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Pharmaceutical container labels: enhancing preference perceptions with alternative designs and pictorials ¹

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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 at the time of consumption is usually the material found on the product label. Unfortunately, people often 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 on a fictitious prescription drug label. The alternative label designs, with and without pictorials depicting instructions and warnings, were compared to a standard control label. In Expt. 1, 84 undergraduates rated the labels on several preference dimensions, including: 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. Across all dimensions, undergraduates preferred the alternative labels, especially the tag labels, and labels with pictorials. In Expt. 2, the ratings of 58 older adults (mean age = 73 years) showed a similar pattern of results. Implications of these results and recommendations for future research in this area are discussed.

Relevance to industry

Drug manufacturers should incorporate these findings into the design of pharmaceutical labels to make them more attention-getting, readable, and preferred, especially to older adults and persons with poor vision or reading skills. These results may also help health care professionals and their patients by reducing the potential for errors. Finally, these findings could be useful in the redesign of labels for other kinds of products and equipment.

Keywords: Pharmaceutical label; Pictorial; Medication; Instruction; Warning; Older adult

1. 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

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too tightly together in an effort to provide more information (Eustace et al., 1982; Morrell et al., 1990). Watanabe et al. (1994) recently assessed the impact of letter compression and vertical letter height on measures of readability among a group of elderly subjects viewing labels for existing pharmaceuticals (e.g., Tylenol[®], Advil[®]). The results showed that both factors affected the number of errors subjects made while reading the labels, but they found point size had a relatively smaller effect compared to compression. A host of other label characteristics not yet examined may also affect readability of prescription drug labels, including line spacing, letter contrast, print and label background color, and type style, to name but a few. People may also have trouble, however, simply understanding or remembering all of the instructions and warnings on prescription labels, including persons lacking literacy or language proficiency and the elderly (Vanderplas and Vanderplas, 1980; Morrell et al., 1989).

Another possible problem associated with prescription drug labels is the lack of formal specifications. 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 and their employers.

For some drugs, the US 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 et al., 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 20% larger font size 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 (Magurno et al., 1994; Wolff and Wogalter, 1993). Pictorials can be used to illustrate a potential hazard, the potential consequences, and/or what to do or not do to avoid the hazard. Well-designed pictorials can communicate large amounts of information in a glance and can be useful in reaching persons who cannot read printed verbal messages, either because of vision problems (e.g., the elderly) or because they do not possess good verbal skills or knowledge of the language being used in the warning (e.g., foreign visitors, illiterates, the less educated, children) (Lerner and Collins, 1980; Collins, 1983; Boersema and Zwaga, 1989; Laux et al., 1989; Easterby and Zwaga, 1984). However, it is also true that poorly designed pictorials may communicate nothing (other than perhaps that a warning is present) or worse, the wrong message (Lerner and Collins, 1980; Laux et al., 1989). In addition, the use of pictorials often requires more space than is possible on standard labels.

The purpose of this research 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. Two alternative label designs, a tag and a fold-out, were compared to a basic pharmaceutical label design (Control bottle). The tag pharmaceutical label was based on the tag design used by Wogalter and Young (1994). In their study, the tag design was more effective in conveying important instructional and warnings information to study participants than a

M.J. Kalsher et al. / International Journal of Industrial Ergonomics 18 (1996) 83-90

standard Control label. The fold-out design is similar to labels currently found on some over-the-counter medications (e.g., Aleve[®]), although currently there are no empirical studies that support the effectiveness of this label design.

2. Experiment 1

2.1. Method

2.1.1. Participants

Eighty-four (50 male and 34 female) Rensselaer Polytechnic Institute undergraduates (M = 21.8 years of age, S.D. = 6.3) participated in the study.

2.1.2. Design

A 3 (Label Type: Tag, Fold-out, Control) $\times 2$ (Pictorial: Absent, Present) within-subjects experimental design was used. Five ratings 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. In addition, 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.

2.1.3. Materials

Six prescription drug labels were constructed according to the 3×2 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 pictorials used in this study were taken from a large set developed for the US Pharmacopoeia Convention (USPC). Prior research has evaluated their ability to visually convey the meaning of instructions and warnings (Wolff and Wogalter, 1993; Magurno et al., 1994). The 4 pictorials used in this study met or exceeded a comprehension criterion of 85%.

The printed 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 AL-COHOL'.

The standard control bottle label contained the written information, directions and warnings described above (refer to Fig. 1). 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 5.08×5.08 cm (2 × 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). 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 3.81 \times 11.43 cm (1.5 \times 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 5.72×7.62 cm (2.25×3 in.). In its folded position, the fold-out label conformed to the shape of the bottle. The total surface areas of the tag and fold-out labels were identical and 40% larger than the surface area of the control label.

Three additional labels were constructed by adding pictorials to each of the 3 label types described previously (i.e., standard control, tag, fold-out). As shown in Fig. 1, the pictorials visually depicted the written directions and warnings.

2.1.4. Procedure

After completing an informed consent form, participants were shown all 6 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 5 measures. Ratings were made on verbally anchored, Likert-type scales. The specific items and rating scales were:

- "How easy is it to read the label?" anchored with (1) extremely difficult, (2) somewhat difficult, (3) somewhat easy, and (4) extremely easy.
- "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.
- "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.
- "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.
- "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 the following sixth item:

• "Please rate the effectiveness of the pictorials in helping you to remember or understand the warnings" 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.

2.2. Results

Cell means for conditions can be seen in Table 1. Standard deviations ranged from 0.70 to 1.27 across all of the cells. Participants' ratings for each of the 5 preference dimensions were analyzed using separate 3 (Label Type: Tag, Fold-out, Control) \times 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, (*p*-values < 0.01). Across all 5 sets of ratings the Tag was

Control Label without Pictorials

Control Label with Pictorials

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

Fig. 1. Representations of the control labels with and without pictorials. Note: size shown in figure is not to scale.

86

M.J. Kalsher et al. / International Journal of Industrial Ergonomics 18 (1996) 83-90

consistently rated the highest and the Control the lowest, with the Fold-out intermediate. Comparisons among the means using Fisher's least significant difference (LSD) test (*p*-values < 0.05) showed that the Tag was rated significantly higher than the Foldout and Control for all except the reading and recommending likelihoods ratings where there was no difference between the Fold-out and the Tag. The Foldout was rated significantly higher than the Control for all measures except for the label preference question, where the difference was not significant.

Also, all 5 repeated measure 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 (*p*-values < 0.0001). For every measure, the presence of pictorials produced significantly higher ratings than their absence. There were no instances of a significant Label Type × Pictorial interaction in the ANOVAs (*p*-values > 0.05).

For the labels with pictorials, participants were asked to rate the effectiveness of the pictorials in helping them to remember or understand the warnings. The results from this item indicated a significant effect of type of label, F(2,37) = 19.29, p < 0.001. 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, 2.77, and 1.38, respectively).

2.3. Discussion

Table 1

The major finding of Expt. 1 was that the undergraduate volunteers 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.

While encouraging, these results do not reflect the potential usefulness of the alternative label designs for persons who may have trouble reading prescription drug labels. In fact, a primary target population for alternate product labels is the elderly. Older adults tend to consume more medicines and are also likely to have more limited sensory and working memory capacity. Thus, the purpose of Expt. 2 was to assess preferences for these label designs using a sample of elderly adults.

3. Experiment 2

3.1. Method

3.1.1. Participants

Fifty-eight (17 male, 41 female) elderly volunteers living in adult group homes in Troy, NY served as participants in this study. Their mean age was 72.9 years (S.D. = 9.9). Fifty of the participants reported wearing corrective lenses and of those, 19 reported that their vision was not corrected to 20/20, even with the use of their corrective lenses. The

Mean preference ratings of undergraduate students as a function of label type and presence vs. absence of pictorials (Expt. 1) Likelihood of recommending Condition Readability Noticeability Likelihood of reading Preference Without pictorials Standard 2.24 1.68 2.04 1.93 1.70 Fold-out 2,62 2.56 2.87 2.12 2.19 3.07 2.71 2.96 2.38 2.40 Tag With pictorials 2.50 2.68 2.90 2.67 2.60 Standard Fold-out 3.06 3.48 3.51 2.83 2.94 3.44 3.71 3.60 3.10 3.18 Tag

87

participants reported taking an average of 2.6 different types of prescription drugs at the time of this study.

3.1.2. Design and procedure

The same 3 (Label Type: Tag, Fold-out, Control) $\times 2$ (Pictorial: Absent, Present) within-subjects experimental design described in Expt. 1 was used for this study. After completing an informed consent form, participants were shown all 6 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 same dimensions described in Expt. 1. After completing the preference ratings, participants were debriefed, thanked, and dismissed.

3.2. Results

Cell means for conditions can be seen in Table 2. Standard deviations for scores within each cell ranged from 0.51 to 1.41. Participants' ratings were analyzed using separate 3 (Label Type: Tag, Fold-out, Control) \times 2 (Pictorial: Absent, Present) repeatedmeasures analyses of variance (ANOVAs). All of the ANOVAs performed on the preference measures showed a significant main effect of Label Type, F(2,114) = 90.45, 54.91, 43.69, 85.86, and 65.14, p-values < 0.0001 for readability, noticeability, likelihood of reading, preference, and likelihood of recommending, respectively. Comparisons among the means using Fisher's LSD test (p-values < 0.05) showed that the alternative label designs were rated significantly higher than the Control label across all dimensions rated. No differences between the foldout and tag labels were significant (all *p*-values > 0.05).

The ANOVAs also showed a significant main effect of Pictorial, F(1,57) = 15.86 and 10.51, for noticeability and likelihood of reading the label, respectively (*p*-values < 0.002). For both measures, the presence of pictorials produced significantly higher ratings than their absence.

For the labels with pictorials, participants were also asked to rate the effectiveness of the pictorials in helping them to remember or understand the warnings. Although the ANOVA on the effectiveness measure did not meet the conventional level of significance (0.05 probability), F(2,24) = 2.75, p < 0.09, the means favored the alternative designs, especially the Tag (M = 2.45), as compared to the Fold-out (M = 1.50) and Control labels (M = 1.13).

3.3. Discussion

Thus, the older adults tested in this study preferred both the Tag and Fold-out labels over the Control label, although there was no difference in their preference between the two alternative label designs. The results also showed a significant preference for pictorials on the label, but only for two of the measures: likelihood of noticing the label and likelihood of reading the label. These results confirm people's preference for the alternative label designs and pictorials as was shown in Expt. 1, although preference for pictorials was not as strong for the elderly participants as it was for the college students.

Table 2

Mean preference ratings of elderly participants as a function of label type and presence vs. absence of pictorials (Expt. 2)

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Condition	Readability	Noticeability	Likelihood of reading	Preference	Likelihood of recommending	
Without picto	rials		denorden over an en ander an en ander an en ander an en a	a a contraction of the second s		
Standard	2.24	2.31	2.72	1.91	1.70	
Fold-out	3.38	3.29	3.52	3.05	3.00	
Tag	3.38	3.28	3.50	3.19	2.90	
With pictoria	ls					
Standard	2.24	2,55	2.85	1.95	1.75	
Fold-out	3.45	3.59	3.76	3.28	2.90	
Tag	3.57	3.60	3.72	3.35	3.18	

M.J. Kalsher et al. / International Journal of Industrial Ergonomics 18 (1996) 83-90

4. General discussion

The finding of a preference for the alternative labels, especially the tag label, confirms the results of other studies of this type (e.g., Barlow and Wogalter, 1991; Wogalter et al., 1993). It also lends support to the findings of Wogalter and Young (1994) who demonstrated greater compliance behavior for a similar tag design attached to a glue bottle. Both the tag and fold-out designs tested in the present study provide greater surface area on which to place more information, including pictorials. These findings take on greater significance when one considers the fact that many of the printed materials (on the labels and in other accompanying materials) currently given out by pharmacies are badly formatted. Thus, better ways to provide clear pharmaceutical medication instructions and warnings are clearly needed.

The use of pictorials may be an important addition to prescription drug labels for several reasons: (1) pictorials are attention getting; (2) they are useful when small print size is used or when print is not legible; and (3) they may be critical for persons who are not proficient with language. Today pharmacies are placing colored stickers with pictorials on pharmaceutical labels to convey various instructions and warnings. However, neither the statements nor the pictorials on many of these stickers have been tested for effectiveness. Therefore, such testing is needed, particularly with older adults and less literate populations, as these persons are the most in need of well-designed labels. The results of Expt. 2 highlight the need for additional research in this regard. Specifically, the older adults did not rate the pictorials as highly as the college students tested in Expt. 1. This result suggests that pharmaceutical pictorials need to be tested not only for comprehension as was done in several recent studies (e.g., Wolff and Wogalter, 1993; Magurno et al., 1994), but also for legibility since even alternative labels have limited space and so they must be reduced in size.

Research in this area warrants further investigation because it holds great promise for elderly persons and those with visual disabilities and poor reading skills. Future research in this area should continue to be performed with populations other than college students, especially older adults. Elderly persons are greatly at risk for misapplication and misuse of pharmaceuticals due to poor vision and other age-related cognitive deficits. Additionally, while much of the present focused on measures of label preference, future research should include additional 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.

Thus, it remains for subsequent research to determine whether these designs can be effective in helping users to more easily read or remember important instructional and warning information contained on prescription drug labels.

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