Perceptions of prescription warning labels within an underserved population

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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

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. According to the Institute of Medicine, over ninety million Americans struggle with low health literacy, including the understanding and utilization of information found on prescription warning labels. This number is likely to continue to rise as we see a growing number of Americans taking prescription medications. With over three billion prescriptions filled by adults annually 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.

Low literacy levels are associated with an increased number of hospitalizations and emergency room visits. 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). Patient confusions with PWLs may lead to incorrect use, reduced drug potency and absorption issues which could decrease the overall effectiveness of a medication. 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.

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. While this problem has been attributed to pharmacists and physicians not emphasizing the importance of the PWL to patients during counseling, PWLs are also not easy to read despite their simplified messages or pictures. Recently, the United States Pharmacopoeial (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. 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. 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.

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. Members of this vulnerable group include older adults, individuals who are poor or have low income, immigrant and minority populations. 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. 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.

If underserved populations often have significant health literacy difficulties and experience barriers in accessing and making sense of health information, 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. 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). 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). 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. 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. 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) |
|-----------------------------------------------|---------|--------|
|                                     | Mean (SD) | Number (%) |
| **Socio-Demographic**                  |          |          |
| **Age**                                 | 50.25 (18.5) | 59 (57.3) |
| **Gender**                              |          |          |
| Male                                    | 59 (57.3) | 47 (45.6) |
| Female                                  | 44 (42.7) | 43 (41.7) |
| **Race**                                |          |          |
| White non-Hispanic                      | 47 (45.6) | 47 (45.6) |
| American Indians                        | 43 (41.7) | 43 (41.7) |
| African American                        | 7 (6.8)   | 7 (6.8)   |
| Asian                                   | 1 (1)     | 1 (1)     |
| Hispanic                                | 1 (1)     | 1 (1)     |
| Other                                   | 4 (3.9)   | 4 (3.9)   |
| **Highest Grade Completed**             |          |          |
| Grades <8                               | 4 (3.9)   | 4 (3.9)   |
| Some high school                        | 12 (11.7) | 12 (11.7) |
| High School or GED\(^a\)                 | 45 (43.7) | 45 (43.7) |
| Some college/technical                  | 18 (17.5) | 18 (17.5) |
| College degree                          | 18 (17.5) | 18 (17.5) |
| Graduate degree                         | 6 (5.8)   | 6 (5.8)   |
| **Self-Reported Overall Health Status**  |          |          |
| Excellent                               | 21 (20.4) | 21 (20.4) |
| Very good                               | 28 (27.2) | 28 (27.2) |
| Good                                    | 37 (35.9) | 37 (35.9) |
| Fair                                    | 13 (12.6) | 13 (12.6) |
| Poor                                    | 4 (3.9)   | 4 (3.9)   |
| **Marital Status**                      |          |          |
| Single                                  | 47 (45.6) | 47 (45.6) |
| Married                                 | 23 (22.3) | 23 (22.3) |
| Separated/Divorced                      | 23 (22.3) | 23 (22.3) |
| Widowed                                 | 9 (8.7)   | 9 (8.7)   |
| **Employment Status**                   |          |          |
| Full time                               | 14 (13.6) | 14 (13.6) |
| Part time                               | 12 (11.7) | 12 (11.7) |
| Unemployed/Laid off/Seeking employment  | 28 (27.2) | 28 (27.2) |
| Unemployed/Laid off/Not seeking employment | 6 (5.8)   | 6 (5.8)   |
| Homemaker                               | 2 (1.9)   | 2 (1.9)   |
| Retired                                 | 21 (20.4) | 21 (20.4) |
| In school                               | 2 (1.9)   | 2 (1.9)   |
| Disabled                                | 12 (11.7) | 12 (11.7) |
| Other                                   | 6 (5.8)   | 6 (5.8)   |
| **Insurance Plan**                      |          |          |
| Individual                              | 7 (6.8)   | 7 (6.8)   |
| Employer                                | 6 (5.8)   | 6 (5.8)   |
| Military/Veteran Affairs                | 5 (4.9)   | 5 (4.9)   |
| Medicaid                                | 18 (17.5) | 18 (17.5) |
| Medicare                                | 9 (8.7)   | 9 (8.7)   |
| No Insurance                            | 41 (39.4) | 41 (39.4) |
| Individual and Medicare                 | 10 (9.7)  | 10 (9.7)  |
| Medicare and Medicaid                   | 3 (2.9)   | 3 (2.9)   |
| Other                                   | 4 (3.9)   | 4 (3.9)   |
| **Health literacy/NVS Literacy Score**  |          |          |
| Limited literacy (0-1)                   | 49 (47.6) | 49 (47.6) |
| Possible limited literacy (2-3)          | 25 (24.3) | 25 (24.3) |
| Adequate literacy (4-6)                  | 29 (28.2) | 29 (28.2) |
| **Currently on prescription medication** |          | 62 (60.2) |
| **Average number of medications**       | 3.46 (10.24) | 75 (72.8) |
| **Reported their prescription medications usually have warning labels** | 75 (72.8) |
| **Number of pharmacies used to fill medications** | 0 (0) | 23 (22.3) |
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\(^a\)GED=General Equivalency Diploma; \(^b\)Missing data on one subject
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 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. 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, 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 labels 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=66, 63.5%) (Table 4).

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

| Label Type | 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) |

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). 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).

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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. These previous studies utilized a similar method of assessing attentiveness to warning labels. 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. 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. 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 of information.
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.21 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 3 (cont.). Association of participants’ characteristics and attendance to the prescription warning label (n=103)

| Label Type       | Participant Characteristic | Chi-square value | P value |
|------------------|----------------------------|------------------|---------|
| Take with food   | Health literacy level (Individuals with limited literacy more likely to ignore) | 14.48            | 0.001 a |
|                  | Gender (Males more likely to ignore than females) | 6.55            | 0.013 e |
|                  | Currently not taking prescription medication | 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            | 0.872   |
| Avoid Sunlight   | Health literacy level (Individuals with limited literacy more likely to ignore) | 19.02            | 0.000 a |
|                  | 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) | 8.85            | 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) | 13.92            | 0.001 a |
|                  | 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) | 4.85            | 0.037 b |
|                  | 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   |
| Do not crush     | Health literacy level (Individuals with limited literacy more likely to ignore) | 7.18            | 0.011 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            | 0.872   |

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.22 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

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 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. 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.

| 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) |
| 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) |

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) |
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. 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 fue de 50,25 años (DE=18,05). La mayoría obedeció las PWL. Los participantes que no usaban actualmente medicamentos y que tenían una literacia en salud más limitada tenían mayor probabilidad de saltarse las etiquetas de advertencia. La mayoría consideró que las instrucciones de avisos eran extremadamente importantes (n=86; 83,5%), quería que el farmacéutico le ayudase a entender las PWL aconsejándole 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...
comprehend by the patients. Additionally, it is necessary to place the PWL on the medicine bottles, so that health professionals can advise the populations carred by their literacy levels on the warning signs, especially to individuals with literacy problems in health and that do not currently take medication.

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

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