

Over-the-Counter Analgesics: A Survey of the Public's Knowledge, Attitudes and Beliefs Regarding Current Labeling Practices

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ABSTRACT

A wide variety of over-the-counter (OTC) medications are currently available to the general public without a prescription. Among the most popular of these are medicines termed *analgesics* that have pain-relieving effects. Unfortunately, many people are not aware of the significant health risks associated with their use. The main purpose of this study was to determine whether people want to be informed of these risks and whether such knowledge would influence self-reported precautionary behavior. The results showed that 92% of the 330 people surveyed wanted to be informed of the risks of OTC analgesics and nearly 95% percent agreed that this information should appear on the product label or in the materials that accompany these products. When asked about the likely actions they would take if provided with organ-specific risk information, a large majority of the respondents indicated they would take one or more precautionary behaviors to reduce the risks (e.g., take smaller dosages). A majority of respondents admitted having placed themselves at risk by taking more than the recommended dose of an OTC analgesic at one time. These results have implications for improving the quality and effectiveness of risk communications.

INTRODUCTION

A large number of over-the-counter (OTC) medications are currently available to the general public without a prescription. Among the most popular of these are pain-relievers, generally called *analgesics*, including aspirin, acetaminophen (Tylenol™), and ibuprofen (e.g., Advil™). Unfortunately, many people are not aware of the health risks associated with the use of each of these products. The medical literature (e.g., PDR, 1999) indicates that each of these medicines can cause specific damage to internal organs in some individuals when taken at or above the upper range of the recommended dosage or when they are used in combination with other substances (e.g., alcohol or other medications).

Research generally shows that a large percentage of people in the U.S. fail to use medications as prescribed (Farley, 1995). This problem may be due, at least in part, to inadequate access to appropriate and complete product information (DeJoy and Brooks, 2000). To address

this problem, the U.S. Food and Drug Administration (FDA) has published guidelines requiring that manufacturers follow a uniform label format for nonprescription medications (Department of Health and Human Services, 1999). The purpose of these guidelines is to help consumers understand drug benefits and risks and to use these medications properly by: (1) requiring that critical information contained on the product label (e.g., uses, warnings) be presented in a standardized order; (2) standardizing graphical features and enhancements; (3) establishing minimum standards for font size and spacing; and (4) encouraging manufacturers to use more concise and understandable language. Meeting these goals, however, is a complex and challenging task. Moreover, these rules do not ensure that consumers will be exposed to all of the important information concerning a particular drug.

Although there are other avenues through which to convey important product information to consumers (e.g., medication leaflets, package inserts, product labels and packaging, advertising, health care providers, and most recently, the

Internet), the information that actually reaches many consumers is the information printed on the product label. Unfortunately, this information focuses primarily on how to use the medication, with only limited information on precautions or adverse effects.

Given this set of circumstances, there is a need to determine whether people want to be better informed of the specific health risks associated with OTC medications, where they would expect to find that information, and the likely effects the inclusion of health-related information would exert on their intended behavior. The present study examines these issues with respect to common OTC analgesics (i.e., aspirin, acetaminophen, and ibuprofen).

METHOD

Participants

The participants were 330 (217 males, 113 females) people living in Raleigh, North Carolina and several other locales. Of these, 221 were full-time students with a mean age of 21.3 years ($SD=2.5$). The mean age of the non-student sample ($n=109$) was 34.2 years ($SD = 13.1$). In terms of ethnic breakdown, 278 of the participants were White; the remaining 52 were African Americans or Asians. A majority of the participants (94.8%) reported English as their first language.

Materials and Procedure

The data for this study were obtained via a questionnaire distributed by students working in collaboration with the Ergonomics Laboratory in the Department of Psychology at North Carolina State University. Participants completed a brief demographic form that requested information, on their age, sex, and ethnic background. Prior to providing their responses to the items pertaining to this research, participants were asked to read the following scenario:

“Medications that have pain-relieving effects are called analgesics. There are several analgesics sold over-the-counter (OTC). OTC medications are available to consumers without a prescription and are sold in various locations, including grocery stores and convenience stores. The most common analgesics are aspirin (for example, Bayer™), acetaminophen (for example, Tylenol™), and ibuprofen (for example, Advil™). It is well documented in the medical science literature that each of these medicines can cause specific diseases in some individuals when taken at the upper range of the recommended dosages.”

“Aspirin is known to cause gastro-intestinal bleeding and ulcers. Acetaminophen is known to cause liver disease. Ibuprofen is known to cause kidney disease. The resulting ailments from these three drugs can, and have, led to death in some cases. Manufacturers are aware of the organ-specific side effects of these products but they do not give this information in the labeling to consumers. Instead, they suggest that potential users contact their doctor before use of the product if they have one of several preexisting diseases such as hypertension and asthma. However, many people do not consult their doctor about the use of OTC medications. Consumers often believe that these products are safe because the FDA allows them to be sold as an OTC medication and because of the substantial amount of advertising promoting the products. Organ specific cautions could let people know that a specific drug may not be appropriate for them because of their family history, previous diagnosis, and so on. The inclusion of this information could also increase the public’s general understanding that OTC medications are not completely safe. Most of the OTC analgesics on the market have a good safety record and work for most users. Drug companies do not want to scare people away from using their drug when it may be safe and effective to most users.”

After they had finished reading the scenario, participants completed items that asked whether they would want to be informed of the organ-specific risks of OTC analgesics and if they thought the risk information should appear on the product label and/or in the accompanying materials. They were also asked to imagine they were considering using an OTC analgesic and were provided with information concerning the product’s organ-specific

risks. Given this scenario, they were asked to indicate which of several possible actions they would most likely take (e.g., take smaller doses, make no changes in their usual use of a product, switch to a different analgesic product, or consult with a doctor before using the product). Finally, two items on the survey requested information concerning participants' usage of OTC analgesics and whether they had ever taken more than the recommended dosage of these products at one time.

RESULTS

As predicted, a large majority of the survey respondents (92%) indicated that they would want to be informed about the organ-specific risks of OTC analgesics. Nearly all of the participants (94%) also indicated this information should appear on the product label or in the materials that accompany the product.

The respondents also indicated the most likely ways they would behave if they were considering using an OTC analgesic. They were provided with several alternatives and could select more than one. The alternatives and the frequencies and percentages that these alternatives were chosen are displayed as Table 1. Nearly three-fourths of the respondents (73.3%) indicated they would take a smaller dose. Nearly half (46.1%) reported that they would not make any changes in their usual use of OTC analgesics. A third of the participants (33%) indicated that they would consult a doctor before using any of the products mentioned (i.e., aspirin, acetaminophen, ibuprofen) and a similar percentage (30%) said they might decide not to use any of the products or use a different analgesic. An "Other" category was included as an option so that participants could write in other anticipated actions they might take that were not included as part of those listed in the survey. Only a small number of participants (2.7%) selected this option.

Finally, two items on the survey requested information concerning participants' usage of OTC analgesics and whether they had ever taken more than the recommended dosage of these products at one time. These data are presented in Table 2.

Table 1. The frequencies (*f*) and percentages (%) of participants who endorsed possible actions they might take if they were considering using an OTC analgesic and were provided with information concerning the organ-specific risks.

Participant Action	<i>f</i>	%
I would take a smaller dose.	242	73.3
I would not make any changes to my usual use of OTC analgesics.	152	46.1
I would consult with a doctor before using any of the products mentioned above.	109	33.0
I might decide not to use any of the products mentioned above. I would try to get another analgesic, possibly from a doctor.	99	30.0
Other	9	2.7

DISCUSSION

The most important finding of this research is that people clearly want to be informed of the risks associated with the OTC medications considered here. Indeed, nearly all the participants in this study expressed a desire to have access to information concerning the organ specific risks associated with the use of aspirin, acetaminophen, and ibuprofen.

It is also important to point out that when participants were given access to this information, they tended to endorse actions that would effectively reduce these risks. For example, the most frequent preventive action that participants said they would take was reducing the size of their usual dosage. Other actions frequently endorsed included deciding not to use any of the products, trying to get another type of analgesic, or consulting with a doctor before using the products. Still, about half of the participants indicated they would not

Table 2. *Items concerning participants' reported use of OTC analgesics.*

Survey Question		Aspirin	Acetaminophen	Ibuprofen
In an average month, how many pills of each of the [listed] OTC medications have you taken?	Mean	2.73	2.58	6.16
	S.D.	8.0	6.29	12.39
Have you on occasion taken more than the recommended dose of the OTC medications [listed above] at one time?	Yes	No		
	57.5%	42.5%		

make any changes in their use of OTC analgesics based on the additional information, confirming previous research suggesting that simply providing information is not always sufficient to produce behavior change. This is a particularly important finding given the fact that a majority of the respondents admitted placing themselves at risk by taking more than the recommended dose of an OTC analgesic at one time.

Whether the preventive behaviors endorsed by the respondents are appropriate or whether they can or would be carried out is not clear at this point. A host of other factors may also play influential roles in risk-related information processing and decision-making. In this case, these factors include the participants' experience with OTC analgesics and related medications, their health status and relationship with their healthcare provider, their access to relevant information (e.g., newspapers, healthcare magazines, the Internet), and their knowledge of possible interactions between OTC analgesics and other products (e.g., alcohol).

Clearly, the participants of this study believed that organ-specific risk information should be included with the product, either on the product label or in materials that typically accompany these medications. Moreover, they said that they would act upon this information by reducing the usual dosage or making some other change to reduce their

risk. The OTC analgesics evaluated in this study now contain some organ-specific risk information as part of its labeling materials. For example, labels on containers of acetaminophen provide information that it can cause liver damage and labels on containers of ibuprofen and aspirin provide a statement regarding stomach bleeding. It would seem prudent for manufacturers to continue this positive trend. Specifically, manufacturers should provide additional information about risks not yet communicated to consumers, including the specific reasons why they need to comply with the stated directives and warnings.

These results not only have applicability to the specific risks described in this report, but also may have applicability to risk communications more generally. People want to know or have access to risk information concerning the products that they use or may use.

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