The Ordering of Over-the-Counter Pharmaceutical Label Components

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ABSTRACT

Recently there has been increasing interest in enabling consumers to more easily acquire information from over-the-counter (OTC) nonprescription pharmaceutical labels. Standardization of the format of labels is being considered by industry, government, and health-related professional organizations as a way to facilitate their usability. Potentially standardization could assist consumers in quickly locating information that they need to use the medication safely. The purpose of the present research is to determine whether consumers have a consistent preference for the ordering of information (component headings) on OTC drug labels. If so then this could serve as a partial basis for standardization. Results showed relatively consistent orders across four drugs and three participant groups (adults attending a flea market, senior citizens, and undergraduates). In general, the data indicate that people prefer that labels first provide what the drug is used for (indications); second provide information on associated hazards (warnings, cautions, drug interaction precautions) and use (directions); and third provide information on active ingredients. The remaining components were preferred in the following order: whether the package is safety sealed, inactive ingredients, storage instructions, manufacturer information, and then finally the bar code. Given the reasonable consistent orders generated by participants it seems plausible that if standardization were implemented that the ordering would roughly reflect this basic ordering.

INTRODUCTION

In recent years, there has been a trend for consumers to take on more responsibility for their health and medical care. In accord with this, there has been increased interest in better enabling consumers to more easily acquire information from over-the-counter (OTC) nonprescription pharmaceutical labels (FDA Public Hearing, 1995). One set of proposals being considered by industry, government, and health-related professional organization is OTC label standardization. This interest derives in part from the highly successful nutrition label in the U.S. that was mandated in 1990 through passage of the Nutrition Labeling and Education Act (NLEA). The NLEA requires most food products to have "Nutrition Facts" labels (Federal Register, 1991) with a standardized content and format, e.g., placement of information, wording, serving sizes, etc. (Wogalter, Kalsher, and Litynski, 1996).

Widespread belief that standardized labels is beneficial is also apparent in the American National Standards Institute's (ANSI, 1991) guidelines for consumer product warnings, ANSI Z535.4. This standard specifies particular formats, styles, colors, and words for warning labels, based on the idea that having a consistent look will aid consumers.

What are the potential benefits of standardized labels, and in particular OTC labels? One possible advantage of a uniform format is that consumers will be able to quickly and efficiently locate the information on the label (Wogalter and Kalsher, 1994). This may be important when comparing OTC products in the store, or critical when determining in an emergency medical situation whether a particular medication is appropriate. Consistency in format has been shown to be beneficial in other domains. For example, search speed and accuracy is facilitated by preserving information groupings across computer display panels (Tullis, 1984) and by consistent placement of commands menus and other categorized lists (Somberg, 1987). Also, standardization may help certain groups of individuals (e.g., the lay public, but most particularly, the elderly) to become more familiar with the expected location of relevant information on drug labels.

In recent testimony given to the U.S. Food and Drug Administration on OTC Drug Labeling, the American Pharmaceutical Association (APhA) (1995) focused on four categories of information for possible standardization: (1) primary use of the product; (2) dosage; (3) cautions and major side effects associated with the product's proper use; and (4) active ingredients. However, the APhA offered no recommendations on the order or format of such information on OTC drug labels. In addition, the Nonprescription Drug Manufacturers Association has proposed a standard format for OTC labels, but has offered no empirical performance data to support its utility with lay consumers.

Unlike posted warning signs which generally describe a single hazard with only a few words, OTC drug labeling usually contains substantial amounts of information. Important information can be buried in other less important information. The question addressed in the present research is how to best sequence this information so that consumers

will be able to find what they need when they need it. Possibly some sort of prioritization scheme can be found based on pre-existing consumer expectations that will facilitate information search.

Recent research on the ordering of warnings in product operators' manuals offers some guidance for OTC label prioritization. Product manuals, like many OTC labels, contain substantial amounts of information. Research suggests that how safety warnings are sequenced in a list can determine the extent to which product manual warnings are read. Using focus groups, Showers, Celuch, and Lust (1992) noted that presenting obvious (already well known) warnings first in a list might deter the reading of subsequent (lesser known) warnings in the list. However they were unable to verify this finding in a subsequent experiment (Lust, Celuch, and Showers, 1995). In other recent research, Vigilante and Wogalter (1996) used an empirical procedure to determine a preferred ordering of safety warnings for various power-tool manuals based on perceived importance by lay consumers.

The purpose of the present study is determine whether a consistent ordering of components based on consumer expectations can be found for OTC drug labels. The procedure employs a technique similar to that used by Vigilante and Wogalter (1996) for the prioritization of product manual warnings Similarly, Morrow, Leirer, Altieri, and Tanke (1991) found that elders tended to group and order prescription drug information into three categories: (a) general information: with doctor's name first, medication name second, and purpose third; (b) how to take: dosage ordered fourth, schedule fifth, duration sixth, and warnings seventh; and (c) possible outcomes: mild side-effects eighth, severe side-effects ninth, and emergency information last.

It is possible that peoples' judgments of the importance of OTC label components depend on the particular drug. For some medications, the warnings and cautions may be viewed as the most important, whereas for other medications, the indications (what the drug is used for) may be viewed as the most important. Moreover, consumers' judgments may depend on demographic membership, or the situation in which the drug is taken. If so, then it might not be possible to find a consistent ordering that could be used for all OTC medications to benefit consumers under most circumstances. However, if a consistent ordering of label information is found, then the issue becomes: what is its form?

In the present investigation, information from four actual OTC drug labels was used, and three populations of consumers (adults attending a flea market, senior citizens, and undergraduate students) were sampled. They ordered label components according to four specific label-use scenarios and one general (overall) best order.

METHOD

Participants

A total of 140 individuals participated. They were composed of three subgroups. One consisted of 50 adults solicited at a flea-market in Raleigh, NC (42% females); they had a mean age of 38 (*SD* = 10.57) ranging from 23 to 60. They reported their highest attained educational level as follows: 6% did not complete high school, 8% completed high school, 28% had some college or trade school, 44% had a bachelors degree, 2% had some post-graduate study, 8% had a masters degree, and 4% had a doctoral degree.

A second subgroup consisted of 40 senior citizens recruited from a retirement community in Chapel Hill, NC (60% females); they had a mean age of 78 (*SD* = 7.35) with ages ranging from 61 to 91. They reported their highest attained educational levels as follows: 5% completed high school, 7.5% had some college or trade school, 32.5% had a bachelors degree, 15% had some post-graduate study, 17.5% had a masters degree, and 22.5% had a doctoral degree.

A third subgroup consisted of 50 undergraduate students from North Carolina State University, who received credit in their introductory psychology course (60% females); they had a mean age of 19 (*SD* = 1.76) ranging from 17 to 25.

Stimulus Materials

The material used as the stimuli came directly from the text of four actual (store-bought) OTC pharmaceutical products: (a) Marezine® (for motion sickness), Himmel Pharmaceuticals Inc., Hypoluxo, FL; (b) Tavist-D® (antihistamine/nasal decongestant), Sandoz Consumer Pharmaceuticals Div., East Hanover, NJ; (c) Nytol® (sleep aid), Block Drug Company Inc.; Jersey City, NJ; and (d) New-Skin® (liquid bandage), Medtech Laboratories Inc., Jackson, WY. The four drugs represent a sample of available OTC products that consumers might purchase and administer without the advice of a trained professional health-care provider. The drugs Tavist-D® and Nytol® are frequently-advertised products and are probably familiar (in name and its potential use) to most U.S. citizens, whereas the drugs Marezine® and New-Skin® are lesser known products. Informal interviews during debriefing confirmed the differences in familiarity between the two pairs of products.

Table 1 shows the headings in the order that they originally appeared on the labels. Tavist-D® and Nytol® each contained ten components while Marezine® and New Skin® only contained nine. Headings and associated textual material were re-printed in 46-point bold and 12-point regular Times font, respectively. The print size was enlarged (and held constant) from the actual drug labels so as not to introduce another confounding variable, print size. Issues associated with print size on drug labels has been investigated in other research (e.g., Wogalter and Dietrich, 1995; Wogalter, Magurno, Scott, and Dietrich, 1996). Each heading was accompanied by its associated text and printed on separate 10.2 x 15.2 cm (4 x 6 inch) cards.

Procedure

Participants first completed a consent form and then a questionnaire requesting demographic information such as

gender, age, and highest educational level. Participants were told that they would be ordering a set of label components from four actual nonprescription medications. They were told to arrange these headings considering five scenarios in which they might need to consult the label.

Participants were asked to sort the heading-text cards (label components), in the best possible order, given each of the following five situations:

(1) *Purchasing*: When you are deciding whether to buy the drug;
(2) *Taking the medication*: When you are about to take the drug;
(3) *Administering to another individual*: When you are deciding whether to give the drug to another person;
(4) *Emergency*: When you are involved in a medical-crisis situation (e.g., an overdose or allergic reaction);
(5) *For all situations*: Given there will be only one order on the label and considering all possible situations that the label would be consulted.

The participants were first given one of the first four scenarios (in a randomized order for each participant) and asked to sort the cards for each of the four drugs (randomized before every scenario). After completing the ordering of components for the four drugs for one scenario, the sequence was repeated for another scenario, and this procedure continued until all drug labels were sorted with respect to the first four scenarios. The first four scenarios set the stage for the fifth judgment, always presented last, that asked for the best possible ordering for each of the drugs. After the participants sorted each drug for every scenario, they were debriefed, thanked, and released.

RESULTS

Only the data from the fifth scenario (all situations in which the label would be consulted) are presented in this article. An enlarged description of this study with analyses for all scenarios will be available in a future report.

Table 1

Order of Component Headings on Actual Labels of the Four Drugs.

Marezine®	*Tavist-D®*	*Nytol®*	*New Skin®*
Indications	Indications	Safety Sealed	Indications
Directions	Directions	Active Ingredients	Caution
Warnings	Warnings	Inactive Ingredients	Directions
Active Ingredients	Drug Interaction Precaution	Indications	Warnings
Inactive Ingredients	Active Ingredients	Directions	Storage
Storage	Inactive Ingredients	Warnings	Active Ingredients
Manufacturer	Storage	Storage	Manufacturer
Bar Code	Bar Code	Caution	Bar Code
Safety Sealed	Safety Sealed	Manufacturer	Safety Sealed
	Manufacturer	Bar Code	

The orders were converted to rank scores with low numbers representing positions closer to the top of label. Table 2 shows the mean rankings for each component for each participant group separately as well as composite mean rank for all participants (using an unweighted means computation).

The component orders for each drug and participant group were first analyzed using the nonparametric multi-condition within-subjects Friedman test. All were significant, $ps<.0001$. These analyses were followed by paired comparisons among label components using the Wilcoxon Matched-Pair Signed-Rank test. Because there were as many as 36 pairwise comparisons among components for each drug, experiment-wise alpha error rate was controlled by using the Bonferroni correction technique which indicated the use of a .001 probability level for establishing significance.

Results of the Wilcoxon test for the four drugs can be found in Table 2. The headings in this table are ordered by mean rank for all participant groups combined. The subscripts following each of the components in the table indicate which components are significantly different, $p<.001$, from other components within each drug/participant grouping. Components with the same letter subscript are not significantly different. As can be seen in the table, across the three population groups and four drugs, the ordering of components is reasonably consistent. Generally, the components are arranged in the following order: (1) the Indications component was always ranked first; (2) the next set of components was personal hazard information (including Warnings, Caution, and Drug Interaction Precautions) and Directions, (3) the third grouping tended to consist of Active Ingredient, Safety Sealed, and Inactive Ingredients, and (4) lastly by separate groupings of Storage, Manufacturer, and Bar Code, in this order.

While the relative order among components did not vary much, the clusters of statistically significant differences among the components varied depending on drug and group examined. The senior citizens showed the fewest distinct groupings among the label components (indicating that they were somewhat more variable in their orderings). The flea market adults and students were less variable and most similar in terms of order and number of distinct groupings of components. The student population's orderings most closely resembled the overall (all) headings' orderings for the drugs Marezine®, Nytol®, and New-Skin®. The flea-market group most closely resembled the overall (all) heading's ordering for the drug Tavist-D®.

DISCUSSION

This study provides evidence for the existence of a preferred order of drug label components that is reasonably consistent across drugs and participant groups. If people did not have an ordering preferences, then the components would

Table 2

Label Components Ordered by Mean Rank for Each Drug and Population Group.

All (N = 140)		*Students (N = 50)*		*Flea Market (N = 50)*		*Seniors (N = 40)*	
Marezine®							
1.63[a]	Indications	1.52[a]	Indications	1.70[a]	Indications	1.68[a]	Indications
2.63[b]	Warnings	2.40[b]	Warnings	2.40[ab]	Directions	2.55[ab]	Directions
2.81[b]	Directions	3.42[c]	Directions	2.68[b]	Warnings	2.85[b]	Warnings
4.41[c]	Active Ingredient	4.40[c]	Active Ingredient	4.30[c]	Active Ingredient	4.53[c]	Safety Sealed
4.76[c]	Safety Sealed	4.58[cd]	Safety Sealed	5.12[cd]	Safety Sealed	4.58[c]	Active Ingredient
5.59[d]	Inactive Ingredients	5.66[de]	Inactive Ingredients	5.30[d]	Inactive Ingredients	5.85[cd]	Inactive Ingredients
6.47[e]	Storage	6.26[e]	Storage	6.66[e]	Storage	6.50[d]	Storage
7.76[f]	Manufacturer	7.78[f]	Manufacturer	7.88[f]	Manufacturer	7.58[e]	Manufacturer
8.96[g]	Bar Code	9.00[g]	Bar Code	8.96[g]	Bar Code	8.90[f]	Bar Code
Tavist-D®							
1.87[a]	Indications	1.80[a]	Indications	1.74[a]	Indications	2.13[a]	Indications
2.95[b]	Warnings	2.58[ab]	Drug Interaction Precaut.	2.34[ab]	Warnings	2.58[ab]	Directions
3.16[b]	Directions	3.12[b]	Warnings	2.52[b]	Directions	3.25[ab]	Drug Interaction Precaut.
3.19[b]	Drug Interaction Precaut.	4.28[c]	Directions	3.76[c]	Drug Interaction Precaut.	3.53[b]	Warnings
5.41[c]	Active Ingredient	5.28[c]	Active Ingredient	5.36[d]	Active Ingredient	5.63[c]	Active Ingredient
5.79[c]	Safety Sealed	5.34[cd]	Safety Sealed	6.30[de]	Safety Sealed	5.73[cd]	Safety Sealed
6.80[d]	Inactive Ingredients	6.60[de]	Inactive Ingredients	7.10[ef]	Inactive Ingredients	6.68[d]	Inactive Ingredients
7.34[d]	Storage	7.26[e]	Storage	7.46[f]	Storage	7.30[d]	Storage
8.55[e]	Manufacturer	8.74[f]	Manufacturer	8.42[g]	Manufacturer	8.48[e]	Manufacturer
9.96[f]	Bar Code	10.00[g]	Bar Code	10.00[h]	Bar Code	9.85[f]	Bar Code
Maximum Strength Nytol®							
1.70[a]	Indications	1.70[a]	Indications	1.58[a]	Indications	1.85[a]	Indications
3.06[b]	Warnings	2.88[b]	Warnings	2.34[b]	Directions	3.08[b]	Warnings
3.27[b]	Directions	3.20[b]	Caution	3.22[c]	Warnings	3.23[bc]	Directions
3.42[b]	Caution	4.24[c]	Directions	3.40[c]	Caution	3.73[cd]	Caution
5.24[c]	Active Ingredient	5.18[c]	Active Ingredient	5.40[d]	Active Ingredient	5.13[e]	Active Ingredient
5.79[cd]	Safety Sealed	5.42[cd]	Safety Sealed	6.32[de]	Safety Sealed	5.58[def]	Safety Sealed
6.61[d]	Inactive Ingredients	6.54[de]	Inactive Ingredients	6.70[e]	Inactive Ingredients	6.58[fg]	Inactive Ingredients
7.49[e]	Storage	7.16[e]	Storage	7.86[f]	Storage	7.43[g]	Storage
8.36[f]	Manufacturer	8.68[f]	Manufacturer	8.20[f]	Manufacturer	8.18[h]	Manufacturer
9.99[g]	Bar Code	10.00[g]	Bar Code	9.98[g]	Bar Code	9.98[i]	Bar Code
New Skin®							
1.93[a]	Indications	1.70[a]	Indications	1.96[a]	Indications	2.18[a]	Indications
2.94[b]	Caution	2.82[b]	Caution	2.24[ab]	Directions	2.88[abc]	Directions
3.06[bc]	Directions	3.20[bc]	Warnings	2.98[b]	Caution	3.03[ab]	Caution
3.59[c]	Warnings	4.04[cd]	Directions	3.80[c]	Warnings	3.83[bd]	Warnings
5.14[d]	Safety Sealed	4.74[de]	Safety Sealed	5.20[d]	Active Ingredient	4.78[cde]	Safety Sealed
5.20[d]	Active Ingredient	5.22[e]	Active Ingredient	5.84[de]	Safety Sealed	5.18[e]	Active Ingredient
6.61[e]	Storage	6.52[f]	Storage	6.60[e]	Storage	6.75[f]	Storage
7.59[f]	Manufacturer	7.76[g]	Manufacturer	7.44[f]	Manufacturer	7.58[f]	Manufacturer
8.94[g]	Bar Code	9.00[h]	Bar Code	8.94[g]	Bar Code	8.88[g]	Bar Code

Note. Pairwise comparisons between mean ranks for components of each drug and population group. Components with different letter superscripts are significantly different at the .001 level.

be ordered randomly and there would be no (or a few as a result of chance) statistically significant differences between the components.

The orderings found in this study indicate that people expect/desire labels first to tell what the drug is used for (Indications); second, to tell about the hazards associated with the drug (Warnings, Cautions, Drug Interaction Precautions) and how to use the drug (Directions); third about the chemicals involved (Active and Inactive Ingredients) and whether the container is Safety Sealed; followed by information on Storage, the Manufacturer, and lastly by the Bar Code. These results are similar to those reported by Morrow et al. (1991) which found that elderly people prefer prescription drug information to be ordered according to (1) what the product is and/or used for, (2) how the drug should be taken, and (3) warnings and hazards associated with the drug along with emergency information. As with the results found by Morrow et al. (1991) the orderings are likely to be based on peoples' mental models of how to take the drugs. Making use of consumers pre-existing cognitions when designing OTC labels is likely to benefit proper use.

Three of the drugs tested in present study (Marezine®, Tavist-D®, and New Skin®) yielded component orderings that are similar to the original orderings of the components on the drugs' original labels. The component ordering Nytol®, however, varied greatly from the label.

Given the reasonable consistent orders generated by participants it seems reasonable that if standardization were implemented that the ordering would roughly reflect this basic ordering. There are, however, other factors that may be important for OTC label standardization-related decisions that still need to be addressed in research. These include:

(1) a consideration of the size of sections relative to the label configuration and size (e.g., some sections maybe too long for a single column of text on some containers and may not fit or look right in some label arrangements);
(2) whether pictorials/icons, if any, should be included;
(3) the possible need for flexibility when a drug has critical lesser-known risks that need to be communicated to consumers;
(4) whether to use bullet-type marks to highlight main points; and
(5) how to make the tradeoff between print size and white space for label design.

Future research should be conducted to determine whether a standard preferred ordering of information does in fact facilitate information search and acquisition. For this determination, performance (e.g., reaction time and accuracy) in information search tasks could be measured.

Investigation is also needed on potential negative effects of label standardization. A potential downside of standardizing OTC drug labels is that consumers may habituate to them and not notice important safety information. Problems can also arise if a product is changed in some fashion (e.g., a revision in ingredients or dosage); consumers may become so accustomed to a particular format that they may not notice subtle differences. Trying to communicate new information might (or might not) be more difficult with standardized labels than without.

Other potential problems with standardizing drug labels include: deciding which headings should be contained on all labels (and which might be optional), what the names of the headings should be, and where information should be placed. Of the four drugs used in this study none had exactly the same set of headings. Also, information found under one heading for a particular drug was sometimes listed under a different heading for another drug.

The problems of standardizing OTC-drug labels can be addressed through research. Label designs and formats should not be based only on information from focus groups or expert judgments but should also include evaluations from consumers using performance measures to empirically determine whether the labels are usable. Research conducted for the purpose of finding the best ways to present information is likely to benefit consumers by facilitating knowledge acquisition and prevent potential negative outcomes from inappropriate medication use.

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