Facilitating Information Acquisition for Over-the-Counter Drugs using Supplemental Labels

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ABSTRACT

This study examined the effect of the presence and color of a supplemental cap label on medication information acquisition and container preference. Participants were 75 elders from a retirement community who were asked to examine one of five manipulated labels on a fictitious but realistic-appearing over-the-counter (OTC) pharmaceutical product container and then to respond to questions concerning their knowledge about the medication. Later they were shown all five manipulated bottle labels and asked which they preferred in effectively communicating medication information. The five bottles differed in the use of labeled surface area and color. Two bottles, displaying labels only on the body of the bottle, served as controls. One control had only a front label, and the other control was conventionally labeled with printed information on the front, back and sides of the bottle. The three other bottles were identical to the conventionally labeled control bottle except they included a supplemental cap label that reprinted the most critical product-use information in large type on three different colored backgrounds. The results showed greater medication-related knowledge for the bottles with supplemental cap labels compared to bottles without the supplemental cap label, with no significant difference among the different colored caps. Participants indicated a strong preference for the bottles with supplemental cap labels over the two control bottles. A distinctive cap color (different from the main label color) was most preferred. Making use of extended surface areas on medication containers to print important information in a more noticeable, legible form benefits elders' knowledge about proper use and hazards.

INTRODUCTION

Pharmaceutical products sold over-the-counter (OTC) in the U.S. generally have labeling displaying directions for use, contraindications, warnings, and other information. The information may be on the product container itself, on inserts, or on exterior packaging. The information included with the product is often the only way for many consumers to learn about the characteristics of OTC medications. In order to provide a complete set of relevant information, most OTC labels contain so much information that the text size must be substantially reduced to fit on the available surface of the container or packaging. Individuals with vision problems have difficulty reading the reduced print (Vanderplas and Vanderplas, 1980; Zuccollo and Liddell, 1985). The elderly, who tend to have age-related visual difficulties (e.g., presbyopia, cataracts), are more likely than other age groups to take more medicines. As a consequence, seniors with these age-related visual conditions have difficulty reading important information about the drugs that they take. Although additional space may be available on insert sheets and on exterior packages to make the print larger, this is seldom done. Moreover, these separate and unattached items are frequently discarded after initial use of the product. As a result, these materials are of little help when the product is used at a later time (Wogalter, Forbes, and Barlow, 1993).

One possible solution to this labeling-communication problem is to enlarge the surface space of the container to attach a more legible label. The added surface area could also be used for more elaborative instructions and warnings. In one study (Wogalter and Young, 1994), the surface area of a small glue container was expanded by using an extended tag label. The tag allowed the use of larger fonts than the original label. Results showed that compliance behavior (wearing protective gloves) increased with the tag label compared to a control label without the tag.

Barlow and Wogalter (1991) and Wogalter et al. (1993) found that the elderly preferred glue containers having labels with increased surface area. One of the most preferred bottle designs by this population was a wings (or fin) design that not only provided more surface area for print information but also made it easier to hold and turn the cap. Recently, several drug manufacturers have begun to package OTC pain medications in easy-open containers with caps having extended fins. This new design makes it easier for someone with arthritis or with a hand/arm disability to open the container. Current versions of the easy-open feature lack child resistance, however.

This new easy-open container design also increases the usable surface area of the container (relative to other

containers) that could allow the printing of larger instructions and warnings. Wogalter and Dietrich (1995) examined the effect of making use of this added surface area by reprinting and extending some of the most important warnings and instructions for use onto the container cap section. The product used was Motrin IB® (Upjohn Co, Kalamazoo, MI), a national brand of ibuprofen in an easy-open bottle. They found that the elderly participants preferred the bottles with the cap label over control bottles without the cap labels. Of the four cap labels that differed in background color (orange, white, two-toned orange and white, and fluorescent green), they most preferred the green cap label. These subjective evaluations indicate a preference for more readable and noticeable labels afforded by the enlarged print and use of color. However, these preference judgments may not reflect any actual performance advantages for these labels (i.e., increased transmission of information). Moreover, the reason for the color effect is unclear. The main body label of the Motrin IB® was orange and white and the lesser preferred caps used those same colors. Thus, the green preference might be due to distinctiveness with respect to the main label, simple color preference, or because it was a fluorescent hue.

The current research attempts to clarify the Wogalter and Dietrich (1995) study by examining the effect of the supplemental cap label and its color using performance and preference measures. Addressed are whether the supplemental label facilitates performance in a knowledge acquisition task and whether color adds to this effect. Additionally, the study attempts to replicate the preference findings of the earlier study examining whether color distinctiveness is responsible for the elevated evaluations.

Preliminary testing with the Motrin IB® container labels used by Wogalter and Dietrich (1995) failed to show differences in knowledge after brief exposure. High levels of product knowledge was found for all conditions, suggesting the presence of a ceiling effect that was probably due to the elderly population's high level of familiarity with this particular medication. The present study uses an unfamiliar product to reduce the possibility of a ceiling effect by reducing the influence of pre-existing knowledge that might mask differences between different versions of bottle labels.

It was expected that the bottles with supplemental cap labels would produce greater knowledge about the medication and be preferred compared to bottles without supplemental labels. Two distinctive cap colors (fluorescent yellow and fluorescent green) were expected to be preferred and produce greater knowledge than a fluorescent orange cap that matched the primary color of the main label.

METHOD

Participants

Seventy-five volunteers from a retirement community in Chapel Hill, North Carolina participated. Mean age of participants was 79 years (*SD* = 5.8, ranging from 69 to 90), 77% were females, and all were Caucasian. A monetary contribution was made to the community fund in appreciation for residents' participation.

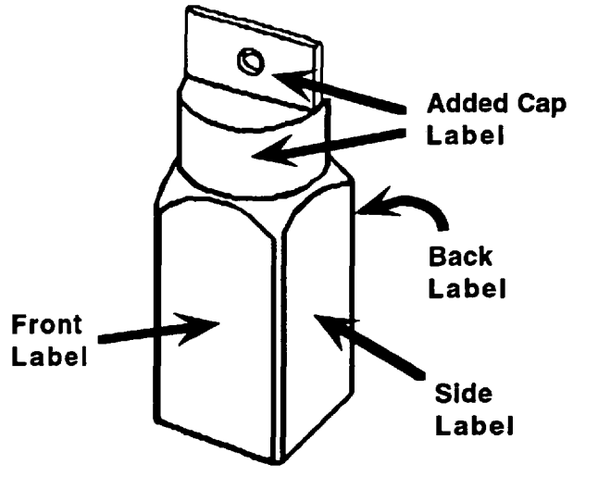
Materials

In a preliminary trial, a purchased bottle of the pain reliever Datril® (Bristol-Myers Co, New York, NY), a brand-name acetominophen product, was shown to participants. The trial run was used to get participants acquainted with the main experimental procedure.

For the main experimental trials, "Marvine," a fictitious OTC motion sickness preparation, was created. Most people are relatively unfamiliar with motion sickness preparations, and thus pre-existing knowledge that could enable participants to score highly on a subsequent knowledge test without having examined the experimental labels was expected to be limited. Although the product was fictitious with respect to active ingredient and manufacturer, the text on the labels was constructed to be plausible and realistic containing information from currently available motion sickness preparations and information from the Physicians' Desk Reference (1993).

The Marvine container shown in Figure 1 had a physical height of 4.2 cm and a width of 4.0 cm. The cap height was 2.4 cm with a circumference of 13.5 cm. The main label (front, back and sides), as shown in Figure 2, was attached around the the body of the container, as is typical. The text of the main label was formatted to be similar to other OTC labels currently on the market. The front panel contained the product name, chemical name, indications for use, and other typical principal display panel information, printed in sizes

Figure 1. Representation of the Marvine Container and Label Placement.



ranging from 7 to 14 point black type. On the back and side panels, type size (4 point) was the same as is found on other commercially-available OTC products (e.g., Motrin IB®). The main label background color was fluorescent orange.

All bottles except for one of the controls had the complete main label on all four sides of the bottle. The control condition without the complete main label had only the front label attached to the bottle (i.e., it lacked the back and side panels). The other (conventional) control had the complete main label on all four sides of the bottle but lacked the supplemental cap label, as is typical for products using this container design.

The three other bottles were the same as the conventional control, with labels on all four sides of the bottle, but also displayed a supplemental cap label. The textual content and layout of the three cap labels was identical, varying only in the background color of the label: orange, yellow, and green. All were fluorescent hues. The orange cap label was identical to the background color of the main label, while the other two cap labels were different. The cap label text was black print, in New Helvetica Narrow font, having type sizes ranging from 7 to 17 point.

The information on the cap label was extracted from the main label text and was chosen, based on consultation with a pharmacist, to reflect the most important cautions and directions for proper, safe use of the product. The supplemental cap labels were composed of three parts. One was positioned on the front extended tab on the cap top. This section contained the WARNING signal word and the signal alert icon (an exclamation point surrounded by a triangle). The other two sections of the cap label completely wrapped around the base of the cap so that one part faced the front and the other part faced the back of the bottle. Important cautions were printed on the front and dosage information on the back. The text of these labels is shown in Figure 3.

All labels were produced on a 600 dpi laser printer. The labels were attached bottles with glue and overlayed with clear plastic lamination.

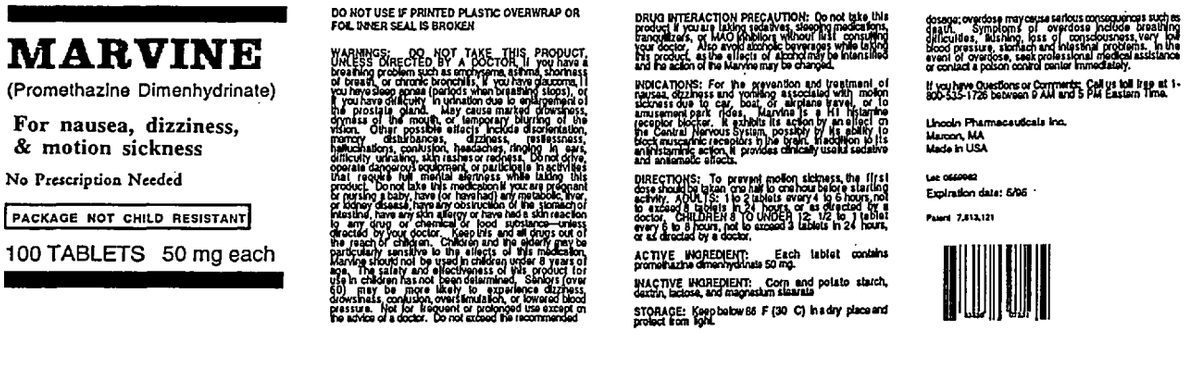
A medication knowledge test was developed concerning information on the Marzine label. The 12-item test (with a total of 42 subparts) consisted of open-ended and probe-type questions concerning what the drug treats, when and how much of the drug to take, when not to take the drug, signs/indications of overdose, side effects, whether the drug can be given to children of various ages, and the bottle's adequacy of child proofing. The test was administered in an interview format, with the experimenter recording everything the participant said in response to each item.

Procedure

The study was conducted in a conference room at the retirement community. Participants arrived at prearranged times, and were tested individually. The experimenter explained to participants that the purpose of the study was to investigate their impressions of labels on medicine bottles. Participants were told they would be shown drug containers, and then would be asked questions about the medications. Participants signed a consent form before beginning the study.

The first phase of the study was a trial run intended to acquaint participants with the type of task they would be performing in the main experiment. The experimenter read aloud a scenario in which participants were to assume they were shopping for a pain reliever to be used by family members of various ages and with various medical histories. They were asked to read the label for information on how to use the product, and who should or should not take it. The participant was handed a Datril® bottle, and after 60 s the bottle was removed and the participant was asked three questions about the product's use by children, by someone allergic to aspirin, and by someone with a peptic ulcer. Responses from this phase were recorded but not analyzed.

Figure 2. Text of the Main Label (Front, Back and Side) in Actual Size.



MARVINE

(Promethazine Dimenhydrinate)

For nausea, dizziness, & motion sickness

No Prescription Needed

PACKAGE NOT CHILD RESISTANT

100 TABLETS 50 mg each

DO NOT USE IF PRINTED PLASTIC OVERWRAP OR FOIL INNER SEAL IS BROKEN

WARNINGS: DO NOT TAKE THIS PRODUCT, UNLESS DIRECTED BY A DOCTOR. If you have a breathing problem such as emphysema, asthma, shortness of breath, or chronic bronchitis, if you have glaucoma, if you have sleep apnea (periods when breathing stops), or if you have difficulty in urination due to enlargement of the prostate gland, may cause marked drowsiness, dryness of the mouth, or temporary blurring of the vision. Other possible effects include disorientation, memory disturbances, dizziness, restlessness, hallucinations, confusion, headaches, ringing in ears, difficulty urinating, skin rashes or redness. Do not drive, operate dangerous equipment, or participate in activities that require full mental alertness while taking this product. Do not take this medication if you are pregnant or nursing a baby, have (or have had) any metabolic, liver, or kidney disease, have any obstruction of the stomach or intestine, have any skin allergy or have had a skin reaction to any drug or chemical or food substance—unless directed by your doctor. Keep this and all drugs out of the reach of children. Children and the elderly may be particularly sensitive to the effects of this medication. Marvine should not be used in children under 6 years of age. The safety and effectiveness of this product for use in children has not been determined. Elderly (over 60) may be more likely to experience dizziness, drowsiness, confusion, overstimulation, or lowered blood pressure. Not for frequent or prolonged use except on the advice of a doctor. Do not exceed the recommended

DRUG INTERACTION PRECAUTION: Do not take this product if you are taking sedatives, sleeping medications, tranquilizers, or MAO inhibitors without first consulting your doctor. Also avoid alcoholic beverages while taking this product, as the effects of alcohol may be intensified and the action of the Marvine may be changed.

INDICATIONS: For the prevention and treatment of nausea, dizziness and vomiting associated with motion sickness due to car, boat, or airplane travel, or to amusement park rides. Marvine is a H1 histamine receptor blocker. It exhibits its action by an effect on the Central Nervous System, possibly by its ability to block muscarinic receptors in the brain. In addition to its antihistaminic action, it provides clinically useful sedative and antiemetic effects.

DIRECTIONS: To prevent motion sickness, the first dose should be taken one half to one hour before starting activity. ADULTS: 1 to 2 tablets every 4 to 6 hours, not to exceed 8 tablets in 24 hours, or as directed by a doctor. CHILDREN 6 TO UNDER 12, 1/2 to 1 tablet every 6 to 8 hours, not to exceed 3 tablets in 24 hours, or as directed by a doctor.

ACTIVE INGREDIENT: Each tablet contains promethazine dimenhydrinate 50 mg.

INACTIVE INGREDIENT: Corn and potato starch, dextrin, lactose, and magnesium stearate

STORAGE: Keep below 86 F (30 C) in a dry place and protect from light.

dosage; overdose may cause serious consequences such as death. Symptoms of overdose include breathing difficulties, fainting, loss of consciousness, very low blood pressure, stomach and intestinal problems. In the event of overdose, seek professional medical assistance or contact a poison control center immediately.

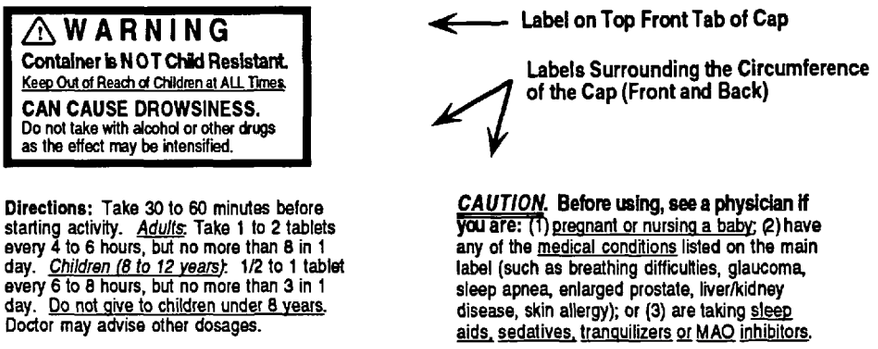
If you have Questions or Comments, Call us toll free at 1-800-535-1726 between 9 AM and 5 PM Eastern Time.

Lincoln Pharmaceuticals Inc.
Marcom, MA
Made in USA

Lot: 0660982
Expiration date: 6/96

Patent 7,813,121

Figure 3. Text of the Supplemental Cap Label in Actual Size.



In the second (main experimental) phase, another scenario was presented to participants. They were asked to assume they were buying a motion sickness medication in preparation for a one-day bus trip on winding mountain roads. Further, they were to assume that fellow travelers would have a variety of medical conditions and would be of different ages. The purpose of the scenario was to provide realism as well as relevance to encourage careful examination of the label for a broad range of purposes. Each participant was then presented with one of the five Marvine bottles(depending on the condition for which they were randomly assigned) and asked to examine the label so that they could answer questions on the medication. After three minutes elapsed, the Marvine bottle was removed and the knowledge test was given. Participants were encouraged to give answers to all the questions, based on the information viewed on the label and any background knowledge they had regarding the motion sickness medication.

In the final phase, participants were given all five bottles of Marvine and asked to rank the bottles from most preferred to least preferred. Participants were instructed to consider overall effectiveness in communicating important medication information, ease in reading, likelihood of reading, and likelihood of purchase. Later, participants were debriefed and thanked for their assistance.

RESULTS

Knowledge Test

Each subpart item of the knowledge test was scored as correct = 1 or incorrect = 0. Data analysis used the mean proportion correct score for each participant (based on a total of 42 subpart items). Prior to analysis, a second judge re-graded the open-ended responses. Inter-rater reliability (calculated as number of agreements/total X 100) was nearly perfect (99.75%).

The mean proportion correct knowledge scores are shown at the top of Table 1. A one-way between-subjects analysis of variance showed a significant effect of bottle label conditions, $F(4, 70) = 17.82$, $p < .0001$). Comparisons using Newman-Keuls Multiple-Range test showed that the three cap label conditions produced significantly higher scores than the two control label conditions ($p < .05$). The three cap label conditions did not differ among themselves ($p > .05$). The 4-panel (front, back, and sides) control label condition produced significantly higher knowledge scores than the front-panel-only control condition.

Preference Ranks

Mean preference ranks for the five label conditions are shown at the bottom of Table 1. Lower rank means indicate greater preference. The data were analyzed using the non-parametric repeated-measures Friedman test. This test showed a significant effect of label condition, $\chi^2(4, N = 75) = 223.05$, $p < .0001$). Paired comparisons were performed using the Wilcoxon Matched-Pair Signed-Rank test. The table shows that the yellow cap received the lowest mean rank, and was significantly preferred over the orange cap ($p < .05$). The green cap was intermediate between these two conditions but did not significantly differ from the two other cap colors ($p > .05$). All three cap conditions were judged significantly better than the two no-cap label controls ($ps < .05$). The 4-panel control label was significantly preferred over the front-panel-only control ($p < .05$).

DISCUSSION

This study showed improved knowledge acquisition with the addition of the cap labels. These labels reprinted the most critical information on the product's use and warnings. Apparently this method was more effective in providing this information than the conventional label method.

The different colors of the additional label did not make a

Table 1. Mean Knowledge Score and Preference Rank of Container Label Configurations..

	Control Containers		Experimental Containers with Front Back & Side Labels and Supplemental Information on Color Cap		
	Front Panel Only No Back or Side Labels	With Front, Back & Side Labels	Orange	Green	Yellow
Knowledge					
Mean	.15	.38	.57	.51	.55
SD	.11	.23	.15	.16	.12
Preference Rank					
Mean	4.97	3.85	2.33	2.05	1.79
SD	.16	.69	.88	.77	.86

Note. Higher comprehension and lower ranks indicate better scores.

difference in knowledge acquisition scores, but did have an effect on preference. Wogalter and Dietrich (1995) found that participants preferred a fluorescent green cap that was distinctly different from the color of the main bottle label (orange). In the present study, yellow was preferred over orange, with green intermediate between these two. This finding partially clarifies an unresolved issue of color preference in the earlier study. Although the green cap in the present study was not significantly preferred over the orange cap, the yellow cap was. This suggests that the effect found earlier was not due to the particular color green, but appears to be its distinctiveness from the main label.

The fact that the two control conditions (front panel-only vs. front, back, and sides) differed for both knowledge acquisition and preference indicates that at least some of the elders used some of the information the additional panels provide. Nevertheless, several participants spontaneously commented that the back and side panels were very difficult for them to read. Some participants reported that they were not able to read the main label at all (meaning only the information on the cap labels was available to them). Some participants stated that they would be less likely to purchase a product if the print was too small for them to read. Some noted that they routinely carry with them a magnifier.

The easy-open OTC container provides additional surface area to present important information. Direct attachment of the label to the medication container avoids the pitfalls of methods like inserts and external packaging which might be discarded or lost after initial use of the product. It also allows the use of enhancements such as larger print size and pictorials (Kalsher, Wogalter, and Racicot, 1996). Informal discussions with participants in the post-experiment debriefing phase suggested that being able to read labels is important to elderly consumers, and that this need is not being met by current labels.

More research is needed on ways to increase the legibility and understandability of pharmaceutical labels. Necessarily, considerable information needs to be communicated, and increasing the surface area of medication containers is one way to enable use of larger, more legible print. There are other methods of extending the surface area of labels. One, a foldout method, is used on some labels of Aleve® (Procter & Gamble, Cincinnati, OH) pain reliever. Additional research will help to determine the factors that enhance people's knowledge of pharmaceuticals.

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