

# Comprehension of Over-the-Counter Drug Label Warnings Concerning Consumption of Acetaminophen and Alcohol

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## Abstract

This study compared several existing acetaminophen-containing product labels to a revised label with additional perceptual features and more explicit text regarding an alcohol-related hazard. The existing labels differed generally according to the amount and explicitness of alcohol-related warning information. Two-hundred sixty participants from a flea and farmer's markets in Raleigh, NC were shown one of the labels and a knowledge questionnaire was completed. Results indicated that responses regarding the combination of alcohol and acetaminophen were more accurate by participants having viewed the revised label compared to the existing labels. There are implications for the design of effective over-the-counter drug labels stemming from this study.

## INTRODUCTION

More drugs that were once available only by prescription are being sold over-the-counter (OTC). As a result, consumers are self-prescribing medications for a number of medical problems instead of relying on the assistance of a physician. This trend makes it critical that the labeling of OTC pharmaceuticals be made to convey important information to consumers in a clear manner so that they can make informed decisions on whether the medication is appropriate, safe, and effective for themselves or others to use. Important information such as warnings needs to be prominently displayed, easy to read, and understandable. Well-designed information presentations are particularly important because OTC medications are perceived as familiar and safe, which can reduce the likelihood that the labels will be examined. Thus the labels need to possess characteristics that aid in capturing and holding attention and make the information easy to comprehend.

OTC analgesics such as acetaminophen-containing products are frequently used for pain relief as well as other symptoms. They are likely to be perceived as familiar and safe due to prior use and extensive advertising emphasizing safety and effectiveness. Advertising stresses the benefits, but, unlike direct-to-consumer prescription ads, OTC drug ads convey little or no information about the risks or hazards associated with their use. One hazard associated with acetaminophen use is that it can produce liver damage or death in persons who consume higher-levels of alcohol on a regular basis.

The association between the ingestion of acetaminophen-containing products by individuals who regularly consume alcohol and liver disease has been described in the technical

medical literature (Black, 1980; Maddrey, 1987; McClain et al., 1980). However, not until recent years have U.S. consumers been warned of certain aspects of this hazard. While some warning information has been added and modified since the early to mid 1990s to acetaminophen product labels (e.g., liver damage by those who drink a high level of alcohol on a regular basis), the warnings to date may not be giving an adequate presentation of information to produce knowledge on the specific conditions of risk. Newer labels note the connection between regular consumption of high levels of alcohol and liver damage, however, the language does not indicate an important aspect of the hazard. The label does not indicate that the alcohol/acetaminophen hazard exists even if the alcohol and acetaminophen are consumed at different times, or in other words, there is a liver-damage risk even if alcohol and acetaminophen are not consumed simultaneously or in the same time frame.

The focus of the present study is to examine the relative effectiveness of various alcohol warnings that have been included on acetaminophen-containing products concerning the knowledge and understanding of non-simultaneous use of acetaminophen and alcohol by those who consume high levels of alcohol on a regular basis.

One warning that was included on a 1994 acetaminophen package of a well-known brand of acetaminophen in the U.S. is:

**ALCOHOL WARNING: IF YOU GENERALLY CONSUME 3 OR MORE ALCOHOL CONTAINING DRINKS PER DAY, YOU SHOULD CONSULT YOUR PHYSICIAN FOR ADVICE ON WHEN AND HOW YOU SHOULD TAKE {PRODUCT NAME} AND OTHER PAIN RELIEVERS.**

Another iteration of this warning from a 1999 label appears below:

**ALCOHOL WARNING:**

If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

This more recent label has some improvements over the 1994 label as it gives aspects of the hazard relating to alcohol consumption on a regular basis. However, the newer warning is not explicit about the specifics of the hazard described above, i.e., that combining alcohol and acetaminophen is dangerous even if the two are not taken simultaneously.

There are also format deficiencies in the above two warnings as printed on the packaging. The two warnings lack components of conspicuity that are known to benefit the salience and the effectiveness of warning information. Research has shown that aspects such as the use of a signal word, color, spacing, and letter case affect perceptions of hazard (Braun and Silver, 1995; Cheatham and Wogalter, 1999; Wogalter et al., 1998). In addition to the considerable human factors research, the American National Standards Institute (ANSI) published a standard (ANSI Z535.4, 1991, 1998) regarding the design and format of warning labels. This standard recommends certain format characteristics such as the use of a banner panel containing an alert symbol (a triangle surrounding an explanation point), a signal word (DANGER, WARNING, or CAUTION), and color (RED, ORANGE, or YELLOW) to serve to capture people's attention and give an indication of the degree of hazard involved. This ANSI standard also recommends that warning label content include information about the hazard, instructions on how to avoid the hazard, and consequences of failing to comply with the instructions. Warnings research supports the benefits of including this content in warnings (Wogalter et al., 1987).

The warning research literature also indicates that comprehension is facilitated by explicit descriptions of these content components. Warnings research has shown "explicit" warnings are better than "nonexplicit" (general) warnings (e.g., Laughery & Stanush, 1989). The 1994 acetaminophen warning provides no information about consequences of consuming high levels of alcohol on a regular basis and ingesting acetaminophen. While the 1999 warning includes some consequence information (i.e., liver damage), it lacks explicitness and has ambiguous wording about the hazard of combining acetaminophen and alcohol even when the two components are consumed at separate times.

The present study is an empirical comparison of several (pre-) existing acetaminophen containing product labels with a revised label containing a more explicit warning, which also included additional features known to enhance warning effectiveness. The existing labels were from a well-known extra strength (ES) acetaminophen-containing product as well

as a night time (NT) formula of the same brand of medication. The purpose of the study was to evaluate hazard comprehension of the alcohol/acetaminophen warning after exposure to one of these labels. This study was suggested by litigation that alleged inadequate label warnings.

## METHOD

### *Participants*

Two-hundred sixty participants (145 females and 115 males) from a Raleigh, NC flea market and farmer's market participated. Participant ages ranged from 17 to 82, with a mean age of 41.2 years (SD=15.01). The education levels reported were: 5% some high school, 15% high school, 7.7% technical/trade school, 21.9% some college, 41.2% college, and 9.2% post-baccalaureate degree. Reported ethnicity was: 72.6% Caucasian, 18.1% African-American, 4.6% Hispanic, and 4.6% other. Participants were randomly assigned to label conditions and were paid \$15.00 each for their time. In all of the ES medication product groups,  $n = 30$  and in the NT formula,  $n = 20$ .

### *Materials*

Ten labels were used. Nine were color laser photographs of the entire outer packaging of pre-existing labels from the packaging of a well-known brand of acetaminophen. A revised warning based on the pre-existing labels was also created.

The pre-existing nine labels dated from 1994 to 1999. The text of the 1999 and 1994 labels were given earlier. In addition to the 1994 warning on a package label, a 1994 sample packet was tested.

The 1996 packaging label appeared in black print on a yellow background, stating:

**ALCOHOL WARNING: FOR THIS AND ALL OTHER PAIN RELIEVERS, INCLUDING ASPIRIN, IBUPROFEN, KETOPROFEN, AND NAPROXEN SODIUM, IF YOU GENERALLY CONSUME 3 OR MORE ALCOHOL-CONTAINING DRINKS PER DAY, YOU SHOULD CONSULT YOUR PHYSICIAN FOR ADVICE ON WHEN AND HOW YOU SHOULD TAKE PAIN RELIEVERS.**

Alcohol warning text on the 1998 label contained the following:

**ALCOHOL WARNING:** If you drink 3 or more alcoholic beverages every day, ask your doctor if you should take {Product name} or other pain relievers. Chronic heavy alcohol users may be at increased risk of liver damage when taking more than the recommended dose (overdose) of {Product name}.

The night time (NT) formula labels had additional warning information as it also contained as an active ingredient the antihistamine Diphenhydramine HCl which can cause drowsiness. With regard to the alcohol-related warning, 1994 NT label had the following text:

**ALCOHOL WARNING:** If you generally consume 3 or more alcohol-containing drinks per day, you should consult your physician for advice on when and how you should take {Product name} and other pain relievers.

The 1996 NT label had the alcohol warning located in the second paragraph of the right column. The 1997 NT label was located in a similar position on the label. The warning was:

**ALCOHOL WARNING:** For this and all other pain relievers including ibuprofen, ketoprofen, and naproxen sodium, if you generally consume 3 or more alcoholic-containing drinks per day, you should consult your physician for advice on when and how you should take pain relievers.

Alcohol warnings on the 1998 and 1999 NT labels both appeared with red 'Alcohol Warning' headings. The 1998 alcohol warning text appears below:

#### Warnings

Alcohol Warning: If you drink 3 or more alcoholic beverages every day, ask your doctor if you should take {Product name} or other products containing acetaminophen or other pain relievers. Chronic heavy alcohol users may be at increased risk of liver damage when taking more than the recommended dose (overdose) of acetaminophen.

The 1999 NT's alcohol warning text was:

Alcohol Warning:  
If you drink 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

The revised label included 'ALCOHOL WARNING' in red print and was preceded by an alert symbol (i.e., triangle enclosing an exclamation mark). Explicit language regarding the hazard associated with combining alcohol and acetaminophen was added. Specifically, it was stated that combining acetaminophen and alcohol was dangerous whether or not they were taken simultaneously. The revised label appeared in the context of an actual label, and stated:

**ALCOHOL WARNING:** If you consume 3 or more alcoholic drinks every day, this product and other

products containing acetaminophen can cause liver damage, which can result in serious illness or death, even if you have not consumed alcohol at the time the medication is taken. Ask a doctor whether you should take acetaminophen.

Two questionnaires were employed. One asked demographic background questions including age, gender, education and ethnicity. This questionnaire also asked about the frequency of purchasing over-the-counter medications, whether they had ever purchased or used the acetaminophen-containing product, and if they consumed three or more alcoholic beverages a day on a regular basis.

The second questionnaire contained eight questions of which seven concerned non-alcohol related aspects of the acetaminophen-containing product. Particular interest was focused on the responses to a question asking: "If a consumer drinks alcohol on a regular basis, but at the time he or she ingests the acetaminophen product has no alcohol in his or her system, are there dangers associated with ingesting the acetaminophen product?" The participants were given blanks for a yes or no answer. This item will be referred to as the 'alcohol/acetaminophen combination' item.

In addition there were two sheets used to assess participants' knowledge of potential hazards and side effects associated with taking the acetaminophen-containing medication with blank areas for recording their answer. These sheets were used in the preliminary and the post-exposure hazard knowledge tests.

#### Procedure

A pilot test employed a small number of participants together with expert heuristic evaluation was used to determine aspects of already-existing acetaminophen warnings that might be producing misapprehension of the alcohol/acetaminophen combination hazard. Initially, existing labels were given to five pilot participants who were asked to examine them, and later asked whether they noticed any warning information and what they thought it meant. If the alcohol warning was noticed, participants were asked to describe the meaning of the warning and to identify the hazard and consequences. From this information, two prototype versions of the revised warning were tested as part of a second pilot test with eight additional participants asked similar questions as the first group. From these data, combined with the application of human factors/ergonomics principles of warning design and a heuristic evaluation, a revised label was produced for the main experiment (Wogalter, Conzola, and Vigilante, 1999).

Participants were randomly assigned to one of the ten label conditions. All participants completed the demographic questionnaire followed by a preliminary background knowledge test. Prior to examining the label, each participant was asked to indicate any potential hazards or side effects

associated with the use of the acetaminophen-containing drug, of which he or she is aware; this task is referred to as the background or preliminary knowledge test. Responses were recorded by the experimenter.

After completing this question, a scenario was read aloud to participants by the experimenter:

You are buying over-the-counter medication for a friend. She has been complaining of a fever and headache, and you are considering purchasing an acetaminophen-containing drug at a local drugstore. Take a few minutes to examine the packaging.

Participants were then given one of the ten labels for a timed duration of 5 minutes. After this label-exposure time was completed the label was taken away and the post-exposure knowledge question described above was asked in which participants were to list the potential hazards and side effects associated with taking the acetaminophen product. The presentation order of the post-exposure knowledge test and the 8-item questionnaire was balanced such that half completed the two tasks in one order and the other half completed the tasks in the reverse order.

## RESULTS

To the question: "How often do you use or purchase over-the-counter (OTC) medications?" participants reported: 5.4% never, 43.1% less than three times a year, 37.3% monthly, 6.5% weekly, and 7.7% two or more times a week. To the question: "Have you ever purchased or used {Product name}?" the responses were 75% yes, 8.1% no, and 16.9% don't know. To the question: "Do you consume 3 or more alcoholic beverages a day on a regular basis?" the responses were 93.1% no and 6.9% yes.

### Acetaminophen/alcohol combination

A major focus was the participants' comprehension of the dangers associated with the combination consumption of alcohol and acetaminophen (i.e., even when not consumed simultaneously) as a function of existing labels versus the revised labels. Planned comparisons using a composite condition of the existing label conditions showed that significantly more participants correctly answered the question regarding the alcohol/acetaminophen combination in the revised label condition (70%) than in the composite existing label condition (41%),  $ps < .05$ . Planned comparisons between the revised label condition and each of the existing label conditions showed the revised label condition produced significantly higher percentages correct than 5 of the nine existing-label conditions,  $ps < .05$ . The percentage of correct scores for the label conditions are shown in Table 1.

Table 1  
Percentage correct for alcohol/acetaminophen combination question as a function of label

Label	% Correct
1994 ES label	33*
1994 version 2 ES label	37*
1996 ES label	50
1998 ES label	40*
1999 ES label	33*
1994 NT label	40*
1997 NT label	45
1998 NT label	45
1999 NT label	50
Revised label	70

\*  $p < .05$  compared to Revised label.

### Pre-and post-exposure hazard knowledge

*Pre-exposure hazard knowledge.* Responses to the question asking the potential hazards and side effects associated with the acetaminophen-containing product were examined for reporting both alcohol and liver by participants as a function of label condition. Planned comparisons similar to the type described above showed that knowledge did not significantly differ between the revised label condition compared to the existing label conditions *prior* to exposure to the labels ( $ps > .05$ ).

*Post-exposure hazard knowledge.* After exposure to labels, there was an assessment of knowledge similar to the pre-exposure question above. A planned comparison for responses including both alcohol and liver for the revised label (47%) versus a composite score of the existing label conditions (5%) was significant. Likewise comparisons of the revised versus each of the separate label conditions were significant in all nine tests ( $ps < .05$ ). The percentages are shown in Table 2. Thus, significantly more participants recalled both alcohol and liver information after examining the revised label than did participants examining any of the other (existing) labels.

### Analyses of demographics and other questionnaire items

Analyses of variance were used to determine if there were demographic differences as a function of the label conditions for the alcohol and acetaminophen combination hazard items described earlier.

The age variable was split into two groups at the median (40 years) forming a younger and an older group. There was no significant main effect or interaction of age group for either the alcohol/acetaminophen combination or the post-exposure hazard knowledge items ( $ps > .05$ ).

Table 2  
Percentage of participants reporting both alcohol and liver hazard information after label exposure

Label	% Reporting Alcohol and Liver
1994 ES label	7*
1994 version 2 ES label	7*
1996 ES label	0*
1998 ES label	3*
1999 ES label	10*
1994 NT label	0*
1997 NT label	10*
1998 NT label	10*
1999 NT label	0*
Revised label	47

\*  $p < .05$  compared to Revised label.

Analyses using gender as a factor together with label condition showed a significant main effect of gender and an interaction. Significantly more females (12.4%) recalled alcohol and liver information during the post-exposure hazard knowledge test than males (7%). The pattern of the cell means indicated that both males and females had approximately the same score in the existing label conditions (males = 5%, females = 6%), but in the revised condition more females (55%) recalled the alcohol and liver information than males (30%). Analyses were not conducted with the demographic factors of ethnicity and education categories because of small cell sizes.

Other analyses examined whether hazard knowledge performance differed between participants who reported daily consumption of three or more alcohol drinks differed from those who did not report this level of alcohol consumption. No significant differences were found, perhaps, in part because relatively few participants in the overall sample reported consuming three or more drinks of alcohol daily.

Analyses also examined the total number of errors on the eight post-exposure questionnaire items (seven of which were filler items). Comparisons between the revised label and the existing labels showed significantly lower errors for those who reviewed the revised label ( $M = 2.33$  errors) compared to the 1994 NT ( $M = 3.40$  errors), 1997 NT ( $M = 3.25$  errors), and 1999 NT ( $M = 3.45$  errors) labels ( $ps < .05$ ). No other comparisons were significant.

## DISCUSSION

The present study compared the effectiveness of existing OTC acetaminophen-containing product warning labels with a revised label that incorporated more explicit wording about an alcohol/acetaminophen combination hazard and several basic warning design characteristics. Across several analyses, the results showed that participants exposed to the revised label were more knowledgeable about the acetaminophen/alcohol

combination hazard than those who saw the pre-existing labels. In addition, more participants were aware of both the hazard (acetaminophen-alcohol combination) and consequence (liver damage) information after examining the revised label than the other versions of the label.

This study clearly demonstrates that a label could be produced that provides consumers a better warning regarding the hazard associated with consuming acetaminophen-containing medications by persons who consume higher levels of alcohol on a regular basis. It also shows the importance of conducting consumer testing of warning labels prior to their implementation to have greater assurance that the intended hazard information is being conveyed. Computer software, scanners and color printers allow the manipulation of labels so that such testing can take place. The benefit to consumers is that they are given the opportunity to learn about hazards for the substance that they consume, and thus can potentially make better decisions about their health and safety.

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