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Improving Information Processing: The Effect of Label Format Among Current and Potential Over-the-Counter Medication Users

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Abstract

Objective: To test the effect of current versus 2 experimental label formats on information processing among current and potential over-the-counter (OTC) users. *Methods:* A cross-sectional survey was conducted in a cohort of adults across a metropolitan community, Houston, Texas. Three labels were designed. We placed a chunk of like information together (uses, direction, other information). Label A (control) followed the format of the existing FDA Drug Facts panel format for an antiallergy medication, label B had warnings placed before, while label C had warnings placed after the chunk. The 2 label designs were compared using the information-processing constructs derived from the OTC Label Evaluation Process Model (LEPM). *Results:* A multivariate analysis of covariance and Dunnett's test revealed that the mean scores for constructs of OTC LEPM were significantly better for label C compared to the control and label B ($P < .0001$). *Conclusion:* Our label format improved information processing among consumers but only when warning placement was placed at the end in the Drug Facts panel, giving an opportunity for the FDA to consider revising the format of the OTC Drug Facts panel, to improve patient understanding and reciprocally enhance patient safety.

Keywords

over-the-counter; label format; information processing; patient understanding

Introduction

Currently, 42% of the United States population consumes over-the-counter (OTC) medications, making it a US$19.1 billion market.[1] The popularity of OTC medications can be accounted for their easy availability and the freedom to choose.[2,3] The World Health Organization (WHO) strongly promotes the involvement and participation of patients in practicing self-care. OTC products provide autonomy to patients, which adds to their appeal.[4] However, this increased trend in self-care raises several patient safety questions.[5]

The safe and effective use of OTC medications is a responsibility of the patient, as it can be consumed in the absence of a health care professional.[6] This shift in decision making has several potential benefits, such as increased access, decreased health care costs, and consumer empowerment.[7] It is also accompanied by hazards such as inaccurate self-diagnosis, inappropriate use, and overdosage, which may in turn increase health care utilization while hampering patient safety.[8,9]

To ensure that a drug is consumed as intended, the label should be able to guide the medication-taking behavior of its end users.[6,7] Drug safety is associated with maximizing the potential benefits while minimizing the risks. It is imperative the drug be used for the appropriate indication while regulating dosage the way it is intended by the manufacturers and minimizing any potential for side effects.[10] Adverse events are anticipated to be relatively low with OTC medications compared to prescription medication. Thus, the package label becomes an important and useful tool to indicate any potential harmful effects, allowing a patient to practice effective risk management while debating the risk/benefit of taking the medication. Given labels are the only link of information between the manufacturer and the patient, as well as the expanding market of OTC medications, there is an increased need for more involvement by health care professionals, regulators, and manufacturers to design comprehensible OTC medication labels.

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Label assessment is an important aspect for regulators, patients, and manufacturers. For safe and effective use and to ensure complete benefit of OTC medication, the patient must be able to understand the label. The label should be able to tell a patient what symptoms and indications the drug is intended for. The US Food and Drug Administration (FDA) recommends that the label should be self-sufficient to communicate the right dosage, frequency of taking the drug, and possible contraindications, such as allergy or existing comorbid conditions, that may elevate the probable risk associated with the product.[6] Lastly, the label guides the ability to comprehend the gravity of the risks associated with warnings. If the label is lucid and correctly educates the patient, there may be a lower probability of adverse drug events.

OTC medications are responsible for multiple overdosage incidences and emergency room (ER) visits, among which half to two-thirds are unintentional.[1,4,11] The FDA has standardized the label format and content of the OTC Drug Facts panel in order to facilitate safe and effective use by patients.[1] FDA states labels as the most essential source of warning information during purchase and use of OTC products,[7] thus making OTC medication labels an essential aspect of the patient's medication consumption process. Because misunderstanding label information has been commonly identified in OTC medication use,[12] designing labels that improve patient understanding may reduce OTC-related medication errors.[13]

The proposed study compares 2 experimental labels developed on the concepts of information congruency, chunking, and hierarchy of information used on the current FDA-suggested Drug Facts panel of the OTC medication label. When the format of information provided matches the logic in the mind of the reader, it leads to congruency of information.[14,15] This information congruency is achieved when information with logical flow are placed together, defining them as a chunk of information.[16] However, within this chunk, it is essential to place information in the order of utmost importance in the minds of the patients, leading to hierarchy of information.[17,18]

This study applies the theory of CHREST[17,19] (Chunking Hierarchy and Retrieval Structures) and proposes that chunking information on a label and following a logical hierarchy will meet the schema (pattern) in the mind of the reader, thus improving information processing. This aids in understanding information, which will help patients follow the instruction on the label better and reduce the likelihood of unintentional adverse events. To our knowledge, no other study has focused on improving information processing by applying CHREST theory.

Our hypotheses were as follows:

Hypothesis 1: OTC medication labels with congruent information are better processed cognitively than the information provided using the current format by the FDA

Hypothesis 2: Information processing is affected by placement of warnings before as compared to after uses, directions, and other information on the Drug Facts panel.

Material and Methods

Study Design and Questionnaire Development

The study had a cross-sectional, randomized, between- and within-subjects experimental design and was conducted across the Texas Medical Center (TMC) in Houston, Texas. The participants were selected using convenient sampling. Potential participants were excluded if they could not read, write, speak, or understand English, as the study was tested among English-speaking participants. Participant demographics such as age, gender, level of education, and their most important source of information for OTC medications were measured. A previously validated questionnaire was used to measure the constructs of the OTC Label Evaluation Process Model (OTC LEPM).[20,21] The OTC LEPM postulates that, upon determination of the ease of reading the label, a patient comprehends the information on the label. The patient then performs product evaluation, which affects his or her intention to purchase the product. The patient's attitude toward the label also alters his or her product evaluation and intention to buy the product.[2,22] The degree to which the object or product is personally relevant increases the motivation toward the product. This motivation is defined as the *level of involvement* they have toward the product.[2,23] Level of involvement among the participants was measured by a 7-item, 5-point Likert scale developed by Gore et al.[24] Figure 1 provides the model tested in this study to evaluate the effect of label design. The dependent variables were adapted from the OTC LEPM.

Information Processing Measurement

The OTC LEPM explains how patients who purchase and use OTC medications process label information.[2,20,22,25] The model is measured by the following variables: ease of use, label comprehension, attitude toward the product, product evaluation, and purchase intention. It states that the ease with which a patient can search information affects the comprehension of the label. Comprehension provides a good understanding of all components of the label, thus assisting in making an informed decision. *Ease of use* was defined as ease of finding information on the label. It was measured using 2 items on a 10-point Likert scale. *Label comprehension* was defined as a patient's accurate interpretation of information viewed on the package label and was measured using 14 items on a 5-point Likert scale.[20] Four dummy questions were added to check the reliability of the construct. *Attitude toward the product label* is the predisposition to respond in a favorable or unfavorable manner toward the product,[26] and it was measured using 4 items on a 5-point Likert scale. *Product evaluation* is performed by patients regarding information viewed on the product label,[20] and *purchase intention* is the likelihood of the patient to buy the product.[27,28] Product evaluation was measured using 4 items, and purchase intention using a single item on a 10-point Likert scale.

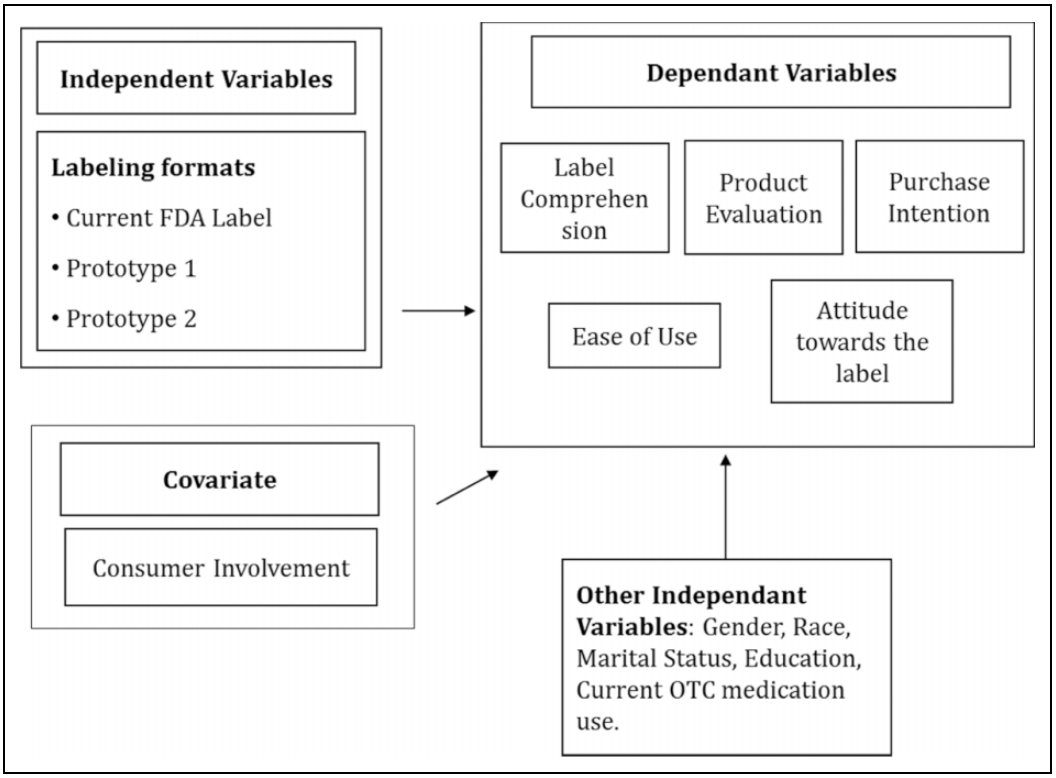

Figure 1. Model tested: Effect of information congruence on information processing.

Survey Label Design

The study consisted of a comparison between 2 experimental labels and the current FDA label (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143551.htm). The current FDA label used was designed based on the FDA guidelines and served as a control comparator. It was named label A (Figure 2). The 2 experimental labels were designed based on the concepts of information congruency, where we defined "chunk" as *uses-directions-other information*. Studies by Vigilante and Wogalter[16,29] state that uses-directions-other information follow the schema of how and when to use the product, whereas a warning is personal hazard information. Hence, we defined uses-directions-other information as a single chunk to test the effect of congruency. This congruent information was placed after the warnings in label B and before the warnings in label C to test the effect of warnings placement (Figure 2). The current FDA format has warnings placed within the chunk, which may differ from the schema in the minds of the patients.

Randomization of Labels

The order in which the participants viewed labels was randomized. Each individual was presented with a folder containing the study consent form, 3 labels, and the study questionnaire. Upon confirmation that they understood the study process, they were asked to view the first label for as much time as they needed. Based on the information they retained after viewing the first label, they completed the label comprehension portion of OTC-LEPM. They were then asked to compare all 3 labels for ease of use, attitude toward the label, product evaluation, and purchase intention.

Statistical Analyses

The SAS 9.3 statistical package (SAS Institute Inc, Cary, NC) was used to analyze the data set at an a priori significance level of 0.05 after the data were coded and validated.[30] Descriptive statistics (percentages, means, and standard deviations) were used to summarize the age, race, education level, and OTC use. The primary dependent variables, the constructs of the OTC LEPM, were ease of use, label comprehension, attitude toward the label, product evaluation, and purchase intention. The independent variable was label format: 1 control (label A) and 2 experimental (labels B and C). Cronbach's alpha was performed to test the reliability for ease of use, attitude toward the label, and product evaluation.[31] Since purchase intention was measured using a single item, no reliability testing was performed. The multivariate analysis of covariance (MANCOVA) was performed to test a multivariate association, followed by univariate association between the OTC LEPM variables (ease of use, attitude, product evaluation, and purchase intention) as outcome and 3 labels as independent variables. A post hoc analysis using Dunnett's test was performed to compare the mean scores of each constructs across the 3 labels where significance was found in the previous multivariate analyses.

LABEL A

Drug Facts

Active Ingredient
Purpose
(in each tablet)
ABCDE Hydrochloride.....XYZVW

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- nasal congestion
- sinus congestion and pressure
- itchy, watery eyes
- itching of nose or throat
- sneezing

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- thyroid disease
- heart disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

- do not use more than directed
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilisers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask doctor if
- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Directions

adults and children 12 years and over	▪ take 1 tablet every 4 to 6 hours ▪ do not take more than 6 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other Information
- store at 20-25°C (68-77°F)

Inactive ingredients
carnauba wax, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide.

Question or comments?
Call toll-free. 1-800-719-9260

Figure 2. Labels A, B, and C used to test the effect of congruent information on information processing.

Results

Characteristics of the Survey Participants

Of the 307 participants who were approached for participation, 249 completed the survey, giving a response rate of 81.4%. Nonrespondents cited lack of time, language barrier, and disinterest as reasons for nonparticipation in the study. The majority of the participants were females (55.4%) and African American (60.6%). The a mean ($\pm$SD) age 36.8 $\pm$ 9.6 years. Almost 95% had a college education and 44.2% claimed to use labels as the most important source of drug information (Figure 3). Approximately 61.4% of them were in or associated


LABEL B

Drug Facts

Active Ingredient
Purpose
(in each tablet)
ABCDE Hydrochloride.....XYZVW

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
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- itchy, watery eyes
- itching of nose or throat
- sneezing

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Figure 2. (Continued).

with the health care profession; however, only 24% of them claimed to read the label completely (Table 1).

Effect of Label Format on OTC LEPM

The results for the MANCOVA denoted a significant difference for each dependent variable. Thus, the model null hypothesis was rejected ($F = 40.4$, $P < .0001$), implying that the mean scores measuring information processing differed across the 3 labels. Involvement had a significant effect, indicating that the level of involvement plays a significant role along with label type. Thus, the difference in means of ease of use, product evaluation, purchase


LABEL C

Drug Facts

Active Ingredient
Purpose
(in each tablet)
ABCDE Hydrochloride.....XYZVW

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- nasal congestion
- sinus congestion and pressure
- itchy, watery eyes
- itching of nose or throat
- sneezing

Directions

adults and children 12 years and over	▪ take 1 tablet every 4 to 6 hours ▪ do not take more than 6 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other Information
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Question or comments?
Call toll-free. 1-800-719-9260

Figure 2. (Continued).

intention, and attitude toward the label was attributed to label type.

The effect of label format on label comprehension was tested using an analysis of covariance (ANCOVA). The mean scores differed significantly for each variable across each label, which was tested using Dunnett's test (Table 2).

Label C (warnings after the chunk) had significantly higher means at alpha level 0.05 in comparison to label A (control) for the variables in the OTC LEPM (ease of use, attitude, product evaluation, and purchase intention). Label C had significantly higher mean scores for the same variables compared to label B (warnings before the chunk).

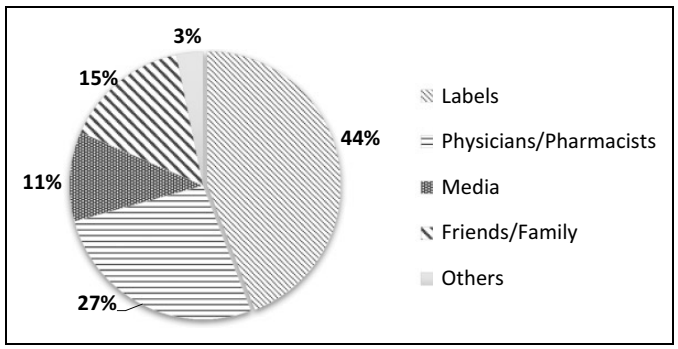

Figure 3. Patients' perception of important sources of over-the-counter medication information.

The respondents were asked to rank labels in the order of their preference. Results of this ranking process provide similar findings, as depicted in Table 3. Label C was ranked the most preferred, followed by label A and label B.

Discussion

This study found that the current FDA-approved OTC label does not lead to effective patient understanding and indicates that label C, where information is congruent, leads to better information processing. The study reinstates our proposed theory that chunking of like information leads to cognizant patients. The current OTC label exhibited lower average scores for ease of use, comprehension, attitude toward the label, product evaluation, and purchase intention compared to label C (warnings placed after the chunk) The rationale of developing new labels was to achieve hierarchy and congruence by adding a logical flow to the information.

The present study reiterates the theory proposed by Chandra and Krovi[15] that when the visual flow of information matches the logical schema in the mind of the reader, it leads to representational congruence, which enhances information processing. However, chunking by itself does not improve patient understanding. Placement of warnings is also important. Patients prefer to have warnings placed after the chunk, as warnings represent personal hazard information. They prefer to see what the product is used for first, followed by how to use the product and any other information regarding the drug. Placement of warnings plays a crucial role, as it is intended to prevent mishaps such as injury or adverse drug events.[32]

A majority of the participants in the current study worked in the health care field. A similar study conducted in college students showed results akin to our results. It would be interesting to see the study replicated in a subset of elderly patients. Processing of information from OTC medication labels is believed to be associated with several internal factors such as health literacy and language barriers and external factors such as text size, label size, and container type. After controlling for as many factors as possible, the experimental nature of the study may have left out some factors, such as need for the OTC product and participants' income. Information on only a single drug was provided to maintain uniformity. Furthermore, because of the experimental simulated condition, the participants may have read the label more carefully than they would in reality, thus overestimating the results of label comprehension. However, in our study, we had patients who were categorized as highly involved with OTC purchase and use.

The subjects in this study represented a highly educated sector of the society. While studies have depicted that patients with just elementary or no schooling are less likely to participate in health care surveys,[33] we can only generalize to the population in our study sample.

OTC labels with the best format will communicate the desired information in the most effective manner. Better information processing leads to better assessment of benefits/risks associated with OTC medications, which will lead to informed decision making. When information on when and how to use the medication is better understood, it lowers the chances of drug misuse. When the warnings are better communicated, it may lead to lower incidences of OTC-related adverse events. Regulators and policy makers play a prominent role in relaying useful information, which can be enhanced by following the concepts of information congruency.

Table 1. Participant Characteristics and Descriptive Information (N = 249 Participants).

Characteristic	Mean ± SD or n (%)
Age, y	36.8 ± 9.6
Gender	
Male	111 (44.58%)
Female	138 (55.42%)
Race	
White	98 (39.4%)
Black	151 (60.6%)
Asian	54 (21.7%)
Hispanic	30 (12.05%)
Other	14 (5.26%)
Highest education level	
High school	12 (4.8%)
College	123 (49.4%)
Master's	72 (28.9%)
Doctoral (PhD)	42 (16.87%)
Taking OTC medication	
Yes	96 (38.6%)
No	153 (61.4%)
Reading the label completely	
Always	60 (24.0%)
Often	77 (23.7%)
Sometimes	97 (38.9%)
Never	15 (6.0%)
Working or studying in a health-related field	
Health care field	153 (61.4%)
Non–health care field	96 (38.6%)

Abbreviations: OTC, over the counter; SD, standard deviation.

Table 2. Effect of Label Format on Constructs of the Over-the-Counter Label Evaluation Process Model.

Variable[a]	Label Format, Mean ± SD[b]			Difference Between Means	
	Label A	Label B	Label C	a (C – A)	b (B – A)
Label comprehension	4.1 ± 0.5	3.9 ± 0.5	4.1 ± 0.6	0.06*	–0.14
Ease of use	6.6 ± 2.4	5.6 ± 2.5	8.7 ± 1.8	2.15*	–0.90*
Attitude toward label	6.4 ± 2.3	5.5 ± 2.5	8.8 ± 1.6	2.32*	–0.95*
Product evaluation	6.8 ± 2.0	6.1 ± 2.2	8.8 ± 1.4	1.99*	–0.66*
Purchase intention	6.4 ± 2.4	5.7 ± 2.6	8.7 ± 1.8	2.21*	–0.75*

Abbreviation: SD, standard deviation.
[a]Label comprehension was measured using a 14-item, 5-point Likert scale; ease of use was measured using a 2-item, 10-point Likert scale; attitude was measured using a 4-item, 10-point Likert scale; product evaluation was measured using a 4-item, 10-point Likert scale; purchase intention was measured using a single item on a 10-point Likert scale.
[b]Order of information: Label A: (Current FDA format) uses, warnings, directions, other information; label B: warnings, uses, directions, other information; label C: uses, directions, other information, warnings.
*Denotes significance at 0.05 alpha level.

Table 3. Participant Preference of the Labels.

Label type[a]	Preference, n (%)[b]		
	Rank 1	Rank 2	Rank 3
Label A	34 (13.65%)	128 (51.41%)	87 (34.94%)
Label B	17 (6.83%)	94 (37.75%)	138 (55.42%)
Label C	198 (79.52%)	27 (10.84%)	24 (9.64%)

[a]Order of information: Label A: (current FDA format) uses, warnings, directions, other information; label B: warnings, uses, directions, other information; label C: uses, directions, other information, warnings.
[b]Rankings: 1 = most preferred, 3 = least preferred.

Conclusions

The study findings highlight the role of presenting information in the format that matches the logical flow in the mind of patients. Experimental labels with congruent information showed better processing of information and patient understanding compared to the current FDA label. While both the experimental labels had congruent information, placement of warning information was a driving factor in label processing. Patients found that warnings placed after the chunk of uses-directions-other information to be the most optimum format, leading to better understanding.

Declaration of Conflicting Interests

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