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Original Research

Perceptions of prescription warning labels within an underserved population

Olayinka O. SHIYANBOLA, Brittney A. MEYER, Michelle R. LOCKE, Sara WETTERGREEN.

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ABSTRACT[*]

Objective: To understand how underserved populations attend to prescription warning label (PWL) instructions, examine the importance of PWL instructions to participants and describe the challenges associated with interpreting the information on PWLs.

Methods: Adults from an underserved population (racial and ethnic minorities, individuals with low income, older adults) who had a history of prescription medication use and were able to understand English took part in semi-structured interviews. Participants were presented with eight different prescription bottles with an attached PWL. Participants were asked, "If this prescription was yours, what information would you need to know about the medicine?" The number of participants who attended to the warning labels was noted. Other questions assessed the importance of PWLs, the challenges with understanding PWLs, and ways a pharmacist could help participant understanding of the PWL.

Results: There were 103 participants. The mean age was 50.25 years (SD=18.05). Majority attended to the PWL. Participants not currently taking medications and who had limited health literacy were likely to overlook the warning labels. Majority rated the warning instructions to be extremely important (n=86, 83.5 %), wanted the pharmacist to help them understand PWLs by counseling them on the information on the label (n=63, 61.2%), and thought the graphics made the label information easy to understand.

Conclusions: PWLs are an important method of communicating medication information, as long as they are easily comprehensible to patients. In addition to placing PWLs on prescription bottles, health care providers need to counsel underserved populations on medication warnings, especially individuals with limited health literacy who are not currently using a prescription medication.

Keywords: Drug Labeling; Patient Education as Topic; Patient Safety; Vulnerable Populations; Health Literacy; United States

[*] **Olayinka O. SHIYANBOLA**. PhD. (Past Assistant Professor, Department of Pharmacy Practice, South Dakota State University, at the time of the study) Assistant Professor. Division of Social and Administrative Sciences, University of Wisconsin-Madison. Madison, WI (United States). oshiyanbola@pharmacy.wisc.edu

Brittney A. MEYER. Pharm D. Assistant Professor. Department of Pharmacy Practice, South Dakota State University. Brookings, SD (United States). brittney.meyer@sdstate.edu

Michelle R. LOCKE. Pharm D. (Past Pharm D Candidate, South Dakota State University, at the time of the study) Lieutenant, United States Public Health Service, Indian Health Service, Alaska Native Medical Center. Anchorage, AK (United States). mlocke386@gmail.com

Sara WETTERGREEN. BS. College of Pharmacy, South Dakota State University. Brookings, SD (United States). sawettergreen@jacks.sdstate.edu

INTRODUCTION

Poor health literacy, described as a struggle with understanding and acting on health information, has become a major cause of medication errors and a patient safety concern.[1] According to the Institute of Medicine, over ninety million Americans struggle with low health literacy[2], including the understanding and utilization of information found on prescription warning labels.[3,4] This number is likely to continue to rise as we see a growing number of Americans taking prescription medications.[1] With over three billion prescriptions filled by adults annually[5] and a healthcare emphasis on outpatient care versus inpatient care, it is very important for patients to understand how to properly and safely use their medication.[1,6]

Low literacy levels are associated with an increased number of hospitalizations and emergency room visits.[6] In addition, patients with low literacy and individuals taking more medications are at a greater risk for poor adherence, increased adverse effects, and worse health outcomes due to misunderstandings of common prescription warning labels (PWLs).[3,4] Patient confusions with PWLs may lead to incorrect use, reduced drug potency and absorption issues which could decrease the overall effectiveness of a medication.[7,8] Low literacy levels has been identified as a significant independent predictor of incorrect interpretation of warning labels. Patients with limited literacy are three times less likely to correctly interpret a PWL.[4]

Prescription warning labels are small colored stickers placed adjacent to the drug label on a prescription bottle that provides important cautionary information concerning the safe administration of a medicine. For example, "take with food" or "limit time in sunlight when taking this medication". Past studies show that patients often do not pay attention to PWL when interpreting the instructions on their prescription bottle.[3,4] While this problem has been attributed to pharmacists and physicians not emphasizing the importance of the PWL to patients during counseling[3], PWLs are also not easy to read despite their simplified messages or pictures.[4,9] Recently, the United States Pharmacopeial (USP) and National Association of Boards of Pharmacy (NABP) developed universal standards for patient-friendly prescription container labels which are supposed to help improve patient understanding of labels.[10] These standards address the problems of PWLs previously identified in studies and emphasize the use of explicit language and instructions, the appropriate placement of vital prescription instructions, a large font size, high contrast print, and improved typography, as well as

inclusion of the prescribed medication indication on the container label. However, there are currently no standards for PWLs.

Supplementary consumer medication information sheets and guides are given to patients at the time of dispensing. However, these materials are usually not read by the patient.[11] Prescription drug labels are one of the most tangible and frequently used means of educating patients on how to self-administer their medication. Yet, prescription drug labels are presently not designed in the most patient-friendly manner, due to vague instructions and poor patient understanding of directions. This problem is even more troublesome for patients with low health literacy.[12]

In health promotion efforts, increasing patient understanding of health information is essential, especially for members of underserved populations who are likely to have low health literacy levels.[13,14] Members of this vulnerable group include older adults, individuals who are poor or have low income, immigrant and minority populations.[15] Currently, there are insufficient resources that provide underserved populations with relevant information to enable them to make informed decisions about their health, including the appropriate use of medicines.[16] Kreps *et al*. noted that one of the strategies necessary to meet the health literacy needs of the underserved is to increase the effectiveness of health communication interventions and empower consumers with the use of health education efforts.[13]

If underserved populations often have significant health literacy difficulties and experience barriers in accessing and making sense of health information[17,18], it is important to assess how this population understands and interprets PWLs as an important step to ensuring equity in access to patient medication information.[19] This is the first study to examine how underserved populations utilize and interpret prescription warning label information. The objectives of the study were to:

1) Understand how underserved populations attend to prescription warning label instructions.
2) Examine the importance of prescription warning label instructions to participants.
3) Describe the challenges associated with interpreting the information on prescription warning labels.

METHODS

Design

The design of this study was cross-sectional using semi-structured interviews as the method for data collection.

Sample

Using convenience sampling, participants were recruited from a food pantry, a senior citizens center, and a daytime shelter in two mid-western towns. The specific recruitment areas were utilized because of this study definition for being underserved. Qualifying participants had to be (a) 18 years of age or older, (b) currently taking (or have previously taken) a prescription medication, (c) able to understand English, d) without hearing or vision loss and (e) from an underserved population (defined as an older adult, poor, or from a population other than White, non-Hispanic).[15] This study was conducted from April to July 2012 and participants were compensated with a USD10 grocery gift card for their time. This project was approved by the Institutional Review Board of the investigators' university.

The Interview

After participants consented to be included in the study, semi-structured face-to-face interviews that lasted between 15–20 minutes were administered by trained research assistants (RA) and the investigators. A brief questionnaire was used to assess participant self-reported socio-demographic and clinical characteristics including age, gender, highest grade completed, health status and number of prescription medications used.

A health literacy assessment was done using the standardized Newest Vital Sign (NVS).[19] The NVS is a reliable and validated quick screening tool that identifies patients at risk for low health literacy and is based on a nutrition label from an ice cream container. Participants were given the label and then asked six questions about how they would interpret and act on the information contained on the nutrition label.[21] The questions were asked orally and the responses were recorded on a score sheet that contained the correct answers. Based on the number of correct responses, the participants' health literacy level was assessed. Compared to other available health literacy tests, the NVS was used because the questions involve a math skill, a reading and comprehension skill and an abstract reasoning skill.[20] These skills are all important when interpreting a prescription drug label.

During the interview, participants were asked various questions. The study research team developed the interview questions using literature review and the research objectives. The first question asked 'Have you ever seen a prescription warning label?' while providing an example of a warning label. During the next series of questions, the participants were presented with eight different prescription pill bottle containers with the following attached warning labels:

1. You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication
2. Medication should be taken with plenty of water
3. Do not crush or chew, swallow whole
4. Take with food

Four of the prescription bottles had warning labels with graphics and four bottles had identical warning labels without the graphics. Only one warning label was placed on each prescription bottle and no specific order was used to present the different prescription bottles. Preliminary studies have shown that the four labels listed above are some of the most commonly misinterpreted prescription warning labels probably because of their complexity and

vagueness.[3,4] When presented with each of these prescription bottles, participants were asked the following interview questions:

1. If this prescription was yours, what information would you need to know about this medicine?
2. What makes the information on this prescription bottle easy or difficult to interpret?

Other questions included:

1. When picking up your prescription, do you always look at the warning labels?
2. On a scale of 0-5 (0 for not important at all, 5 for very important), how important do you think it is to follow the instructions on the warning label?
3. In what ways can a pharmacist help you understand prescription warning labels?

Except for the scale of importance question that was in a rank order format, each question was open-ended. For the question that examined what information participants needed to know about their medication, participants were not encouraged to notice the warning labels or their instructions. It was expected that this question would serve as a prompt for the participants to thoroughly examine the prescription bottle for all medication information.

Attending to the warning label was conceptualized as physically turning the bottle, inspecting the colored stickers on which the warning messages were placed, and attempting to interpret the warning instruction.[9,12] Participants' attendance to the warning label was noted as a 'yes' if the behavior was noticed by the reviewer, and a 'no' if the

Table 1. Descriptive characteristics of participants (n=103)

Socio-Demographic		Mean (SD)	Number (%)
Age		50.25 (18.5)	
Gender (Male)			59 (57.3)
Race	White non-Hispanic		47 (45.6)
	American Indians		43 (41.7)
	African American		7 (6.8)
	Asian		1 (1)
	Hispanic		1 (1)
	Other		4 (3.9)
Highest Grade Completed	Grades <8		4 (3.9)
	Some high school		12 (11.7)
	High School or GED[a]		45 (43.7)
	Some college/technical		18 (17.5)
	College degree		18 (17.5)
	Graduate degree		6 (5.8)
Self-Reported Overall Health Status	Excellent		21 (20.4)
	Very good		28 (27.2)
	Good		37 (35.9)
	Fair		13 (12.6)
	Poor		4 (3.9)
Marital Status [b]	Single		47 (45.6)
	Married		23 (22.3)
	Separated/Divorced		23 (22.3)
	Widowed		9 (8.7)
Employment Status	Full time		14 (13.6)
	Part time		12 (11.7)
	Unemployed/Laid off/Seeking employment		28 (27.2)
	Unemployed/Laid off/Not seeking employment		6 (5.8)
	Homemaker		2 (1.9)
	Retired		21 (20.4)
	In school		2 (1.9)
	Disabled		12 (11.7)
	Other		6 (5.8)
Insurance Plan	Individual		7 (6.8)
	Employer		6 (5.8)
	Military/Veteran Affairs		5 (4.9)
	Medicaid		18 (17.5)
	Medicare		9 (8.7)
	No Insurance		41 (39.4)
	Individual and Medicare		10 (9.7)
	Medicare and Medicaid		3 (2.9)
	Other		4 (3.9)
Health literacy/NVS Literacy Score	Limited literacy (0-1)		49 (47.6)
	Possible limited literacy (2-3)		25 (24.3)
	Adequate literacy (4-6)		29 (28.2)
Currently on prescription medication	Yes		62 (60.2)
Average number of medications		3.46 (10.24)	
Reported their prescription medications usually have warning labels			75 (72.8)
Number of pharmacies used to fill medications	0		23 (22.3)
	1		51 (49.5)
	2		23 (22.3)
	>3		4 (3.9)

[a]GED=General Equivalency Diploma; [b]Missing data on one subject

warning label was ignored. All responses were recorded by hand on each interview sheet.

Analysis

The health literacy assessment was coded based on the NVS standardized scores and literacy equivalent. Possible scores ranged from 0 to 6 with a score of 0-1 interpreted as a high likelihood (50% or more) of limited literacy, a score of 2-3 interpreted as a possibility of limited literacy, and a score of 4-6 indicated as adequate literacy.[21] Participants' attendance to the labels was coded as either 'Yes' or 'No'. A thematic analysis of the open-ended interview responses identified common themes regarding the challenges and strategies needed to understand and utilize the information on a PWL. Each researcher coded the interview responses separately. Any discrepancies between all coded themes were discussed among all researchers prior to final coding and a concluding determination was reached. Interview responses (qualitative data) were further coded into quantitative data by creating variables using the most common responses. This helped to simplify the data, provide ease of interpretation of participant response and analyze the data quantitatively.

All data from the questionnaire were entered into an excel spreadsheet. Data were then transferred into another spreadsheet constructed in an SPSS database. SPSS 19.0 was used for all data coding and analysis (SPSS Inc., Chicago, IL). All data was cleaned by constructing frequency tables to check for irregularities in the responses. Descriptive statistics determined the percentages and mean of participant characteristics. Chi-square tests were used to examine the association between participants' socio-demographic and clinical characteristics and the attendance to the PWL, as well as an association between participant characteristics and their perception of the importance of the instruction on the PWL. Using logistic regression, the predictors of attentiveness to PWL was examined. Health literacy, race, age, gender and number of medications were included as predictor variables.

RESULTS

One hundred and three participants completed the study. The mean age of participants was 50.25 years (SD=18.05). The majority of participants were white males who had a high school degree as the highest grade completed, had a good overall health status, and had no health insurance. Most of the participants were currently taking a prescription medication and took an average of 3.46 (SD=10.24) medications (Table 1). Most participants had limited health literacy with a mean NVS score of 2.21 (SD=1.94) on a scale of zero to six.

The majority of participants attended to the prescription warning label information on the prescription bottle regardless of whether the PWL had a graphic or not (Table 2). Twenty eight participants (27.2%) did not attend to the instructions or notice the warning labels when they examined the prescription bottles. The label "You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication" without graphics had the highest number of participants (n=43, 41.7%) who did not notice and/or attempt to interpret the warning label instruction. In addition, thematic analysis showed that the most common challenge participants experienced with the warning labels was with the same "Avoid sunlight" label.

Table 2. Percentage of participants who attended to the prescription warning label instruction based on label type (n=103)

Label Type [a]	Number (%)
No Graphics	
Take with water	71 (69.6)
Do not crush	69 (67.6)
Take with food	66 (64.1)
Avoid Sunlight	59 (57.8)
Graphics	
Do not crush	76 (75.2)
Take with food	75 (73.5)
Take with water	75 (73.5)
Avoid Sunlight	64 (62.7)

a= Full label text condensed

Regardless of whether the label had a graphic or not, there were no statistically significant relationships between age, race, highest grade completed, overall health status, health insurance, or whether they attended to the warning label and its instruction (Table 3). Among all the labels, participants with limited health literacy were likely to overlook the warning labels compared to those with adequate health literacy. In addition, males were more likely to overlook the warning labels compared to females (Table 3). For all labels except the graphic "Take with food" label and the graphic "Do not crush, swallow whole" label, participants not currently taking prescription medications were more likely to overlook the warning label compared to individuals currently taking medications (Table 3). Most participants thought the graphics on the label were helpful in their interpretation of the instructions. Compared to other race or ethnic groups, American Indians were more likely to indicate that having a label with graphics was helpful (chi-square=28.43, p=0.019). Most participants (n=75, 72.8%) stated that they looked at their warning labels when picking up their prescription from the pharmacy and rated the instructions on the label to be extremely important (n=86, 83.5%) (Table 4).

There were no statistically significant relationships between participants' perception of the importance of prescription warning labels with health literacy, highest grade completed, gender, overall health status, age, race or if they were currently on prescription medications (results not reported). However, individuals who reported they had no insurance were more likely to rate prescription warning labels as extremely important compared to individuals of other insurance groups (chi-square=57.61, p=0.04).

Most participants thought the pharmacist could help them in understanding prescription warning labels by counseling them on the information on the label (n=63, 61.2%) (Table 5).

Table 3. Association of participants' characteristics and attendance to the prescription warning label (n=103)

Label Type [a]	Participant Characteristic	Chi-square value	P value
No Graphics			
Take with food	Health literacy level (Individuals with limited literacy more likely to ignore)	11.93	0.003[b]
	Gender (Males more likely to ignore than females)	3.98	0.062
	Currently not taking prescription medication (likely to ignore than those currently taking medications)	5.78	0.021[b]
	Highest grade completed	0.57	0.989
	Overall health status	2.75	0.601
	Health Insurance Plan	4.35	0.824
	Age	2.73	0.256
	Race	3.72	0.591
Avoid Sunlight	Health literacy level (Individuals with limited literacy more likely to ignore)	8.16	0.017[b]
	Gender (Males more likely to ignore than females)	7.03	0.009[b]
	Currently not taking prescription medication (likely to ignore than those currently taking medications)	4.67	0.041[b]
	Highest grade completed	1.51	0.912
	Overall health status	5.03	0.284
	Health Insurance Plan	4.49	0.81
	Age	2.91	0.234
	Race	2.07	0.839
Take with water	Health literacy level (Individuals with limited literacy more likely to ignore)	16.68	0.00[b]
	Gender (Males more likely to ignore than females)	5.45	0.029[b]
	Currently not taking prescription medication (likely to ignore than those currently taking medications)	8.05	0.005[b]
	Highest grade completed	4.32	0.504
	Overall health status	5.08	0.28
	Health Insurance Plan	3.77	0.877
	Age	4.15	0.125
	Race	3.19	0.67
Do not crush	Health literacy level (Individuals with limited literacy more likely to ignore)	10.08	0.006[b]
	Gender (Males more likely to ignore than females)	9.56	0.003[b]
	Currently not taking prescription medication (likely to ignore than those currently taking medications)	5.16	0.031[b]
	Highest grade completed	1.92	0.86
	Overall health status	4.36	0.36
	Health Insurance Plan	6.67	0.57
	Age	4.75	0.093
	Race	3.44	0.63

a= Full label text condensed; b= p<0.05

Being male was associated with less attentiveness to the PWLs (OR=0.17, 95%CI=0.033-0.878, p=0.03). All other variables were not statistically significant (Table 6).

DISCUSSION

Most of the participants in this study paid attention to the prescription warning labels and their instructions when they examined the prescription bottles. This is contrary to previous studies that showed most patients ignored and did not pay attention to the warning label when asked to interpret the use of a prescription medication.[3,4] These previous studies utilized a similar method of assessing attentiveness to warning labels. However, the participants in this present study may have attended to the labels more frequently than previous studies because they were asked if they had seen a prescription warning label as an initial question during the interview. This question may have prompted them to pay specific attention to the warning label. The researchers in this study felt it was important to ask this question as they recognized that previous observations of PWLs may improve the patient's attentiveness to the label. Some participants who had previously used prescription medications still did not attend to the PWLs, demonstrating the need for education and counseling efforts for patients who may be receiving a new prescription and may need a reminder prompt for medication warnings and instructions.

When participants examined the prescription bottles, males overlooked the warning label instruction more often than females, and these differences were statistically significant. Also, the regression analysis showed that being male was related to less attentiveness to the PWL. This is similar to a study by Wolf *et al*., which showed the male gender as a significant predictor of poor attendance to warning messages.[9] In addition, women are more likely to utilize health care services than men, have a greater likelihood of reporting symptoms and illness, and have a greater probability of seeking help for prevention and illness.[22] Their affinity for seeking health information might be related to their attendance to medication information.

Participants who were not currently taking medications were less likely to mention the PWL as useful information for them to know about their medication, compared to those currently taking medication. Previous studies have shown a relationship between taking a greater number of medications and misunderstanding label instructions, probably because of the confusion

Table 3 (cont.). Association of participants' characteristics and attendance to the prescription warning label (n=103)

Label Type [a]	Participant Characteristic	Chi-square value	P value
Graphics			
Take with food	Health literacy level (Individuals with limited literacy more likely to ignore)	13.92	0.001 [b]
	Gender (Males more likely to ignore than females)	6.55	0.013 [b]
	Currently not taking prescription medication	3.11	0.109
	Highest grade completed	4.29	0.508
	Overall health status	0.31	0.989
	Health Insurance Plan	6.81	0.558
	Age	1.32	0.516
	Race	4.09	0.536
Avoid Sunlight	Health literacy level (Individuals with limited literacy more likely to ignore)	19.02	0.00 [b]
	Gender (Males more likely to ignore than females)	6.98	0.013 [b]
	Currently not taking prescription medication (likely to ignore than those currently taking medications)	4.85	0.037 [b]
	Highest grade completed	4.95	0.422
	Overall health status	2.28	0.684
	Health Insurance Plan	3.12	0.927
	Age	1.74	0.418
	Race	5.09	0.405
Take with water	Health literacy level (Individuals with limited literacy more likely to ignore)	14.48	0.001 [b]
	Gender (Males more likely to ignore than females)	6.55	0.013 [b]
	Currently not taking prescription medication (likely to ignore than those currently taking medications)	7.18	0.011 [b]
	Highest grade completed	3.79	0.58
	Overall health status	3.27	0.51
	Health Insurance Plan	4.77	0.78
	Age	1.89	0.389
	Race	3.18	0.672
Do not crush	Health literacy level (Individuals with limited literacy more likely to ignore)	6.18	0.045
	Gender (Males more likely to ignore than females)	7.50	0.01 [b]
	Currently not taking prescription medication	0.29	0.645
	Highest grade completed	2.39	0.79
	Overall health status	0.37	0.99
	Health Insurance Plan	9.96	0.268
	Age	1.87	0.392
	Race	6.46	0.264

a= Full label text condensed; b= p<0.05

associated with managing multiple medication instructions.[3,4] Patients who are currently taking medications may be familiar with monitoring the adverse effects from their medication. Hence, they may pay particular attention to all possible information about their prescriptions. It is also possible that patients are distracted by the considerable amount of content placed on a prescription bottle with limited space; therefore, leaving no room for focus on the important warnings.[12] This problem may be enhanced in patients who are not currently taking prescription medications since they may have forgotten and/or unfamiliar with the different parts of a label.

Regardless of whether the PWL had graphics or not, participants with limited health literacy still did not pay attention to the warning label information compared to those with adequate health literacy. Wolf et al showed that patients with low literacy skills do not attend to drug warnings regardless of whether the labels are enhanced with simplified texts and graphical icons.[23] In fact, Wolf et al suggested that including graphics to support the understanding of warning labels among the elderly and patients with limited health literacy would not provide assistance to the individual and may even impair their comprehension of the information.[23] The finding from Wolf's study was based on the development and assessment of a 'patient centered label' that graphically depicted the medication dose and the time period a medicine should be taken. It is possible that patients with low health literacy view PWLs as important but find the medication information overwhelming or incomprehensible, increasing the likelihood that they will not pay attention to them. Though it is important to utilize patient warning labels that are clear, concise and easy to understand, simply placing graphics on the labels may be insufficient for enhancing patients' understanding of a warning label itself.[23] Patient counseling is necessary as an additional step for communicating prescription drug warnings, especially for patients with limited health literacy.

Sixty two (60.2%) of the participants in this study thought the graphic on the label was helpful in interpreting the information on the PWL. In a recent article, the USP and NABP released new standards for patient-friendly container labels.[10] These universal standards address legibility by emphasizing a high-contrast print and a large font size for important information. Concerning the usefulness of the graphics on the label, previous study also found similar results among a minority population (results not reported here).[24] In this present study, American Indians were more likely to report labels with graphics as helpful compared to individuals from other races. The use of storytelling in communicating health information has been widely used among this population and may therefore be reflected in their preference for

Table 4. Participants' views of prescription warning labels and their characteristics (N=103)	
Characteristic of Prescription Warning Label	Number (%)
Graphic on label	
Helpful	62 (60.2)
Confusing	20 (19.4)
Indifferent	15 (14.6)
Unsure	6 (5.8)
What makes the label easy to understand?	
The label is hard to understand	21 (20.4)
Large print of prescription label	19 (18.4)
Colored pictures	18 (17.5)
Clear directions	11 (10.7)
Nothing	10 (9.6)
Both the large print and colored picture	7 (6.8)
The picture	7 (6.8)
Other	7 (6.8)
What makes the label hard to understand?	
The label was easy to understand	55 (53.4)
Small font/print	17 (16.5)
Complex wording	7 (6.8)
Vertical placement on the bottle	6 (5.8)
Small picture	7 (6.8)
Both the vertical placement and small print	3 (2.9)
Other	8 (7.8)
Participant looks at label when picking up their prescription at the pharmacy	75 (72.8)
Perception of the importance of following the prescription drug warning label instructions	
Extremely Important	86 (84.3)
Very Important	8 (7.8)
Moderately Important	5 (4.9)
Somewhat Important	1 (1)
Not at all important	2 (2)

graphics on the PWLs presented to them.[25] Contrarily, Wolf et al. reported that using pictorial icons to support the understanding of warning labels among the elderly and those with low health literacy (an underserved population) would give no added benefit and may even distort their ability to understand the information.[23] Future studies need to examine if the use of graphics on warning labels may harm or benefit specific patient populations.

Some of the challenges related to interpreting PWL were small fonts and pictures, complex wording and the vertical placement of the PWL on the bottle. While the new USP and NABP recommendations addresses some of these challenges, it is also important to consider using appropriate simple language that patients can understand and convey the same warning message of the PWL. In addition, horizontal placement of the PWL on the prescription bottle might make the label more visible. Hence, patients might be likely to attend to the warning instruction.

Eighty six (84.3%) of the underserved population in this study stated they believe it is extremely important to follow the instructions on warning labels. Prescription warning labels may still be a valid method of communicating medication information, as long as they are clear and easily comprehensible to patients; however, proper counseling is needed to point out the information on the warning label for those populations who may not regard them. In fact, it has been noted that prescription labels offer a benefit over other methods of preventing adverse drug events because they are affordable, remain with the package for the longest time and are readily accessible to the patient when needed.[26,27]

Individuals who had no insurance were more likely to rate following PWL instructions as extremely important compared to individuals of other insurance groups. It is not clear why these differences occur. However, it is possible that the latter groups who have their medication paid by a third party payer are accustomed to having their prescriptions filled frequently and may therefore regard the warning label information on the prescription bottle as less serious. They may also have increased exposure to health care professionals who provide necessary drug information repeatedly, making the warning label information redundant and regarded less importantly.

Sixty three (61.2%) of the participants in this study thought the pharmacist could help them in understanding PWLs by counseling them on the label information. It is known that physicians (at the point of prescribing) and pharmacists (at the point of dispensing a prescription) do not routinely review medication instructions or verbally counsel patients.[28,29] Simple and clear communication on the safe use of medication is an important step in reducing preventable adverse events and improving medication management. Patient-provider discussions that allow concise and appropriate description and demonstration of medication information should be done.[2]

Table 5. Ways a pharmacist can help participants understand prescription warning labels (n=103).	
Suggestion	Number (%)
Pharmacist counseling	63 (61.2)
Other	10 (9.7)
Nothing will be helpful	8 (7.8)
Drug information sheet	7 (6.8)
Counseling with information sheet	7 (6.8)
Pharmacists are already doing well	6 (5.8)

Table 6. Logistic regression (odds ratio and 95% confidence interval) analysis of predictors of attentiveness to prescription warning labels (n=97).

Variable	Odd ratios (95% CI)
Age	
18-29	1.0
30-64	0.42 (0.01-13.14)
≥ 65	0.67 (0.09-5.22)
Gender †	
Female	1.0
Male	0.17 (0.03-0.88)
Racial background	
White, not Hispanic	1.0
American Indian	1.05 (0.12-9.18)
Other	0.48 (0.07-3.33)
Health literacy	
Limited literacy	1.0
Possible limited literacy	0.25 (0.04-1.57)
Adequate literacy	2.67 (0.16-45.95)
Number of medications	0.98 (0.93-1.04)

a. Original data n=103. n=6 respondents who had missing data from all other variables and were excluded from analysis.
b. Pseudo-R^2 statistics=0.304; chi-square=12.11, df= 8, p>0.05 (Hosmer and Lemeshow test)
† Statistically significant at p<0.05

This study had limitations. The generalizability of the results of the study is limited by the small sample size, convenience sample, racial make-up of the participants, and the use of a limited number of sites. Also, participants' interpretation of the warning labels was not analyzed as correct or incorrect. Although patients may recognize that a label is important, the benefit of utilizing the label is not seen unless the patient is also able to correctly interpret the label and respond appropriately. The prescription bottles were not given in a certain order each time, so the effect of attending to the label on one bottle to prompt the patient to notice the label on subsequent bottles could not be evaluated. A patient's motivation and attendance to prescription label information may differ if they were reporting on the medication prescribed by their health provider or a prescription that belonged to their children as compared to the prescriptions in this study. The participants in this study may have attended to the labels more frequently than previous studies because they were asked if they had seen a prescription warning label as an initial question during the interview. Inter-rater reliability was not assessed in this study but consensus was reached after discussions among the interviewers.

CONCLUSIONS

This study fills a vital knowledge gap in the literature on how underserved populations attend to PWL information and the importance of the information presented in a warning label. The study findings show that though PWLs are an important means of communicating medication information, they should be used as an educational resource in addition to counseling patients, and should be easily comprehensible to patients.

In this study, some participants overlooked their prescription warning labels when they communicated to the researcher on how they would take the prescription medicine presented to them. In addition to placing warning labels on prescription bottles, considerable efforts need to be made by health care providers to counsel patients on their medications and point out pertinent medication warnings and precautions, especially among men with limited health literacy. Educational strategies that address the importance of a warning label on prescription bottles and the ways of utilizing the health information should be developed for these patients including those who may be currently receiving a new prescription. This is particularly important since physicians often fail to inform patients receiving a new medication of the vital elements related to the use of their medications. This error may contribute to potential misunderstandings of medication use directions.[29] Future research should continue to evaluate optimal ways of educating various populations about safe and effective use of prescription medications.

CONFLICT OF INTEREST

The authors have no conflict of interest.

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PERCEPCIÓN DE LAS ETIQUETAS DE ADVERTENCIAS DE LOS MEDICAMENTOS EN UNA POBLACIÓN MARGINADA

RESUMEN

Objetivo: Entender si las poblaciones marginadas prestan atención a indicaciones de las etiquetas de advertencia de los medicamentos (PWL), examinar la importancia de las indicaciones de las PWL para los participantes y describir los riesgos asociados a la interpretación de la información de las PWL.

Métodos: Adultos de una población marginada (minorías raciales y étnicas, individuos de ingresos bajos, y ancianos) que tenían histórico de uso de medicamentos y eran capaces de entender inglés, tomaron parte en unas entrevistas semi-estructuradas. Se presentó a los participantes 8 frascos de medicamentos con un PWL anexado. Se preguntó a los participantes: "Si este medicamento fuese suyo, ¿qué información necesitarías conocer sobre el medicamento?" Se registró el número de participantes que obedecía las etiquetas de advertencia. Otras preguntas evaluaban la importancia de las PWL, los riesgos de entender las PWL, y los modos en que un farmacéutico podría ayudar al participante a entender las PWL.

Resultados: Hubo 103 participantes. La media de edad fuie de 50,25 años (DE=18,05). La mayoría obedeció las PWL. Los participantes que no usaban actualmente medicamentos y que tenían una literacía en salud más limitada tenían mayor probabilidad de saltarse las etiquetas de advertencia. La mayoría consideró que las instrucciones de avisos era extremamente importantes (n=86; 83,5%), quería que el farmacéutico le ayudase a entender las PWL aconsejándoles sobre las etiquetas de advertencias /n=63; 61,2%) y pensaba que los dibujos hacían que la información de la etiqueta fuese más fácil de entender.

Conclusiones: Las PWL son un método importante de comunicar información médica, ya que son fáciles de

comprender por los pacientes. Además de colocar las PWL sobre los frascos de medicamentos, los profesionales de la salud deben aconsejar a las poblaciones marginadas sobre las etiquetas de advertencia, especialmente a los individuos con literacía en salud limitada y que no toman actualmente medicamentos.

Palabras clave: Etiquetado de Medicamentos; Educación del Paciente como Tema; Seguridad del Paciente; Poblaciones Vulnerables; Literacía en salud; Estados Unidos

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