

## **The role of picture-based patient education pamphlets for enhancement of patient comprehension of prescription medication information**

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### Introduction

The reading level of the average adult citizen of the United States is estimated at the 8<sup>th</sup> or 9<sup>th</sup> grade level; however, more than half of written healthcare instructions recently surveyed are at a 10<sup>th</sup> grade or higher reading level.<sup>1</sup> Further, it has been shown that in the United States, 23% and 34% of English and Spanish speaking patients, respectively, cannot adequately read and understand medical information in their spoken languages.<sup>2</sup>

United States Pharmacopoeia (USP) pictograms are standardized graphic images that help convey medication instructions, precautions, and/or warnings to patients and consumers. Pictograms are particularly helpful in passing on important information to patients with a lower level reading ability and patients for whom English is a second language.<sup>3</sup>

Using an icon depicting medication dose and time information, Morrow et al. found that prescription recall questions were answered more accurately when an icon was present ( $p < 0.05$ ).<sup>4</sup> Icons contained a timeline with arrows depicting the number of tablets and the specific times at which these should be taken, and the compliance to this regimen was measured. Studies evaluating pictograms in prescription instructions have been conducted in low-literacy areas of Africa, mostly with localized pictograms and sometimes compared to USP pictograms.<sup>5,6,7</sup> There is currently no published literature regarding the effect of pictograms in improving patient education in the United States.

Patient information handouts, or consumer medication information (CMI) are not subject to Food and Drug Administration (FDA) regulations.<sup>8</sup> A recent study evaluating disseminated patient medication information material in 365 United States pharmacies found the length varied greatly from a few sentences to pages, and although longer leaflets met more content criteria, the greater length led to confusion and raised concerns of overload, patient willingness to read the information, and retention of warnings.<sup>9</sup>

At present, the FDA offers a guidance document with recommended criteria to define “useful” information, including one aimed at the presentation of medical information. To ensure the materials are legible and readable, it is recommended that consumer medical information reflect widely recognized standards used by designers and publishers of written information. Specifically, the format should ensure the prominence of important information and the content should be written clearly and concisely, avoiding complex terms.<sup>10</sup>

This study seeks to determine the effect of USP pictograms included within patient information handouts on patient learning in a community pharmacy setting in the United States. Data collected from this research will provide valuable information on how pictograms affect patient utilization of medication handouts and may guide future efforts in improving health education for the patient.

### Methods

#### *Study site and study population*

Two independent community pharmacy settings were selected in Atlanta, Georgia, both associated with medical facilities in the area. One project coordinator and two interviewers assisted in the distribution of the patient information handout and collection of survey responses. Pharmacists and pharmacy interns were

licensed by the Georgia State Board of Pharmacy. All study participants were provided written consent prior to the presentation of the patient information handout and study survey. Approval of the study was obtained from the Mercer University Institutional Review Board.

#### *Patient education material*

Patient information handouts were made for each store's top 20 medications, determined by self-reported 2009 prescription-based sales volume, using drug information from Medline Plus (available at: [medlineplus.gov](http://medlineplus.gov)). Table 1 includes the list of top 20 drugs for each site.

Two sets of patient information handouts were designed for each site, one containing picture-based patient information handouts and the other containing the same textual substance without USP pictograms. Pictograms were included into the text of the picture-based patient information handout whenever one of the 81 available USP pictograms illustrated written information. Figure 1 presents examples of the patient information handouts made for Suboxone<sup>®</sup> (buprenorphine and naloxone).

#### *Interview process and data collection*

For a period of six weeks, investigators counseled the patients receiving any new or refill medication on the pre-determined medication list specific to each site. Participants, blinded to study protocol, were counseled using either the text only or text plus pictogram patient information handouts, selected at random.

To determine the effectiveness of pictures in patient information handouts, a four question survey was created (see Figure 2) and offered to all patients at the conclusion of the counseling session. Based on a 5-point Likert scale, participants were asked to assess the overall effectiveness, the user-friendliness of the format, and the understandability of the material presented. Participants were also asked to rate the likelihood of referring back to the patient information handout in the future. Participants were afforded a private area to complete the survey and no personal information was collected.

#### *Statistical analysis*

Data from those participants counseled using picture-based handouts were compared to data from those participants counseled using non-picture-based handouts, analyzed with descriptive statistics using aggregate data from both sites as well as individually using data from each site. The Mann-Whitney U test was applied to independent test samples (corresponding to survey questions 1, 2, and 4) to detect differences in the central values. The association between whether participants received text only information handouts and the likelihood of referring to the handout in the future (corresponding to survey question 3) was evaluated via two by two tables. Only the results of Fisher's exact tests were used because the other measures may be misleading for a small sample size. Statistical analyses were performed using Statistix<sup>®</sup> (version 9).

#### Results

Table 2 presents a summary of the most common responses to each survey question, separated between picture-based and non-picture-based counseling, presented individually for each site as well as combined using aggregate data.

#### Discussion

According to the National Council on Patient Information and Education (NCPIE), medication non-adherence affects Americans of all ages, races, genders, degrees of education, and socioeconomic levels, resulting in complications and progressions of disease, decreased quality of life, death, and increased healthcare costs. Currently, NCPIE is promoting a new model in which the patient and healthcare team work together to attain and maintain adherence, recommending better education to foster adherence.<sup>11</sup>

Considering the present lack of standardization of patient information handouts, new standards to guide the content, language, format and appearance of prescription medication labels to reflect how patients read and understand medication instructions are being proposed on a national level. In particular, a proposed standard to "limit auxiliary information" reads: "Labels, stickers, or other supplemental information should be expressed in simple and explicit language that is minimized to avoid distracting patients with nonessential information." Another recommendation is to "simplify language".<sup>12</sup>

The addition of pictograms to patient information handouts can facilitate communication of drug information, as demonstrated by the finding that patients who received drug information handouts with pictograms were more likely to refer back to the material in the future. Non-significant differences between groups for the other survey variables may be attributed to overwhelmingly positive responses to non-picture based counseling, possibly attributable to the investigators counseling as opposed to the materials used to counsel. Pictograms may be especially helpful to patients with low literacy skills, potentially increasing medication compliance.

Future research should be designed to evaluate the most effective pictograms for facilitation of communication, the effect of the pictograms on the patient's ability to recall the information, and the threshold for the amount of information that can be comprehended. Furthermore, since pictograms may not be interpreted uniformly, future studies should be aimed at assessing potentially negative implications of picture-based drug information.

### Conclusion

Pictograms included within health materials can significantly increase the effectiveness of health communications, though future research is needed to substantiate the results.

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**Table 1: Top 20 Drugs for Each Site (arranged alphabetically)**

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Site 1	Site 2
Abilify®	Ambien®
Aricept®	Aricept®
Celexa®	Calciferol®
Cymbalta®	Desyrel®
Effexor®	Fosamax®
Geodon®	Glucophage®
Lexapro®	Klor-Con®
Lipitor®	Lasix®
Namenda®	Namenda®
Neurontin®	Neurontin®
Nexium®	Nexium®
Plavix®	Norvasc®
Prozac®	Novolog®
Seroquel®	Plavix®
Singulair®	Prilosec®
Suboxone®	Prometrium®
Trazodone®	Toprol, Lopressor®
Wellbutrin®	Valsartan®
Zoloft®	Zestril®
Zyprexa®	Zetia®

**Table 2: Median Responses to Survey Questions**

		Site 1 (N = 62)	<i>p</i>	Site 2 (N = 22)	<i>p</i>	Site 1 & 2 (N= 84)	<i>p</i>
How would you rate the effectiveness of this patient education material to provide the information you need?	Pictogram	5	0.553	5	0.182	5	0.575
	Non-Pictogram	5*		4		5**	
How would you rate the user-friendliness of the format in which this patient education material was presented?	Pictogram	5	0.822	5	0.01	5	0.117
	Non-Pictogram	5		3		5	
In the future, do you foresee referring back to the patient education material as a reference to review your medication taking behavior?	Pictogram	2 <sup>+</sup>	0.721	2	0.011	2 <sup>++</sup>	0.033
	Non-Pictogram Yes(2)/No(1)	2 <sup>+</sup>		1		2 <sup>++</sup>	
How would you rate your long-term understanding of the patient education material presented today?	Pictogram	5	0.096	5	0.002	5	0.386
	Non-Pictogram	5		3		5	

\* n = 61    + n = 60

\*\* n = 83    ++ n = 82

**Figure 1: Example of Picture-based and Corresponding Non-picture-based Patient Information Handout**

Suboxone®

**How should this medication be taken?**

- Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take buprenorphine or buprenorphine and naloxone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.
- Buprenorphine and the combination of buprenorphine and naloxone come as sublingual tablets to taken under the tongue.
- They are usually taken once a day. To help you remember to take buprenorphine or buprenorphine and naloxone, take it around the same time every day.
- You will start your treatment with buprenorphine, which you will take in the doctor's office. Your doctor will start you on a low dose of buprenorphine and will increase your dose for several days before switching you to buprenorphine and naloxone. Your doctor may increase or decrease your buprenorphine and naloxone dose until the medication works properly.
- Place the tablets under your tongue until they melt. This should take 2 to 10 minutes. If you are taking more than two tablets, either place them all under your tongue at the same time or place them under your tongue 2 at a time. Do not chew the tablets or swallow them whole.
- Do not stop taking buprenorphine and naloxone without talking to your doctor. Stopping buprenorphine and naloxone too quickly can cause withdrawal symptoms. Your doctor will tell you when and how to stop taking buprenorphine and naloxone.
- Do not inject buprenorphine or buprenorphine and naloxone sublingual tablets. Severe reactions may happen, including withdrawal symptoms.
- Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

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- Do not inject buprenorphine or buprenorphine and naloxone sublingual tablets. Severe reactions may happen, including withdrawal symptoms.
- Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

**Figure 2: Survey Instrument**

Dear Sir/Madame,

This 4 question survey is being conducted as part of a Community Pharmacy Foundation research project through Mercer University College of Pharmacy and Health Sciences. The survey results will be used to assess the effect of pictures to improve patient education. Information shared in this survey will be kept anonymous. We appreciate your participation.

1. How would you rate the effectiveness of this patient education material to provide the information you need?
  - Extremely Effective (5)
  - Somewhat Effective (4)
  - Neutral (3)
  - Somewhat Ineffective (2)
  - Extremely Ineffective (1)
  
2. How would you rate the user-friendliness of the format in which this patient education material was presented?
  - Extremely User-friendly (5)
  - Very User-friendly (4)
  - Neutral (3)
  - Somewhat User-friendly (2)
  - Not User-friendly (1)
  
3. In the future, do you foresee referring back to the patient education material as a reference to review your medication taking behavior?
  - Yes
  - No
  
4. How would you rate your long-term understanding of the patient education material presented today?
  - Complete Understanding (5)
  - Fair Understanding (4)
  - Neutral (3)
  - Little Understanding (2)
  - No Understanding (1)

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