education gap in the U.S.

In conclusion, health communication of EMI is an imperfect construction. The building blocks are there, to be certain (i.e. labeling and counseling), but the evidence suggests it is the architects (government and industry) and workers (health professionals) who are not collectively building the bridge to effectively motivate consumers and patients to obtain, read, understand and act on EMI. On a population basis, effective health communication is

indispensable in achieving safe and beneficial self-care, and so should represent a high priority for government agencies and industry.

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