Improving prescription auxiliary labels to increase patient understanding

Michelle R. Locke, Olayinka O. Shiyanbola, and Elizabeth Gripentrog

Abstract

Objectives: To develop new, easy-to-understand prescription auxiliary labels, assess patient understanding of both new and existing labels, and compare the effectiveness of existing labels with the newly developed ones.

Design: Cross-sectional study.

Setting: Semistructured interviews.

Participants: Convenience sample of adults from minority populations who were currently taking or had previously taken a prescription medication and could understand English.

Intervention: Easy-to-understand prescription auxiliary labels were developed. Both these newly created labels and existing labels were shown to participants. Participants' health literacy levels and understanding of the information provided on the labels were determined. The reading difficulty of the auxiliary labels was determined using a Lexile Score.

Main outcome measures: Interpretation and understanding of prescription auxiliary labels.

Results: The study included 120 participants with a mean age of 40 years (SD = 14). All existing prescription auxiliary labels yielded less than 50% "excellent" interpretations except for those indicating "Take with food" and "Do not chew or crush." The newly designed labels were better understood compared with existing labels. Some existing labels yielded Lexile scores above the sixth-grade reading level. There was an association between higher levels of education ($\chi^2 = 20.86$, $P = 0.02$) or higher REALM-R (Rapid Estimate of Adult Literacy in Medicine, Revised) scores ($\chi^2 = 26.79$, $P = 0.02$) and better interpretation of auxiliary labels.

Conclusion: Simpler auxiliary labels with improved patient comprehension can be developed. Auxiliary label understanding and interpretation is low for commonly used labels. Pharmacies should consider using existing manufacturer auxiliary labels that meet the criteria for patients with low literacy.

Keywords: Prescriptions, auxiliary labels, warning labels, medication safety, health literacy.

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Poor health literacy among adults has become a major cause of medication errors.[1,2] Low literacy levels are correlated with an increased number of hospitalizations and emergency room visits, as well as poor medication adherence and lowered overall health outcomes.[3] With more than two-thirds of adults taking prescription medications at any given time,[3] and a shift in health care's focus from the inpatient setting to the outpatient setting, it is critical that patients fully understand how to properly and safely use their medications.[1,4]

Prescription auxiliary labels are small colored stickers placed on the outside of prescription medication bottles, typically adjacent to the prescription label. These labels provide important information to patients on the safe administration of their medication,[2–3] such as "Take with food" or "Avoid excessive sun exposure."[5] Misunderstanding of auxiliary labels can lead to altered drug potency or absorption issues through incorrect dose administration, mishandling, or improper storage.[5–7]

For decades, warning labels have been designed and used without the incorporation of patient feedback, making them of limited value to patients.[8] Existing warning labels used by pharmacies have been known to confuse patients, rather than help their understanding.[1,3]

The impact of poor health literacy on patient outcomes is an issue that spans all racial/ethnic groups, but it is of particular concern in populations where low literacy levels tend to be more prevalent, including racial and ethnic minorities, older adults, and patients with chronic diseases.[6] In this study, we decided to focus on minority populations in a midwestern state.

At a Glance

Synopsis: In an effort to assess patient comprehension of prescription auxiliary labels, semistructured interviews were conducted with 120 minority adults with low health literacy who were currently taking or had previously taken prescription medication. Researchers compared patient understanding of existing labels with that of newly developed labels featuring simpler, single-step directions and more easily comprehended illustrations. Patients reported improved understanding with the new labels.

Analysis: *The development of simpler prescription auxiliary labels with graphic aids and concise text not exceeding a sixth-grade level can improve patient comprehension and understanding. A standardization of labels using the best evidence-based format can improve medication management for patients receiving prescriptions. Such standardization will allow patients to properly recognize the messages displayed without having to interpret different labels for the same indication.*

Objectives

The objectives of this study were to develop new, easy-to-understand prescription auxiliary labels, assess patient understanding of both new and existing labels, and compare the effectiveness of existing labels with the newly developed labels.

Methods

Design

The design of this study was cross-sectional, with data collected via semistructured interviews.

Sample

Using a convenience sampling approach, participants were recruited from public libraries, community centers, multicultural event forums, and shelter homes in Sioux Falls, SD. Qualifying criteria included being 18 years of age or older; currently taking (or having previously taken) a prescription medication; understanding English; and being from a minority population (defined as race/ethnicity other than non-Hispanic white). Racial/ethnic identification was self-reported by participants.

Participants were given a written informed consent form and asked to read through it before the start of the interview, ask any questions of the researchers before beginning the interview, and initial that they had read the document. Each participant received a copy of the informed consent.

The South Dakota State University Institutional Review Board approved the study.

Label development

Existing prescription auxiliary labels were obtained from four chain community pharmacies. Each pharmacy had the option to submit manufacturer-developed or individualized labels for five separate indications. Each of the five auxiliary label categories included up to six existing labels and one newly developed label. The research team designed the new labels based on previous research that identified confusing wording and imagery as the key barriers to understanding existing prescription auxiliary labels.[3] To make the new labels more comprehensible, the researchers used single-action directions, plain-language text, and explicit pictorial descriptions of the warning message (see Appendix 1, available under Supplemental Content on JAPhA.org).[3]

Several prototypes were developed with the help of an individual with a graphic design background. A discussion of the labels included substantial input from all of the researchers. Feedback on each newly developed label was also obtained from four practicing pharmacists, each with more than 5 years of experience in both the community and hospital pharmacy settings.

The labels were subsequently modified based on the pharmacists' feedback. Since there are no established guidelines for auxiliary labels, none of the new designs