Over-The-Counter (OTC) Drug Labeling: Format Preferences

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Abstract

The present research examines two different consumer groups' perceptions of the readability of OTC medication labels. Twelve labels depicting an OTC medication with a fictitious name were constructed and attached to bottles. The labels varied in (a) print size (4 point, 7 point, 10 point), (b) amount of white space between lines or sections of text (no spacing; label section spacing; and line spacing), and (c) label design (standard vs. extended/pull-out). Ninety-nine older adults and 102 undergraduates rank-ordered the labels according to overall ease of reading. In general, participants preferred the labels printed with larger type and line spacing. White space appeared to have less influence over the rankings than print size for older adults. However, the use of both a larger print size and increased white spacing appeared to influence the undergraduates' ratings. Also, there was no clear preference between the extended and standard label designs but their evaluation was only conducted with for the small print conditions. The implications of these results for the design of OTC medication labels and other consumer products are discussed.

Introduction

In recent years, consumers have assumed more responsibility for their health and medical care. Accordingly, there has been increased interest in better enabling consumers to more easily acquire information from over-the-counter (OTC) nonprescription pharmaceutical labels (Federal Drug Administration, 1995). Manufacturers present OTC drug information in a variety of ways including: packaging, inserts, and most commonly on the drug container itself (Wogalter, Magurno, Dietrich, & Scott, 1999). The need to include all this information on a drug label is problematic when the surface area of a label is relatively small.

One way to accommodate all the drug information is to decrease the print size to fit the information on the drug container's label. However, the decreased print size may be too small to be read by people with poor vision, such as older adults (Vanderplas & Vanderplas, 1980). The problem of using tiny print is exacerbated by the fact that older adults are the largest consumers of pharmaceuticals (Morrow, Leirer, & Skeikh, 1988). Morrow et al. (1988) reported that 40-45% of older adults do not take their medications properly due to poorly designed instructions. A second way to accommodate all of the important information on small surface areas is to use package inserts. The problem with this alternative is that these loose inserts may be discarded or misplaced, and if so, they are of little help when the drug is used at later times (Wogalter, Forbes, & Barlow, 1993). Thus, there is a tradeoff between having legible print size and content completeness for labels directly attached to OTC drug containers.

The drug industry, US government, and health-related professional organizations have proposed OTC drug label standardization as a solution to this tradeoff. These organizations also believe that standardization will help consumers read and better understand OTC drug label information (Federal Register, 1999). This interest in standardization derives in part from the highly successful nutrition label that was mandated in the US 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 standardized content and format, e.g., wording and placement of information (e.g., Wogalter, Kalsher, & Litynski, 1996).

Recently, the FDA has established a set of regulations governing the standardization of OTC drug labels. The regulations deal with such issues as minimum print size and white spacing; standard ordering and layout of label information; and the use of consistent language on OTC drug labels (Federal Register, 1999). The purpose of the regulations is to assist consumers in reading and understanding OTC drug labels that will ultimately enable consumers to use OTC drugs safely and effectively (Federal Register, 1999). The purpose of the present research is to examine the tradeoff between print size, white space, and surface area and how these variables affect the perceived readability of OTC drug labels. Although OTC labels were used in this study, the principles derived from the research may be applicable to labels for other types of consumer products.

Issues Associated with Label Designs

The US FDA mandates that certain types of information need to be present on all OTC drug labels. FDA regulations requires the label to state what the drug is used for, how to use the drug safely and effectively, warnings and drug interaction precautions, information on the drug's active and inactive ingredients, and what to do in case of emergencies (Nonprescription Drug Manufacturers Association, 1996). Typically, this mandate results in a large amount of information that needs to be communicated on a drug's label.

Recent research has been conducted to determine the best way to order this information on OTC drug labels. Vigilante and Wogalter (1997) empirically determined an ordering of OTC label components based on users' beliefs about what was most important. The resulting component orders were similar to orderings found by Morrow et al. (Morrow, Leirer, Andrassy, Tanke, & Stine-Morrow, 1996) using prescription drug labels. Also the NDMA (1995) and the American Pharmaceutical Association (Engle, 1995) have made recommendations to the FDA on how to order drug label information. These recommendations include placing the indications and warnings before other label information.

Besides the ordering of information components, other formatting factors can be standardized to facilitate the reading of OTC labels. Such label formatting factors include the size of the print and the amount of white space between chunks of text. The amount of information that needs to be communicated to consumers, and the label area available to present the information, dictates the size of the print and the spacing of the information. The need to accommodate the complete set of information usually results in OTC drug labels that are printed in small fonts with relatively little unused space. Small print size and lack of white space can be detrimental to a person's ability and willingness to spend the time and effort needed to read the OTC label, particularly persons with poor vision or when they are sick.

Label Space

Recent research has examined the benefit of using the surface space of a supplemental container label to present important information to consumers on OTC drug containers (Wogalter, Magurno, Scott, & Dietrich, 1996). Wogalter et al. (1996) attached a label to the space on an "easy-open" container cap. The authors found that participants, including older adults, had greater medication-related knowledge after viewing OTC drug bottles with a supplemental cap label, compared to OTC drug bottles without the supplemental cap label. Kalsher, Wogalter, and Racicot (1996) found that college students and older adults preferred prescription drug containers that used two alternative label designs (a tag and a fold out label) with more surface space over a conventional label design with less surface space.

Recently, the FDA has recommended the use of supplemental label space for OTC drug containers that are too small to hold all the necessary drug information (Federal Register, 1999). Specifically, the FDA suggests extending a single side panel on small OTC drug containers, to increase the amount of label space in which to print the necessary information (Federal Register, 1999). The first purpose of the present research is to empirically determine if people prefer an extended panel label design.

Print Size

In recent years, research has examined the effects of print size on people's ability and willingness to read warnings and other consumer information. Young, Laughery, and Bell (1992) found that the width space for individual letters affects the perceived legibility and reading speed of printed warnings. Participants preferred normal type widths (100% of the font size) to the smaller type widths (60% and 35% of the font size). Reading speed also differed depending on type width, with the smallest type width (35%) producing significantly longer reading times than the larger type widths (100% and 60%). These results suggest that people may be less likely to read warnings that use very dense print because of the increased effort required to read the compacted text. Another study involving a laundry detergent product found that labels printed in 10-point font were perceived as more readable compared to labels printed in 8-point font (Silver & Braun, 1993).

Research by Smither and Braun (1994) investigated the effects of font type (Century Schoolbook, Courier, and Helvetica), font size (9, 12, and 14 point), and font weight (Roman and Bold) on medication label reading speed and various other dimensions. Younger and older adults were timed as they read several medication labels that were placed on a medication bottle or a flat piece of cardboard (each label differed in font type, size, and width). They found that participants took longer to read the labels printed in 9 point font compared to labels printed in 12 and 14 point fonts. Also, the labels printed in the 14 point font were judged by participants to be easier to read than the labels printed in the 12 and 9 point fonts.

An implication of the preceding research is that people will be less likely to expend the mental energy to read information on densely printed labels. The issues concerning the effects of print size on people's ability to read text has prompted the FDA to mandate that all information on OTC drug labels be printed in a font no less than 6 points. The present research examines people's preference of type printed in several sizes (4, 7, and 10 point font) on an OTC medication label.

Text Grouping and Spacing

Research has also looked at the effects of varying the amount of white space between text on reading performance and preference. Wogalter and Post (1989) looked at the effects of presenting instructions in a paragraph format versus a list format and the addition of screen pictographs on people's response time and accuracy in performing a series of tasks using a computer tutorial. Results indicated that list format instructions that included screen pictographs yielded fewer errors and help requests and decreased task completion times. The authors suggested that the list format allowed participants, particularly those familiar with the computer system, to scan the instructions for keywords. Other research has indicated that information grouping can facilitate the search and acquisition of information (Tullis, 1983). Also, research suggests that list formats allow information to be chunked into meaningful units thereby facilitating comprehension (Frase & Schwartz, 1979).

Increasing the vertical spacing between text has also been shown to facilitate people's reading comprehension (Hartley, 1978). Hartley (1984) has shown that line space between paragraphs helps sections of textual information stand out from the rest of the information, facilitating reading. Recently, Hartley (1999) recommended the use of line spacing to separate sections of medication label information.

Morrow et al. (1998) has also found that increasing the amount of spacing in prescription drug label text can facilitate reading. In two experiments Morrow et al. (1998) found that labels arranged in a list format produced better comprehension and recall performance by older and younger adults compared to labels arranged in a paragraph format. Furthermore, the list format reduced the differences in label comprehension between the older and younger adults. Morrow et al. (1998) concluded that list-organized instructions benefit comprehension and recall of medication information.

The preceding research suggests that grouping or chunking of information by separating them with white spacing is beneficial. Hartley recommended the use of line spacing between sections of medication label information. However, Morrow et al. (1998) recommend using a list format. The present research tested three white spacing formats that reflected the above-mentioned recommendations. The white space formats compared in the present study consisted of no spacing, section spacing, and line spacing.

Present Research

The purpose of the present research is to determine the effects of two different label designs, increased print size, and increased white spacing on consumers' perceptions of OTC drug label readability. Twelve labels depicting an OTC medication with a fictitious name were constructed and attached to bottles. The labels varied in (a) label design (standard versus extended/pull-out), (b) print size (4 point, 7 point and 10 point) and (c) amount of white spacing between lines/sections of text (which consisted of no spacing, section spacing, and line spacing). Older adults and college students were sampled to determine the stability and generalizability of the research findings across different consumer populations. Participants rank ordered 12 different OTC drug container labels according to overall ease of reading.

Method

Participants

Two populations were sampled. One group was comprised of 102 undergraduates from introductory psychology courses at North Carolina State University; students participated for course credit. Fifty-six percent of the students sampled were female. Students reported a mean age of 21 years old (ranging from 18 - 37 years old). The student sample was comprised of 79% Caucasian, 11% African-American, 6.4 % Asian, 1.8 % Mid-Eastern, and 0.9 % Hispanic. Thirty-five percent of the students reported wearing corrective lenses.

Ninety-nine older adults from several retirement communities in the Raleigh, North Carolina area also participated for a small donation (77% female). The seniors reported a mean age of 78 years old (ranging from 58 to 92 years old). All were Caucasian. The use of eyeglasses for reading was reported by 96% of the participants. Participants reported their highest attained educational level as follows: 16% completed high school, 27% had some college or trade school, 16% had a bachelors degree, 11% had some postgraduate study, and 28% had a graduate degree.

Design and Materials

Twelve of the same commonly-used OTC medication bottles were used, along with 12 newly constructed labels. The bottles and labels were constructed to look as realistic as possible. The bottles measured 19 X 9.5 X 5.5 cm (for height, width, and depth respectively). The bottles were all light bluish-green plastic with a metal screw-on lid. All bottles were stripped of their original labels and the experimental labels were pasted to the bottle surface. The bottles also contained front and side marketing labels, which were held constant across all bottles. All labels were printed on a laser printer using an 800 dpi setting with Postscript fonts.

The information for the front, side, and back labels were taken from an actual OTC motion sickness medication sold in stores. However, each bottle's back label was formatted differently and corresponded to the 12 experimental label conditions listed in Table 1.

All of the back labels contained exactly the same information, only the formatting differed. The 12 experimental label conditions were developed using a 3 (print size) X 3 (white spacing) X 2 (label design) design. The actual experiment was not a complete factorial design because implementing all of the possible label format combinations on OTC drug containers would not be realistically implemented. Therefore, the following conditions that would have been part of a complete factorial design were not included: large print line spacing format extended label, and all the large and medium print standard label designs.

The three print sizes were: 4, 7, and 10 point for the small, medium, and large print size conditions, respectively. For all conditions, the back label information was printed in Helvetica-Narrow font type, which is similar to the font used on many OTC drug labels.

Text was continuous prose in the no spacing conditions. The different groupings of information (e.g., directions, warnings) were separated by a line space in the section spacing conditions. In the line spacing condition, each sentence started on a new line using double spacing.

A standard label design and an extended/pull-out label design were used in this study. For the standard label design all of the drug's back label information was printed on one side of a label that was attached to the back of a bottle. For the extended/pull-out label design all of the back label information was printed on three sides of a label that was folded in half. The front (first) side of the label folded out like a book cover revealing the second and third sides of the label. The back (fourth) side of the label was then attached to the back of a bottle.

Table 1. The 12 bottle label conditions.

Original Labels		
small print no spacing	small print section spacing	small print line spacing
Pull-out Labels		
small print no spacing	small print section spacing	small print line spacing
medium print no spacing	medium print section spacing	medium print line spacing
large print no spacing	large print section spacing	no label

Procedure

Participants were first asked to complete a consent form and a demographics questionnaire (e.g., age, gender, education background and eyeglass use). Participants were then given all 12 OTC motion sickness medication bottles and were told that the bottles were all identical except for the back labels. The experimenter orally described the format differences between the label conditions. The participants were instructed to rank order the bottles according to a combination of several criteria: which label formats were easiest, fastest and most comfortable to read. Participants were instructed to choose the bottle with the best label and place it to their left (assigned a rank score of one), then decide which label was next best (assigned a rank score of two) and so forth down to the worst label condition (assigned a rank order of 12). Participants were allowed to change their rank orders until they were satisfied. Ties were allowed in the ranking. Participants also completed a knowledge acquisition task prior to performing the ranking task; these data are not reported in this article.

Results

The data consisted of rank scores with lower numbers indicating greater preference (with respect to readability). The label conditions' rank order was first analyzed using the nonparametric multi-condition within-subjects Friedman test; this test was significant, $p < .0001$. This was followed by paired comparisons among the label conditions using the Wilcoxon Matched-Pair Signed-Rank test. Because there were 70 possible pairwise comparisons, the alpha error rate was controlled by using the Bonferroni correction technique, which indicated the use of a .0007 probability level for determining significance. The mean ranks, standard deviations, and statistically significant differences by participant group are shown in Table 2. Only the significant comparisons are described in the text below.

Older Adults

For older adults, large print was preferred over medium print which in turn was preferred over small print. Within the medium and small print conditions, line spacing was preferred over the no spacing conditions. There were no significant differences between the standard and extended labels between the comparable small-print conditions with which these two designs appeared.

Undergraduates

A similar pattern of rank order means was found for the student population. However, there were more statistically significant differences between these means compared to the older adult means. Large print section spacing was preferred over all other conditions except the medium print line spacing, which in turn was preferred over all other conditions except for large print no spacing. Large print no spacing was preferred over the medium print no spacing and all six small print conditions. Medium print section spacing was preferred over the medium print no spacing and all six small print conditions. Medium print no spacing was preferred over the six small print conditions.

Within the six small print conditions, line spacing was preferred over section spacing and no spacing. Also, section spacing was preferred over no spacing. As with the older adult data, there were no significant differences between the standard and extended labels for the comparable small print conditions.

Discussion

Participants preferred the use of larger print on labels and preferred line spacing to no spacing. Undergraduates and older adults differed in their preference for section spacing. Older adults did not have a significantly different preference for section spacing relative to either the line spacing or no spacing. However, undergraduates preferred the use of line spacing to section spacing and in turn preferred the use of section spacing to no spacing. Also, undergraduates did not prefer the use of a larger print with no spacing to the use of a medium print with section spacing. This suggests that white spacing influences younger adults to a greater extent than older adults.

No significant difference was found between the standard and extended label design. These two designs only co-occurred in comparable conditions in the small print conditions. However, in order to control label size (width and length) across the small print conditions, the no spacing and section spacing extended labels contained too much wasted white space at the bottom of the panels. In fact, many participants made comments about the wasted label space on the small print extended labels. Although the extended label design was not preferred over the standard label design for the small print conditions, the additional label space could be used to increase smaller print sizes on small containers and/or be used to include more hazard information. When questioned, during debriefing all participants agreed that the extended label design was a good way to include an increase in print size and allow for white spacing.

The present results correspond to some of the FDA regulations concerning the standardization of OTC drug labeling format (Federal Register, 1999). The FDA has set the minimum print size to 6 point font, although they encourage the use of the largest font size possible. The FDA requires the use of a horizontal line to separate the information under each major OTC drug label heading and to use a bullet format to list chunks of information. Finally, the FDA also encourages the use of an extended label design when surface area is limited on an OTC bottle.

The findings can also be applied to other consumer product labels, particularly products with small surface areas. Extended label designs, whether it is a pull-out, a tag, or a wing format (Kalsher et al., 1996), allow for the use of larger print and increased white space. Designing product labels in this fashion can make them easier to read. This may benefit consumers by facilitating their search for information and knowledge acquisition, which, in turn, can promote proper medication use and prevent negative outcomes.

Table 2. Mean rank for the 12 label conditions.

Print Size	White Space	Label Design	Older Adult MR	Older Adult SD	Older Adult Diffs	Undergraduate Student MR	Undergraduate Student SD	Undergraduate Student Diffs
Large	Section	Extended	1.62	0.99	a	2.09	1.57	a
Medium	Line	Extended	3.56	0.86	b	2.72	1.59	ab
Large	No	Extended	1.98	1.60	a	3.33	1.80	bc
Medium	Section	Extended	4.03	3.70	bc	3.70	1.31	c
Medium	No	Extended	4.56	1.36	c	4.91	1.32	d
Small	Line	Standard	7.27	2.47	d	6.28	2.08	e
Small	Line	Extended	7.77	1.74	de	6.80	1.59	e
Small	Section	Standard	8.27	1.97	e	8.07	2.06	f
Small	Section	Extended	9.21	1.57	f	8.42	1.38	f
Small	No	Extended	9.50	1.65	f	9.87	1.18	g
Small	No	Standard	9.75	1.49	f	9.88	1.88	g
No Back Label (Control)			11.87	0.75	g	12.00	0.00	h

NOTE.
(1) Lower rank scores indicate greater perceived readability.
(2) Print size: small (4 point), medium (7 point), or large (10 point).
White Spacing: no (no spacing), section (line spacing between main sections), or line (line spacing between listed statements).
Label design: standard or extended/pull-out.
(3) MR = Mean Rank; SD = Standard Deviation
(4) Diffs: Means with different letters are statistically different from each other at $p < .0007$ (Bonferroni correction).
(5) Not all factors are orthogonally crossed (e.g., there is no large print / line spacing condition)

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