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Patient Education and Counseling 72 (2008) 443–449

Patient Education and Counseling

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Patient-centered approach for improving prescription drug warning labels

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Received 31 January 2008; received in revised form 17 May 2008; accepted 28 May 2008

Abstract

Objective: To use a patient-centered approach to refine warning labels promoting the safe use of prescription drugs among patients, regardless of literacy level.

Methods: Ten discussion groups were conducted among adults recruited from a general internal medicine clinic and four adult education classes. Participants completed face-to-face cognitive interviews with literacy assessment to determine comprehension of the 10 most commonly used drug warning labels, followed by a discussion group that solicited feedback for revising text and icons.

Results: In all, 85 adults participated; 56% had limited literacy skills. Feedback from discussion groups indicated that the majority of icons were confusing, used difficult language, and text and icons were often discordant. Participants sought actionable language in the most simple and concise manner. In comprehension testing, five of the warning labels reached a set standard of >80% comprehension; the remaining labels were revised and three others modified on patients' request. A universal icon that conveyed 'Caution' was used for one label (''use only on your skin'') as patients were unable to agree on an acceptable visual representation.

Conclusion: A patient-centered approach to designing consumer medication information could improve the comprehensibility of existing warning labels.

Practice implications: Pharmacies should review existing drug warnings to assess adequacy among patients, particularly those with limited literacy. Pharmacists should confirm patients understand auxiliary warnings to support safe and effective use.

Keywords: Prescription; Drug; Medication; Instructions; Warnings; Misunderstanding; Health literacy; Patient-centered

1. Introduction

The 2006 Institute of Medicine Report, *Preventing Medication Errors*, cited poor patient comprehension and subsequent unintentional misuse of prescription drugs as a leading root cause of medication error, poor adherence, and sub-optimal health outcomes [1]. In particular, recent studies have found that approximately half of primary care patients misunderstand common instructions and warnings placed on prescription container labels [2,3]. Individuals with limited literacy are reported to be at greater risk for poor comprehension of drug information. As adults in the United States are on average taking an increasing number of prescription drugs annually, the ability to accurately interpret medication instructions becomes even more critical for ensuring proper and safe use [1,4,5].

It is important to understand how patients learn to take their prescription drugs properly. Primary information sources include physicians and pharmacists, patient information leaflets

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doi:10.1016/j.pec.2008.05.019

or medication guides, and instructions on prescription container labels [6]. Studies indicate that rates of patient medication counseling by physicians and pharmacists are very low [7,8], and a majority of patients do not read the long and often complex information handout [9,10]. While more medication information materials are becoming available, most have not been tested for use among patients with limited literacy [11]. In light of these failures, prescription drug labels placed on the container itself possess greater salience among patients as they may often be the sole, tangible source of special instructions or warnings and are likely to be repeatedly viewed by patients.

Yet problems are clearly evident with container label instructions, especially warning labels (a.k.a. auxiliary instructions). These often appear as stickers placed on the outside of medication bottles and provide important information regarding the safe administration of prescription drugs. Patients, especially the elderly and those with limited literacy, have difficulty interpreting the many icons used on warning labels, and the text is often complex, contradictory, or includes multiple recommended actions that ultimately get ignored [12–14]. However, failure to heed the warnings or special instructions on the labels could potentially lead to a loss of drug potency or change in rate of absorption of the medication. As a consequence, patients may become ill or gain little or no treatment benefit from taking the prescribed drug [15]. For example, many long-acting hypertensive agents should be swallowed whole, as chewing or crushing them would intensify the dose and cause acute hypotension.

The Food and Drug Administration (FDA), along with the American Pharmaceutical Association (APhA), the American Society of Health-System Pharmacists (ASHSP), and the National Association of Boards of Pharmacy (NABP) are directing greater attention to the quality of prescription and over-the-counter drug container labels, as well as accompanying patient educational handouts [11,16–21]. More than a decade ago the Keystone Dialogue was initiated by the Department of Health and Human Services and the above-mentioned organizations to develop an action plan for improving medication labeling [22]. One of the many recommendations made was to directly involve consumers in the development of prescription drug information, including content on drug warning labels and instructions, to gain assurances that content would be properly understood by patients across all literacy levels. To date, little or no progress has been made to improve or standardize warning labels for prescription drug containers [23].

In this study, we sought to refine, and pilot test 'consumer-improved' prescription drug warning labels that are easily understood by a diverse set of individuals, including those with limited literacy. This process investigated problems with existing graphic icons, use of colors, and comprehensibility of accompanying text on 10 of the most common and important drug warning labels currently in use among a large proportion of pharmacy practices in the United States. A diverse sample of community-dwelling adults was used to guide revisions in each of these aspects of the 10 warning labels.

2. Methods

2.1. Participants

Study participants were adult patients who attended an academic general internal medicine clinic or adult students from 1 of 4 adult basic education classes in Chicago, IL. Participants were eligible if they were 18 years or older and fluent in English. Patients from the general internal medicine clinic were recruited by use of flyers placed in the waiting and check out areas of the clinic. The flyers informed interested patients to contact the research assistant (RA) for information and times for discussion groups. Students were recruited through the adult education center and groups took place during the already scheduled basic education class. The institutional review board approved the study.

2.2. Structured interview and literacy assessment

The discussion groups began with a structured cognitive interview in order to assess understanding of prescription warning label instructions. This process has been widely used by the research team, among others [1,2,12]. A trained RA administered the interview to consenting patients that included self-report of sociodemographic information (age, gender, race/ethnicity, education, martial status, and work status), number of daily prescription medications currently taken, and whether their physician or pharmacist talked with them about how to take their medication. In addition, an actual prescription pill bottle container with a prototype enhanced warning label design was shown to each participant in order to get his or her interpretation of the label. Specifically, the warning label's language was simplified and placed in a central location with other labels horizontally on the back of the pill bottle. The participants were then tested on their comprehension of 10 common warning labels by being asked to match up warning messages with the corresponding icons. The RA then administered a brief literacy assessment, ending the interview.

2.2.1. Discussion group

After participants completed the cognitive interview, discussion groups were conducted to solicit feedback around improving existing language and content, and revising icons of 10 of the most commonly used warning labels to fit patient mental models of specified behaviors. The discussion groups lasted approximately 45 min and were led by the PI of the study. Groups were videotaped if permitted by the subjects. In addition, RAs documented the subject responses to the warning labels by recording patient responses at the time of the discussion group. The groups were conducted in three phases. After each phase labels were revised according to feedback and participants in the next phase would review the modified labels and make further suggestions. At the end of the 3rd phase, few additional modifications were suggested.

During the discussion group, each of the 10 messages was individually reviewed. First, participants were shown the pre-existing warning message in text form only and were asked, "If