Improving Prescription Auxiliary Labels to Increase Patient Understanding

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BACKGROUND

Poor health literacy among Americans has become a major cause of medication errors[1] and is related to increased emergency room visits, poor medication adherence and lowered overall health outcomes.[2] Over 90 million adult Americans have difficulty understanding medication labels.[3] Furthermore, those with low literacy levels are more likely to misinterpret or even ignore auxiliary labels than those with moderate to high literacy levels.[3] Auxiliary labels are often overlooked entirely by patients with low literacy levels because the labels are not easy to read, have simplified messages or pictures. [4] Though various studies advocate for newer and interpretable prescription labels, little to no effort has been made to develop simpler labels and/or test them among a population.

OBJECTIVES

1. Develop new, easy to understand prescription auxiliary labels.
2. Compare the effectiveness of existing auxiliary labels to newly created ones to determine which label most clearly states its' purpose (and determine why).
3. Compare the effectiveness of existing auxiliary labels to newly created ones by determining the relationship between ease of reading auxiliary labels and corresponding reading level.

METHODS

Adults from a minority background, who were able to understand English, were currently taking (or have taken in the past) a prescription medication, and did not have any hearing or vision loss, were the sample population. Existing (Label 1-5) and newly created auxiliary labels (Label 7) were shown to participants in a 10-15 minute interview and interpretations, level of understanding and health literacy levels (using the REALM-R) were determined. The level of reading difficulty for all labels was determined using the Lexile Score®, based on sentence length and word frequency. Data analysis included descriptive statistics and chi-square tests for all quantitative data and inductive thematic analysis for all open-ended questions.

Table 1: Prescription Auxiliary Labels and Participants Interpretations (N=120)

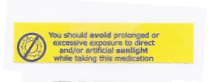
	Interpretations (n,%)			
Labels*	**Excellent**	**Good**	**Poor**	**Incorrect**
Take with food	91, 75.8	23, 19.2	6, 5	Take with hotdog; Medication is hard on liver
Avoid sunlight	37, 30.8	55, 45.8	28, 23.3	Don't take medication when it is hot; Don't leave medicine in sun
Avoid alcohol	47, 39.3	63, 52.5	10 , 8.3	Don't drink anything with medication; Don't overuse
Take plenty of water	47, 39.2	70, 58.3	3, 2.5	Don't put water on medication; Don't take too much water
Do not crush or chew	29, 24.2	74, 61.7	17, 14.2	Don't chew but crush; Dissolve medication in liquid

Table 2: Participants Rankings of Prescription Auxiliary Labels (N=120)

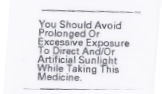
	Label Number (n,%)			
Labels*	**Best represented**	**Worst represented**	**Easiest Understood**	**Hardest Understood**
Take with food	1; 43 (35.8)	5; 71 (59.2)	1; 41 (34.2)	5; 70 (58.3)
Avoid sunlight	7; 61 (51.8)	5; 60 (50)	7; 66 (55)	5; 61 (50.8)
Avoid alcohol	7; 49 (40.8)	5; 67 (55.8)	7; 50 (41.7)	5; 67 (55.8)
Take plenty of water	7; 49 (40.8)	5; 91 (75.8)	7; 50 (41.7)	5; 92 (76.7)
Do not crush or chew	1; 47 (39.2)	5; 81 (67.5)	1; 48 (40)	5; 81 (67.5)

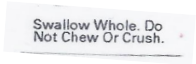
Figure 1: Current Auxiliary Labels and Newly Developed Auxiliary Labels

Label 1:



Label 5:





Label 7:

RESULTS

One hundred and twenty participants completed the study. Most were male, Native American, reported good health and had completed a high school /GED education. Some existing auxiliary labels yielded Lexile® scores above the recommended sixth grade reading level[1] while all the newly developed labels were third grade level and below. All auxiliary labels yielded less than 40% excellent interpretations except for label 'take with food/milk' (Table 1). Newly developed labels (Label 7) were either the best understood, second best understood or had the best representation across the auxiliary labels (Table 2). There was a statistically significant difference in participants interpretation of label 'take with food and milk' based on education completed ($\chi 2$ = 20.857, p=0.02) and health literacy ($\chi 2$ = 26.785, p = 0.02). All other auxiliary labels did not have significant associations with health literacy. Recommendations for improving understanding of auxiliary labels included: larger font, pictures and a colored background.

DISCUSSION/CONCLUSIONS

Incorrect interpretations of auxiliary labels occur across populations, independent of education or health literacy level. Simpler auxiliary labels with improved patient comprehension can be developed. Pharmacies must consider how to include and use existing manufacturer auxiliary labels that meet the acceptable criteria for patients' with low health literacy.

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