A COMPARISON OF OLDER VS. NEWER OVER-THE-COUNTER (OTC) NONPRESCRIPTION DRUG LABELS ON SEARCH TIME ACCURACY

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ABSTRACT

The present study evaluated response time and accuracy to answer a series of questions of information in 16 (8 older and 8 newer 'Drug Facts') over-the-counter (OTC) drug labels. The newer labels include aspects, based on previous research, which should benefit performance. The results indicated that participant's response times were significantly faster with the newer labels compared to the older ones. However, this was not true of all OTC product samples. Accuracy was high (error rate low) for both label formats. Response times for females were significantly faster than males for both label types. The benefits of formatting text for facilitating information acquisition from drug labels and other kinds of printed information are discussed.

INTRODUCTION

In recent years, consumers are taking a more active role in their health and medical care. More consumers are seeking information about the potential benefits and side effects of the over-the-counter (OTC) nonprescription drugs they are currently taking. Effective labeling of OTC drugs is important because the general public would not otherwise know the risks, side effects, and contraindications associated with many types of drugs. A survey by Everett (1991), for example, indicates that people want to be informed of the benefits and risks associated with their medications. Accordingly, OTC drugs should have labeling that facilitates the ease of acquiring important drug information by consumers.

OTC drug manufacturers present product information in several formats: drug labels, inserts, and/or packaging (Wogalter, Magurno, Dietrich, & Scott, 1999). The problem with the latter two methods is that frequently consumers will not retain the inserts (Wogalter, Forbes, & Barlow, 1993) or packaging after opening the package (Cheatham & Wogalter, 2002). Consequently, any information that is included only in the inserts or on the packaging and not on the drug container itself may not be available when the consumer needs it. This suggests that the most important drug information should be included on the container label.

The necessary labeling for OTC drugs is extensive. There are several ways a container label could be configured to include necessary drug information. One method is to decrease the print size. Although this method may provide all the important information on the container label, it has the disadvantage that older adults or individuals with poor vision maybe unable to read it without external magnification devices. Research suggests that poorly designed drug information leads to a substantial number of older adults improperly taking their medications (e.g., Morrow, Leirer, & Sheikh, 1988). Another label configuration method is to use alternative label designs such as tags and fold-outs to increase the available surface area allowing for use of sufficiently large print and inclusion of more drug information (Kalsher, Wogalter, & Racicot, 1996; Wogalter & Vigilante, 2003; Wogalter & Young, 1994). Labels for some current OTC products incorporate aspects of these designs.

Another important aspect of label design is the ordering of the content. A study by Vigilante and Wogalter (1997) had participants sort sections of OTC drug labels (headings such as "Warnings and Directions") and text associated with the sections while considering several different scenarios of exposure to the drug (i.e., purchasing, consuming, administering to others, emergencies, and all situations). They found that younger and older adults produced similar orderings of sections across scenarios. Moreover, they found that for all scenarios besides emergencies, participants preferred the following order: indications, warnings, directions, active ingredients, safety seal, inactive ingredients, storage instructions, manufacturer information, and bar code. For emergency scenarios, the preferred order of the first three sections changed from indications, warnings, and directions to warnings, directions, and indications. All other sections in the emergency scenario remained the same as the other scenarios. The eventual orders used by the FDA when developing their 'Drug Facts' guidelines are similar, though not identical to that of Vigilante and Wogalter (1997). The eventual order is described in the next section.

OTC drug labels sold in the US must adhere to requirements set forth by the Food and Drug

Administration (FDA). Under 21 C.F.R. 201.66, the FDA is charged with regulating the format and content of OTC drug labels (FDA, 2001). Generally, the FDA provides minimum requirements that labels must meet. That is, the regulations do not specify everything that may be necessary to adequately capture consumer's attention and to easily and quickly convey necessary information about the drug.

OTC Labeling Requirements

Another important aspect of drug label design is how best to arrange them to facilitate information acquisition. In March 1999, the FDA passed a final rule requiring a newer standardized label, known as 'Drug Facts,' be used on all OTC drugs beginning on May 16, 2002 (FDA, 2002). The purpose of the rule was to provide a standardized design (e.g., consistent format, minimum font sizes, type style, etc.) across all OTC products and brands, to use less technical terminology, and to increase label readability through the use of clearly marked sections, bullets, and spacing between the lines. The final rule identifies eight sections that are organized in descending order: active ingredients, purpose, uses, warnings, directions, other information, inactive ingredients, and questions. For example, the rule with respect to warnings sections states that "this section contains information regarding when the product should absolutely not be used, drug-drug and drug-food interactions, when to consult a doctor or pharmacist before taking the product, possible side effects, and when to stop use and contact a doctor after taking the product" (FDA, 1999, pp. 13258-13259).

Prior to releasing the OTC final rule in 1999, the FDA conducted two studies (A & B) to determine whether the proposed format would increase OTC drug label understanding and readability and to identify consumer's preferences for certain OTC formats (FDA, 2002). Study A evaluated the effects of label format (older vs. proposed newer label), drug type (cold/cough & pain reliever), highlighting (more vs. less graphical design features), and consumer attention (divided vs. focused) on participant's response time and accuracy of answering questions about OTC drug labels (FDA, 2002). Participants were asked to evaluate one of the label formats with questions to assess their knowledge of the label content. The results indicated that the proposed newer label took less time to read, produced higher response accuracy, and was easier to understand than the old label. Similar results were found for labels with more "highlighting" (e.g., bold and italics font).

Study B evaluated the effects of "Warnings" and "Directions" order, "Active Ingredients" placement (top vs. bottom), use of "Medication Facts" title vs. no title, and section dividing lines (thin vs. thick) on participants preferences for 16 different OTC drug label variations (FDA, 2002). Participants were asked to rank the 16 labels from most to least preferred and to provide a detailed explanation for their top two choices. The results indicated that inclusion of the "Medication Facts" title was the most important factor in their preferences. None of the other three variables produced statistically significant differences.

Present Research

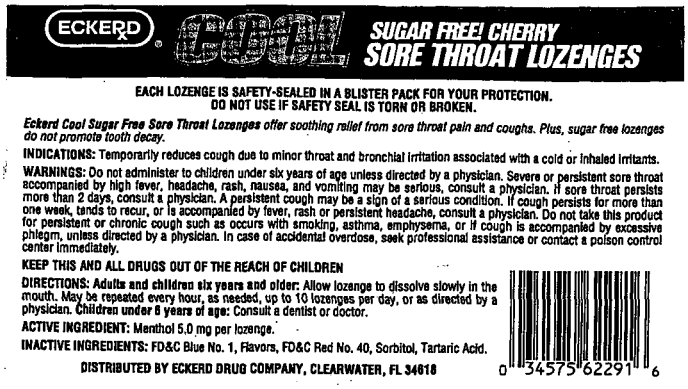
Several factors prompted the present study. First, the older (pre 1999 rule) labels had formats differing considerably from one label to the next, while the newer 'Drug Facts' labels make use of a consistent format. Moreover, the newer labels include formatting characteristics that are advocated in the Human Factors/Ergonomics literature (i.e., consistent format, major categories, varied font sizes, bullet points, etc.); each of which should aid in locating important information. Second, the FDA studies used proposed versions of the revised labels, not the actual format presently required, used only two drugs, used labels printed on sheets of paper and not on multisided boxes and cylindrical bottles. Third, no study has compared the newer label to the older as they were actually implemented on real products.

The purpose of the present research is to determine if differences in label design affect the ability to acquire information from the labels. More specifically, the present research sought to determine whether response time and accuracy of information acquisition are affected differently when comparing the older label to the newer label. Specifically, participants were asked to evaluate one of two sets of 16 products (8 older and 8 newer labels) and answer 10 questions for each. The experimenter recorded the amount of time it took to complete each set of 10 questions and the number of correct answers. It is expected that the consistent format of the newer labels should aid in locating important information, which means these labels should show a decrease in response time and an increase in accuracy compared to the older labels.

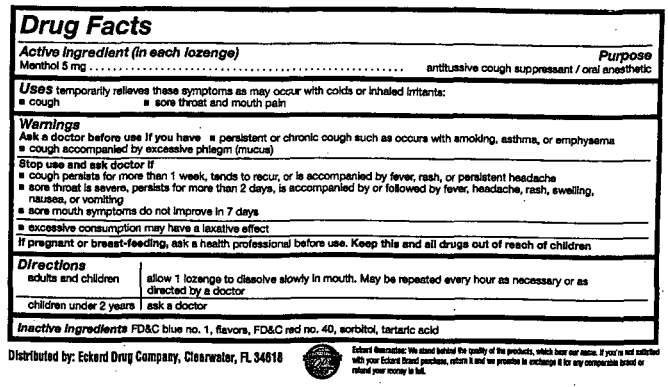
METHOD

Participants

Sixty-four undergraduate students ($M = 18.72$, $SD = 1.34$) from introductory psychology courses at North Carolina State University participated for research credit. Forty (62.5%) of the participants were female. The students were predominately Caucasian (78%), followed by African-American (12.5%), Asian (3%), and other (6.5%). English was the first language for 61 (95%) of the participants.



Older Label



Newer Label

Figure 1. Examples of the older and newer ('Drug Facts') OTC drug labels for Eckerd Cool

Materials and Design

Sixteen older and newer label drug products purchased over a three-year period at local pharmacies in the Raleigh-Durham, North Carolina area were used. Product names and the purposes (indications) of each medication are provided in Table 1. Many of the drugs were of the same classification (i.e., pain reliever, antihistamine, etc.), but none were exactly the same. Example labels are shown in Figure 1.

Participants received a 16-page packet (8 older and 8 newer labels) with each page having 10 questions for one drug. The sets of 10 questions were different for the 16 drugs, but all questions for a given drug concerned information that could be found on both the older and newer labels. All participants viewed all 16 drugs. The sets of drugs were counterbalanced such that half the participants viewed the older and newer labels for drugs in one packet that took the other format for the other half of the participants in the other packet.

All of the questions asked for a one-word or short-phrase answer that could be found on the label. Attempts were made to avoid questions that could be answered with high accuracy without actually looking at the labels. Below are some example questions:

- What is the maximum amount you can take in one day (24 hour period)?
- A doctor should be consulted if you are already taking a prescription drug for what condition?
- After how many days should you discontinue use?
- What phone number should be dialed if you have any questions or comments for the manufacturer?
- If you consume more than three alcoholic drinks per day, is it important to seek medical advice before using this product?

Procedure

Participants were tested individually. Each participant was given one of two 16-page packets. Participants were told that they would be given each drug product individually and that they should answer all of the questions in the order they were presented by writing short answers on the page as quickly and accurately as possible. The experimenter recorded the duration for participants to complete each page of 10 questions in seconds. Thus, there were 16 times recorded, one for each product per participant. Timing began after the participant was first handed the product and stopped when the answer for the tenth question was completed.

RESULTS

The means and standard deviations for question response times, in seconds, for the 16 older and 16 newer labels are provided in Table 1. In the first analysis, the data for each participant was collapsed across the individual labels in the older and newer label conditions. Thus each participant provided two scores in the response time analysis, each an average of the 10 questions for 8 labels. The response time and accuracy data were analyzed using a dependent samples t test. The response time results indicate that participants answered the 10 questions for newer labels ($M = 161.8$) significantly faster than they did for the older labels ($M = 170.8$), $t(63) = 3.11$, $p<.01$. The accuracy data did not show significant differences between newer ($M = 95.4\%$) and older ($M = 95.0\%$) labels, $t(63) = .87$, $p>.05$.

In terms of the means themselves, the table shows that for ten of sixteen of the drugs, the newer label showed a trend of faster response times, whereas six of sixteen showed the opposite trend. To determine whether there was significant difference between the two label formats for each drug, independent samples t tests using a

Table 1

Mean Response Times and Standard Deviations as a Function of Newer and Older Label Formats for 16 OTC Drugs Products. Product Names and the Purpose of Each Drug is Shown.

		Label Format			
		Old		New	
Product Name	Medication Purposes (Indications)	*M*	*SD*	*M*	*SD*
Alka-Seltzer	Analgesic, antacid	156.2	41.9	151.7	33.5
Anusol	Hemorrhoidal suppository	154.6	46.5	137.2	30.9
Bayer Arthritis Pain – Extra Strength	Pain reliever	213.6	51.5	154.7*	38.8
Benadryl – Allergy & Sinus Headache	Pain reliever, antihistamine, nasal decongestant	170.3	41.4	133.6*	28.3
Doans – Extra Strength	Pain reliever	184.8	43.2	149.5*	38.5
Eckerd Allergy Sinus – Max. Strength	Pain reliever/fever reducer, antihistamine, nasal decongestant	179.2	48.0	153.4	37.7
Eckerd Cool	Antitussive cough suppressant/oral anesthetic	169.4	42.0	134.1*	31.4
Eckerd Ibuprofen	Pain reliever/fever reducer	170.7	48.9	186.1	36.9
Mylanta	Antacid, antigas	150.2	27.7	128.5	31.6
Neo-Synephrine	Nasal decongestant	167.6*	35.1	212.4	54.5
Preparation H	Protectant, vasoconstrictor	164.9	37.3	191.0	42.4
Sleepinal – Maximum Strength	Nighttime sleep aid	152.4	46.2	163.5	29.0
Tinactin	Antifungal	151.8	40.2	137.0	31.5
Tylenol – Extra Strength	Pain reliever/fever reducer	185.8	50.5	133.6*	38.0
Vicks DayQuil LiquiCaps	Pain reliever/fever reducer, cough suppressant, nasal decongestant	185.4	55.9	200.7	45.2
Vicks NyQuil Liquid	Pain reliever/fever reducer, cough suppressant, antihistamine, nasal decongestant	176.5*	56.2	221.6	62.1
Mean		170.8	33.3	161.8	35.3

*$p<.05$

Bonferonni correction (to maintain familywise error at .05) were conducted separately for each drug. At an overall criterion of $p<.05$, five of sixteen showed significantly faster response times for the newer label compared to the older label, whereas, two (Neo-Synephrine and Vicks NyQuil Liquid) of the sixteen showed the opposite significant effect. Asterisks in Table 1 identify significantly different response times for older and newer labels, $p<.05$.

Subsequent analyses including demographic variables (gender, age, ethnicity) were conducted. A 2 (gender) x 2 (label condition: older vs. new) mixed-model analysis of variance (ANOVA) revealed significant effects for gender, $F(1, 62)=8.94$, $p<.01$, and label, $F(1, 62)=8.10$, $p<.01$; but not the interaction, $F(1, 62)=.38$, $p>.05$. Females ($M=157.50$) had faster responses than males ($M=180.97$). No significant effects were found using age or ethnicity demographics.

DISCUSSION

In general, the newer 'Drug Facts' labels resulted in significantly faster response times compared to the older labels. This suggests that formatting can improve the ease of acquiring important information from a drug label, allowing individuals to find the information easier and more quickly than the older labels. Moreover, these results confirm the findings of the FDA studies that used prototypes of the current 'Drug Facts' label (FDA, 2002).

Several reasons can be offered for the general finding of faster response times for the newer labels. First, the standardized label format allows for participants to learn

where each of the sections are located, which in turn decreases the amount of time needed to find specific information. The varied placement of sections for the different drugs in the older label does not allow this facilitation. Similar findings have been shown using food nutrition labels (Wogalter & Kalsher, 1994; Wogalter, Shaver, & Chan, 2002) and product manuals (Wogalter & Shaver, 2001). Second, the bulleted, list format of the newer labels have less print density than paragraph format (i.e., older label). Dense print has been shown to decrease response time (Goldberg, Probart, & Zak, 1999). Third, the newer labels tend to have larger sized print and line spacing. Research has shown that individuals prefer and recall more information from OTC labels with these characteristics than without them (Wogalter & Vigilante, 2003). Response accuracy between the two labels formats showed relatively high accuracy. This is not surprising given that participants were allowed to look until they found the requested information, resulting in a ceiling effect for accuracy.

The results showed that females completed the questions faster than males for both types of labels. The reason for this finding is not entirely clear. Previous research has suggested that females report they are more likely to read product labels then males (Larue & Cohen, 1987). It may be the case that women are more interested and experienced with OTC labeling, thus yielding a performance advantage over men. Also, the findings may simply be due to gender differences in verbal language ability.

It should be noted that of the sixteen OTC drugs, two (Neo-Synephrine and Vicks NyQuil) produced significantly faster responses with the older label compared to the corresponding newer label. For Vicks Nyquil, information on the newer label was printed on multiple sides of the product compared to the single panel on the older label. Thus, the newer labels for these products required greater physical manipulation of the product to find the same information than on the older label. However, it is unclear why the newer label on the Neo-Synephrine, which does not have the abovementioned characteristics, produced a slower response time.

Overall, the results support the notion that designing printed text with helpful formatting characteristics are advantageous in assisting people in acquiring information from printed materials, such as labels. Further research may show that this conclusion can be generalized to other risk-related documents such as product manuals, contracts, and informed consent forms. Future research will determine whether most documents can be benefited by the use of consistent well-designed formats that facilitate easy and quick information acquisition to assist in making informed decisions about risk.

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