ENHANCING THE PERCEIVED READABILITY OF PHARMACEUTICAL CONTAINER LABELS AND WARNINGS: THE USE OF ALTERNATIVE DESIGNS AND PICTORIALS

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ABSTRACT

The appropriate use of pharmaceuticals, as well as their hazards, are not commonly known to most people. In fact, the only information available to consumers is usually the material found on the product label. Unfortunately, for some consumers this method of communicating instructions and risks may be ineffective, and potentially dangerous. People may have difficulty with the labels because the print on the label is too small for them to read. Two alternative (tag and fold-out) designs were developed to increase the available surface area for information printed on a fictitious prescription drug label. The alternative label designs were compared to a standard control label. The presence versus the absence of pictorials visually depicting several instructions and warnings was also examined. Participants rated the labels on ease of reading the labels, likelihood of noticing the warnings, likelihood of reading the warnings, preference for each of the labels, and likelihood that they would recommend each label for use by a friend or family member. The results showed that participants (n = 84) preferred the alternative label designs, especially the tag labels, and those with illustrative pictorials. Implications of these results and recommendations for future research in this area are discussed.

INTRODUCTION

The appropriate use and hazards of pharmaceutical drugs are not commonly known to most lay people. In fact, the only printed information available to consumers at the time the product is consumed is usually the material found on the product label. Unfortunately, for some consumers this method of communicating instructions and potential hazards may be ineffective, and potentially dangerous. Some individuals, most notably the elderly, have trouble reading the label itself because the print is too small, or because the information is squeezed too tightly together in an effort to provide more information (Eustace, Johnson, and Gault, 1982; Morrell, Park, and Poon, 1990). Other people simply have trouble understanding, or remembering all of the instructions and warnings on prescription labels, such as people lacking literacy or language proficiency and the elderly (Morrell, Park, and Poon, 1989; Vanderplas and Vanderplas, 1980).

Another reason for problems associated with prescription drug labels is the lack of formal specification of several aspects of uniformity. For example, the order in which the information is displayed and the amount and type of information included on the label is not standardized. Perhaps more importantly, however, this lack of specification has resulted in the omission of important sources of consumer information from prescription drug labels, including warnings. Currently, neither state nor federal law require that warnings be included on prescription drug labels (New York State Education Department, 1992). The law states that the only information necessary on the labels of prescription drugs is the physician's script. Thus, the decision of what additional information to include on prescription drug labels is left to the discretion of individual pharmacists.

For some drugs, the U.S. Food and Drug Administration requires separate prescription product inserts (PPIs) containing information that patients might need to know, relevant warnings, and any directions necessary to ensure correct usage of the drug. Unfortunately, the average consumer may lose or disregard the insert , thereby making it unavailable for future reference (Barlow and Wogalter, 1991).

One potential solution to this problem is to increase the surface area of the prescription label itself, thereby

allowing for the use of larger print and the inclusion of all relevant information, including warnings (Wogalter, Forbes, and Barlow, 1993). In one recent study, Wogalter and Young (1994) tested several alternative labels that were designed to increase the available surface area for a glue product contained in a very small bottle. The increased surface area of the alternative labels allowed for the use of a larger font in the product's warning. Using an incidental exposure procedure, these researchers observed greater compliance to a warning displayed on the larger alternative labels compared to participants exposed to a warning presented on the label of a smaller control bottle. Additional research suggests that, in addition to printed language, the use of well-designed pictorials can also help communicate important information and warnings (Wogalter, Wolff, Magurno, and Kohake, 1994; Wolff and Wogalter, 1993). However, the use of pictorials often requires more space than is possible on standard labels. In addition, not all pictorials are effective in communicating their intended meaning.

The purpose of the present study was to investigate the effects of: (1) alternative ways of increasing the available surface area of prescription drug labels, and (2) presence versus absence of pictorials on measures of prescription drug label preference.

METHOD

Participants

Fifty male and thirty-four female Rensselaer Polytechnic Institute undergraduates (M = 21.8 years of age, SD = 6.3) participated in the study.

Design

A 3 Label Type (Tag, Fold-out, Control) x 2 Pictorial (Absent, Present) within-subjects experimental design was used. Five dependent variables were examined: ease of reading the labels, likelihood of noticing the warnings, likelihood of reading the warnings, preference for each of the prescription labels, and likelihood of recommending each of the prescription labels to a friend or family member.

Materials

Six labels were constructed according to the 3 x 2 design. The resulting product containers resembled those found on prescription drug bottles. All of the labels contained the same fictitious written information, but differed in terms of the labels' design, the available surface area and the presence or absence of pictorials. The written information contained on the label included the name, address, and telephone number of a pharmacy, the date the prescription was filled and the prescription number, the name and address of a patient, the prescribed fictitious drug (Neurath) and dosage, net quantity of the drug in the bottle, and the number of refills allowed. The labels also contained directions for using the product and warnings. The instructions on the label directed users to: "TAKE 1 TABLET AT EACH MEAL AND 1 AT BEDTIME" and "TAKE WITH WATER." The warnings (hazard instructions) on the label were: "MAY CAUSE DROWSINESS" and "DO NOT TAKE WITH ALCOHOL."

The standard control bottle label contained the written information, directions and warnings described above. The text on the control label was written in upper-case letters in 8-point Times Roman font. It should be noted that while current warning design guidelines recommend against all letters of words being capitalized, we did so to maintain similarity to most currently available prescription drug labels. The dimensions of the control bottle label were 5.08 x 5.08 cm (2 x 2 in.).

Two alternative label designs, a *tag* label and a *fold-out* label, were constructed to increase the available surface area, thereby allowing for the use of a 25% larger font-type (10-point Times Roman) and separation of the directions, warnings, and pictorials (when included) from the other written information contained on the control bottles. A *tag* label was constructed so that the directions and warnings were displayed on a tag attached to the side of the bottles. The dimensions of the tag were 3.7 x 11.4 cm (1.5 x 4.5 in.). A *fold-out* label was constructed in which the available surface area was increased by unfolding the label outward from the side of the bottle, and then down. The dimensions of the fold-out were 5.6 x 7.7 cm (2.25 x 3 in.). In its folded position, the fold-out label conformed to the shape of the bottle. The total surface area of both the tag and fold-out labels was identical.

Three additional labels were constructed by adding pictorials to each of the three label types described previously (i.e., standard control, tag, fold-out). The pictorials visually depicted the written directions and warnings. Examples of each of the labels are presented in Figure 1.

Procedure

After completing an informed consent form, participants were shown all six experimental bottles one at a time (the presentation of bottles was counterbalanced across the participants to control for order effects), and asked to rate the bottles on the five dependent measures described above. Ratings were made on verbally-anchored, Likert-type scales. The specific items and rating scales were:

(a) *How easy is it to read the label?* anchored with (1) extremely difficult, (2) somewhat difficult, (3) somewhat easy, and (4) extremely easy,

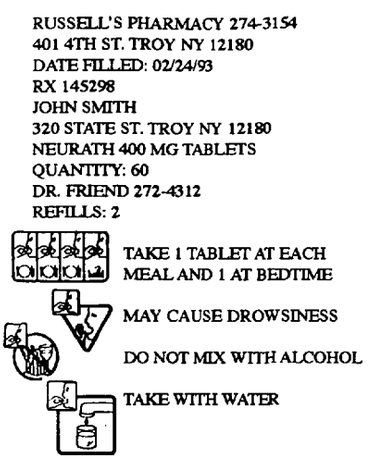
Figure 1

Representative control, fold-out, and tag labels, with and without pictorials. Note that the fold-out and tag labels increase the available surface area, and thereby allow the use of larger print and pictorials compared to the control labels.

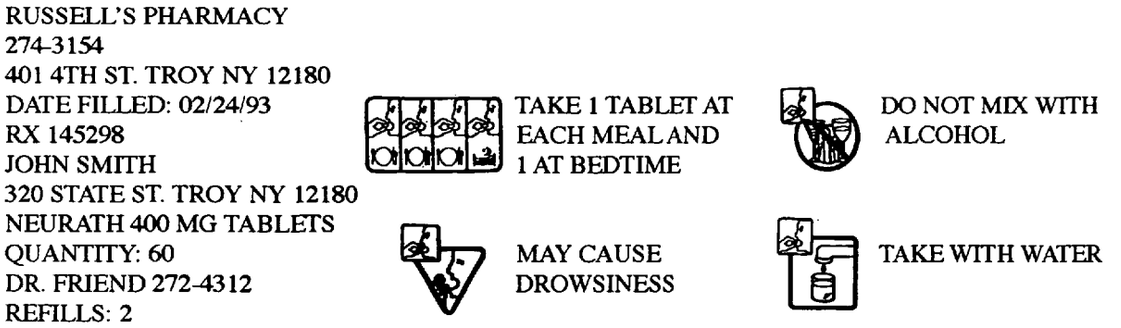
Control Label without Pictorials

RUSSELL'S PHARMACY 274-3154
401 4TH ST. TROY NY 12180
DATE FILLED: 02/24/93
RX 145298
JOHN SMITH
320 STATE ST. TROY NY 12180
NEURATH 400 MG TABLETS
QUANTITY: 60
DR. FRIEND 272-4312
REFILLS: 2
TAKE 1 TABLET AT EACH MEAL AND 1 AT BEDTIME
MAY CAUSE DROWSINESS
DO NOT MIX WITH ALCOHOL
TAKE WITH WATER

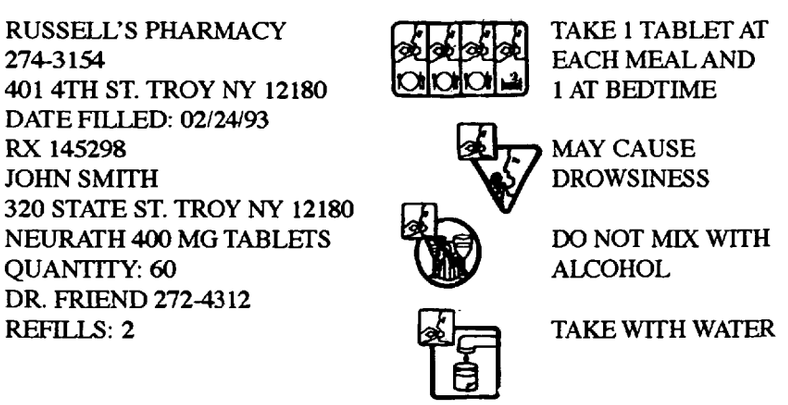
Control Label with Pictorials



Tag Label with Pictorials



Fold-out Label with Pictorials



(b) *How likely would you be to notice the warnings on each label?* anchored with (1) extremely unlikely, (2) somewhat unlikely, (3) somewhat likely, and (4) extremely likely.

(c) *How likely would you be to read the warnings on each label?* anchored with (1) extremely unlikely, (2) somewhat unlikely, (3) somewhat likely, and (4) extremely likely.

(d) *Please rate your preference for each of the prescription labels* anchored with (1) strongly dislike, (2) somewhat dislike, (3) somewhat prefer, and (4) strongly prefer.

(e) *How likely would you be to recommend each label to a friend or family member?* anchored with (1) extremely unlikely, (2) somewhat unlikely, (3) somewhat likely, and (4) extremely likely.

For the labels containing pictorials, participants were also asked to: *rate the effectiveness of the pictorials in helping them to remember or understand the warnings* on a Likert-type scale anchored with (1) not effective, (2) somewhat effective, (3) moderately effective, and (4) extremely effective. After completing the questionnaire, participants were debriefed, thanked, and dismissed.

RESULTS

Cell means for conditions can be seen in Table 1. Standard deviations ranged from .70 to 1.27 across all cell means. Participants' ratings for each of the five preference items were analyzed using separate 3 Label Type (Tag, Fold-out, Control) x 2 Pictorial (Absent, Present) repeated-measures analyses of variance (ANOVAs). All of the ANOVAs showed a significant main effect of Label Type, $F(2, 166) = 33.31, 66.46, 40.66, 5.61, 11.93$ for readability, noticeability, likelihood of reading, preference, and likelihood of recommending, respectively ($ps < .01$). Across all five sets of ratings the Tag was consistently rated the highest and the Control the lowest, with the Fold-out intermediate. Comparisons among the means using Fishers' Least Significant Difference test ($ps < .05$) showed that the Tag was rated significantly higher than the Fold-out and Control for all except the reading and recommending likelihoods ratings where there was no difference between the Fold-out and the Tag. The Fold-out was rated significantly higher than the Control for all measures except for label preference, where the difference was not significant.

Also, all five repeated measures ANOVAs showed a significant main effect of Pictorial, $F(1, 83) = 32.33, 213.03, 115.87, 71.2$, and 122.02 for readability, noticeability, likelihood of reading, preference, and likelihood of recommending, respectively ($ps < .0001$). For every measure, the presence of pictorials produced significantly higher ratings than their absence. There were no instances of a significant Label Type x Pictorial interaction in the ANOVAs ($ps > .05$).

Table 1

Preference Ratings as a Function of Label Type and Presence vs. Absence of Pictorials.

Condition	Readability	Noticeability	Likelihood of Reading	Preference	Likelihood of Recommending
	M	*M*	*M*	*M*	*M*
Standard	2.24	1.68	2.04	1.93	1.70
Standard with pictorial	2.50	2.68	2.90	2.67	2.60
Tag	3.07	2.71	2.96	2.38	2.40
Tag with pictorial	3.44	3.71	3.60	3.10	3.18
Fold-out	2.62	2.56	2.87	2.12	2.19
Fold-out with pictorial	3.06	3.48	3.51	2.83	2.94

[Note. $N = 84$ for all conditions.]

An additional item asked participants who received a label with pictorials to rate the effectiveness of the pictorials in helping them to remember or understand the warnings. The results indicated a significant effect of type of label, $F(2,37) = 19.29$, $p < .001$. Fisher's LSD revealed that the tag and the fold-out labels with pictorials were rated as significantly more effective than the standard label with pictorials (M=3.00, M=2.77, and M=1.38, respectively).

DISCUSSION

The major finding of this study was that participants showed a greater preference for the alternative label designs, especially tag labels, compared to a standard prescription drug label. Across all dimensions, the standard label without the pictorials was less readable, less noticeable, less likely to be read, less preferred, and less likely to be recommended to a friend or family member than the other labels. The results also showed a rather substantial effect of the presence of pictorials on the label. Indeed, across all dimensions, labels containing pictorials were always preferred to the same label without pictorials.

The finding of a preference for the tag label confirms the results of other preference studies (e.g., Wogalter, Forbes and Barlow, 1993; Wogalter and Barlow, 1994) showing the tag to be the preferred label for glue bottles. It also lends support to the findings of Wogalter and Young (1994) who demonstrated greater compliance for a similar tag design attached to a glue bottle. Both the tag and fold-out designs provide greater surface area on which to place more information, including pictorials. The use of pictorials may be an important addition to prescription drug labels for several reasons: pictorials are attention getting, they are useful when small print size is used or when print is not legible, and they may be critical for persons who are not proficient with language.

Results such as those shown in the present study warrant and deserve further research because they hold such great promise for benefitting people, especially persons with visual disabilities and poor reading skills. Although the present study was conducted with college students, future research in this area should be performed with other groups, including the elderly. Older persons are greatly at risk for misapplication and misuse of pharmaceuticals due to poor vision and other age-related cognitive deficits. Additionally, while the present study focused primarily on measures of label preference, future research should also include objective measures of performance (e.g., comprehension of and memory for information contained on the label as well as demonstrations of correct use) to determine other ways in which alternative prescription drug labels can facilitate safe usage of pharmaceutical products.

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