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Randomized Trial of Risk Information Formats in Direct-to-Consumer Prescription Drug Advertisements

Kathryn J. Aikin, PhD, Amie C. O'Donoghue, PhD, John L. Swasy, PhD,
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Background. Federal regulations specify that print advertisements for prescription drugs and biological products must provide a true statement of information “in brief summary” about each advertised product’s “side effects, contraindications, and effectiveness.” Some of the current approaches to fulfilling the brief summary requirement, although adequate from a regulatory perspective, result in ads that may be difficult to read and understand when used in consumer-directed promotion.

Objective. To explore ways in which the brief summary might be improved. **Design.** The authors conducted an experimental study that examined 300 consumers’ (all visitors ever told that they were overweight) understanding of and preference for 4 different brief summary formats: traditional (a plain-language version of the risk sections from professional labeling), question and answer (Q&A; with headings framed in the form of questions), highlights (a summary section from revised professional labeling), and prescription drug facts box (similar to the

current over-the-counter drug facts label). **Results.** The format had several effects. For instance, participants who viewed the drug facts format were better able to recall risks ($P < .01$) and reported greater confidence to perform the tasks ($P < .01$) than those who saw the traditional format. Differences in preference were noted; for example, the drug facts format was ranked highest, followed by the Q&A format, the traditional format, and finally the highlights format, $P < 0.001$. **Conclusions.** Taken together, these data suggest that the traditional method of conveying information in the brief summary is neither the most comprehensible nor the most preferred by consumers. These data provide policy makers and researchers with important information regarding the role of format in consumers’ understanding of the brief summary. **Key words:** randomized trial methodology; risk factor evaluation; population based studies; scale development/validation. (*Med Decis Making* XXXX;XX:xxx-xxx)

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Advertising for prescription drugs has evolved over time. What was once a form of promotion aimed at health care providers has broadened its focus to encompass the general population. By law, prescription drug ads have special requirements. Federal regulations specify that print advertisements for prescription drugs and biological products that make claims about the product’s effectiveness must also provide a true statement of information “in brief summary” about the advertised product’s “side effects, contraindications, and effectiveness.” The information about the product’s risks must include *each specific side effect and contraindication* from the advertised drug’s Food and Drug Administration (FDA)-approved labeling, including the Warnings, Precautions, Adverse Reactions, and other relevant sections.¹ In essence, claims about

the benefits of the product must be balanced with what is known about the product's risks. This is why prescription drug ads are different from ads for other health products, such as over-the-counter drugs and dietary supplements. To fulfill the requirements, print ads for prescription drugs are often 2 (or more) pages long. The first page of the prescription drug ad may feature a picture or visual, information about what the product is intended to be used for, and important information about the product's risks. The second page summarizes *all* the product's risks and may be presented as densely packed text information. The way in which those risks are communicated on this second "brief summary" page in direct-to-consumer (DTC) advertising, however, has been criticized. Historically, sponsors have met the summary requirement by reprinting either the risk-related sections or all sections of the health care professional-directed prescribing information (PI) for the product, even in DTC advertising. This study was designed to explore format variations that may make the brief summary more useful for consumers.

Beyond anecdotal reports, survey research provides some insight into how people use the brief summary in its traditional block text form. In a survey of 944 people who had visited their health care provider in the previous 3 months and had reported seeing a prescription drug ad in a magazine or newspaper, approximately a third of these participants reported reading half or more of the brief summary.² Among those who reported seeing an ad they were especially interested in (46% of those who had seen an ad in magazine or newspaper), approximately 45% read all or almost all of the brief summary of that ad, compared with 78% who said they read all or almost all of the main body copy (display page). Those who self-identified as non-white and those who rated themselves as very or extremely knowledgeable about health and medicine were more likely to report reading all or almost all of the brief summary. More telling, of those who had read at least some of the brief summary, 55% described it as very or somewhat hard to read. Data from a different survey revealed that people were more likely to agree that the brief summary provided useful information for discussing risk with their doctors if they paid frequent attention to the brief summary, perceived the brief summary to be clear, and believed in the educational value of DTC advertising.³ These findings suggest that although patients will make the effort to read the brief summary when they are interested in the product,

a clearer version of the brief summary could benefit consumers.

A few alternatives to the traditional brief summary have been proposed. A question-and-answer format, with headings framed in the form of questions, has the potential advantage of creating a dialog with the reader and may serve to increase interest in and perhaps the comprehension of information. Past industry research⁴⁻⁶ has shown that this format has advantages over the traditional format.

It is possible that the question-and-answer format was successful simply due to the chunking of text with attached headings. We examined this possibility by investigating another proposed format. This format was based on the highlights section of the physician labeling that began to be phased in for all new prescription medications in 2006.⁷ The highlights section of the label contains headers of information (e.g., Warnings and Precautions) followed by bullets of pertinent information. Qualitative research was conducted to determine that physicians liked the highlights section of labeling as part of the drug label. However, it is unclear how well consumers will be able to use a consumer-friendly version of the highlights in an advertisement setting.

Another proposal is a prescription drug facts box that resembles the current over-the-counter (OTC) drug facts label. The OTC drug facts label was based on extensive qualitative and quantitative research.⁸ Two quantitative studies examined the OTC drug facts label prior to its introduction in 1999: one examining people's preference for different formats and another examining their comprehension of information from different formats. The OTC drug facts label demonstrated advantages over the old paragraph format and was subsequently adopted. Other studies have tested a similar prescription drug facts box and have found that it improves comprehension over the traditional format.^{9,10} However, the drug facts box examined in these subsequent studies also included quantitative information on the benefits and risks of the drug. Thus, it is not clear whether the improved comprehension seen was due to the format, the addition of quantitative information, or the combination of the two.

This study was designed to investigate how these various formats affect the processing of information in the brief summary. Comprehension of risk information in the brief summary was our primary end point. In addition to comprehension, we also tested whether the formats differed in how much confidence participants had that they could find and use

the information in the brief summary (self-efficacy¹¹). Self-efficacy has been linked to a range of health behaviors (e.g., see Schwarzer and Renner¹² and Strecher and others¹³), including functional understanding of prescription drug instructions¹⁴; people who are confident they can perform the behavior are more likely to do so. Consumers may examine formats that foster self-efficacy more thoroughly, resulting in potentially better comprehension.

We also measured preference, attitude toward the ad, the amount of time participants spent viewing the ad, their intention to talk to a doctor about the drug and search for more information about the drug (behavioral intentions), and whether the benefits of the drug outweighed the risks (risk/benefit tradeoff). Participants' preference for one format over another is important because, all else being equal, it makes sense to adopt formats that are preferred. However, preference is secondary to comprehension; in previous studies with the nutrition facts label format, the version most preferred by consumers was not the one that resulted in the best comprehension.¹⁵

We predicted that the alternate formats (highlights, question and answer, and drug facts), compared with the traditional format, would be associated with greater comprehension, self-efficacy, behavioral intentions, and preference and more positive attitude toward the ad. We predicted that, because participants would be familiar with the drug facts format from the OTC drug facts label, the drug facts format would be associated with the greatest self-efficacy. We predicted that formats that led to higher self-efficacy would lead to greater comprehension. Comparisons among the alternate formats and analyses with risk/benefit tradeoff and time were considered exploratory.

METHOD

Procedure

The study was conducted at 8 mall-based interviewing facilities in the United States in 2009. The facilities were selected to maximize geographic diversity. Interviewers approached visitors in public spaces in each mall and administered a screening questionnaire. Recruiters, who were blind to study hypotheses, were instructed to approach everyone who appeared 18 years of age or older. The screening questionnaire consisted of 1 question: whether they had ever been told by a doctor or other health care

provider that they had asthma, high cholesterol, or were overweight and needed to lose more than 15 pounds. Prescription drug ads are targeted to people with a particular medical condition. To ensure that people were engaged with the ad (i.e., have high involvement), we recruited participants who had experience with the medical condition of interest. We chose overweight as our medical condition because it is a prevalent medical condition and would allow us to recruit a sufficient number of participants. Only mall visitors who responded that they ever had been told they were overweight and needed to lose more than 15 pounds were qualified to participate in the study.

Participants were also disqualified if 1) they were younger than 18 years of age, 2) they failed to report their age or level of educational attainment, 3) they needed glasses or contact lenses for reading but did not have them with them at the time of the study, or 4) they or anyone in their household worked for a pharmaceutical company, an advertising agency, or a market research company. Quotas were used to ensure that approximately half the participants were female and that at least one-third had a high school education or less. Recruiters approached 3594 people. Many (1782) refused to participate, and so their eligibility was not established. Others (1453) were not eligible. Fifty-nine people who were deemed eligible to participate refused. All participants gave written informed consent.

The study was self-administered via computer. The size of the monitor was uniform and sufficiently large to provide an actual 8.5×11 -inch display of the advertisement pages. Participants were randomly assigned to view an ad for a fictitious prescription weight loss drug with 1 of 4 brief summary formats: traditional, question and answer (Q&A), highlights, or drug facts. Participants did not know the drug was fictitious; rather, they were told that the purpose of the study was to get their opinions on a new product.

For the purposes of this study, we assumed that in real life people have competing demands on their time and would not be able to attend to a brief summary document extensively. Mirroring these time constraints, we provided slight time pressure to read the ad; participants were told they would have up to 4 minutes to read the ad. Only 2 participants spent longer than 4 minutes viewing the ad. After viewing the ad, participants completed questions about the ad they viewed. All participants were then shown all 4 versions of the ad and completed questions about all 4 ads. The order of the 4 versions was randomly varied to account for ordering effects.

At the end of the session, participants were debriefed and paid \$7 for their participation.

Materials

The test advertisement was created to resemble an actual DTC print ad that presented a fictitious prescription weight loss product called Oncazil. The first page of the ad (the display page) was identical for all participants. We maintained as much similarity in content as possible across the 4 brief summary format versions tested (see the Web appendix for images of each brief summary format). The traditional format listed much information in 3 columns of print (word count = 1013). It was not entirely traditional, as it was written in consumer-friendly language and had considerably more white space than some older reproductions of the prescribing information in past print ads. The Q&A format had only 2 columns of information instead of 3, and the headings were framed in the form of questions (word count = 597). The highlights format used standardized section headings such as *Warnings and Precautions* and included a short description of the most important pieces of information about the product (word count = 487). The prescription drug facts box (drug facts) format resembled the current OTC drug facts label (word count = 397). None of the formats contained quantitative information about the benefits or risks of the drug. Although the addition of quantitative information is an important issue, we did *not* include quantitative information in the current study because we wanted to first test the role of format separately.

Measures

Comprehension. We created 2 measures of risk comprehension (see the Web appendix). The first was a measure of recall. Without the ad in front of them, participants saw 10 statements about Oncazil, such as, “You cannot take Oncazil if you have had a stroke,” and were asked to report whether each statement was true, false, or whether they were unsure. In addition, participants were asked to identify what condition Oncazil treated (asthma, weight, high cholesterol, fungus [athlete’s foot], or osteoporosis) and the type of product it was (herbal supplement, over-the-counter drug, or prescription drug). We identified the correct response for each item and coded all other answers (incorrect or unsure) as incorrect. Half of the true and false questions had “false” as a correct response.

We summed the number of correct responses for the 12 items to create a risk recall score.

The second measure tested whether participants were able to apply the information in the ad. For the second measure, participants were shown the ad again. With the ad in front of them, they were given 4 scenarios, such as “You have just learned you have hepatitis C (a disease that affects your liver). Should you take Oncazil?” and were asked to answer yes, no, or not sure. We identified the correct response for each item and coded all other answers (incorrect or unsure) as incorrect. We summed the number of correct responses for the 4 items to create a risk application score.

Risk/benefit tradeoff. Participants were asked to state the extent to which they agreed (1 = *strongly disagree*, 5 = *strongly agree*) with 4 statements about whether the benefits of the drug outweighed the risks (“The benefits and positive effects of Oncazil outweigh the risks and negative effects,” “Even losing a lot of weight would not be enough to balance the risks and negative effects of Oncazil,” “I could deal with the side effects if I lost weight with Oncazil,” and “The risks and negative effects seem reasonable compared with the benefits and positive effects of Oncazil”). We created a measure of risk/benefit tradeoff from the mean of these 4 items (Cronbach’s $\alpha = 0.79$).

Behavioral intention. Participants rated 4 statements (“Talk to my doctor about Oncazil,” “Ask my doctor about getting a free sample of Oncazil,” “Ask my doctor to prescribe Oncazil,” and “Look for more information about Oncazil”) on how likely they were to perform each behavior, using a 5-point scale (1 = *definitely will not*, 5 = *definitely will*). We created a measure of behavioral intention from the mean of these 4 items (Cronbach’s $\alpha = 0.91$).

Self-efficacy. We measured participants’ confidence that they could find and use the information in the brief summary. Participants rated 9 statements (e.g., “Identify which drugs interact with Oncazil,” “Remember the warnings”) on how confident they were that they could perform each task, using an 11-point scale (0 = *no confidence*, 10 = *complete confidence*). We created a measure of self-efficacy from the mean of these 9 items (Cronbach’s $\alpha = 0.92$).

Attitude toward the ad. We had 2 measures of attitude toward the ad. The first measured participants’ attitude toward the single ad they were randomly assigned to view. Participants were asked to state the extent to which they agreed (1 = *strongly disagree*, 5 = *strongly agree*) with 10 statements about their

attitude toward the ad (e.g., “The way the information was presented on this page was useful”). We created a measure of attitude toward the ad from the mean of these 10 items (Cronbach’s $\alpha = 0.83$).

For the second measure, we showed participants all 4 versions of the ad. Participants were asked to rate all 4 versions of the ad on the extent to which they agreed (1 = *not at all*, 10 = *very/extremely*) with 6 statements about their attitude toward the ad (e.g., “how well the important information stood out”). We created a measure of attitude toward the ad from the mean of these 6 items for each version of the ad (Cronbach’s $\alpha = 0.80$ – 0.92). This was a repeated measure.

Preference. For this measure, we showed participants all 4 versions of the ad. Participants were asked to rank the versions of the ad by selecting the ad they preferred most, followed by their second, third, and fourth preferences.

Time. The time participants spent viewing each screen of the study was recorded in milliseconds. We report results for time spent viewing the display page and time spent viewing the brief summary. To correct for the positively skewed nature of the time data, we used a natural log transformation for time. The 2 participants who spent longer than 4 minutes viewing the ad were missing time data for the brief summary page and therefore were dropped from any analyses using this variable.

Reading speed. For each of 3 instruction screens, we divided the time each participant spent viewing the screen by the number of words on the screen. We created an average of the 3 milliseconds/word ratios to estimate reading speed (Cronbach’s $\alpha = 0.70$). To correct for the positively skewed nature of the time data, we used a natural log transformation for reading speed.

Knowledge and severity of medical condition. Participants were asked to report how much they felt they knew about their medical conditions in general on a 5-point scale (1 = *nothing at all*, 5 = *a lot*). They were also asked to report how severe their weight condition currently is on a 5-point scale (1 = *very mild*, 5 = *very serious*).

Demographics and health characteristics. Participants were asked to report their age, gender, race, ethnicity, and educational level. We coded race as white v. nonwhite and did not include ethnicity in further analyses due to our sample characteristics (see Table 1).

Participants were asked to report their height (in inches) and weight (in pounds). We calculated body mass index ($BMI = [\text{weight (pounds)}/\text{height$

(inches)²] $\times 703$).¹⁶ Three participants had BMIs that were more than 3 standard deviations from the mean. In addition, 2 more participants had unrealistic BMIs (which would be considered underweight [$BMI < 18.5$] if accurate). These 5 participants were considered outliers and were not included in analyses using BMI.

Analyses

All analyses were conducted using SPSS (Version 16; SPSS, Inc., an IBM Company, Chicago, IL) statistical software.

Between-subjects analyses. We examined separate analyses of variance (ANOVAs) to test whether comprehension (recall and application), risk/benefit tradeoff, behavioral intention, self-efficacy, attitude toward the ad, log time on the display page, and log time on the brief summary differed by format. When the overall F test was significant, we examined post-hoc contrasts to determine whether any of the formats differed from each other. For contrasts, we used the Bonferroni adjusted P value, defining significance as $P < 0.008$. For all other tests, we defined significance as $P < 0.05$.

We repeated these analyses with age, gender, race (white, nonwhite), educational level, and BMI as covariates. Analyses predicting comprehension (recall and application), risk/benefit tradeoff, behavioral intention, self-efficacy, and attitude toward the ad also included log time on the brief summary as a covariate. All analyses predicting log time on the display page and log time on the brief summary controlled for log reading speed.

Within-subjects analyses. We examined a repeated-measures ANOVA to test whether the within-subjects measure of attitude toward the ad differed by format. When the overall F test was significant, we examined post hoc contrasts to determine whether any of the formats differed from each other. For contrasts, we used the Bonferroni adjusted P value, defining significance as $P < 0.008$. For all other tests, we defined significance as $P < 0.05$. We repeated these analyses with age, gender, race (white, nonwhite), educational level, BMI, and log time on the brief summary as covariates. To determine whether ranking of preference differed by format, we examined a nonparametric Friedman test.

Mediational analysis. We examined the hypothesis that self-efficacy mediates the relation between format and comprehension. We examined a series of regression models to test this hypothesis.¹⁷ First, we conducted a linear regression predicting self-efficacy

Table 1 Sample Characteristics ($N = 300$)

Characteristics	Number	%
Gender		
Male	149	49.7
Female	151	50.3
Ethnicity		
Hispanic or Latino	19	6.3
Not Hispanic or Latino	273	91.0
Don't know or prefer not to answer	8	2.7
Race		
American Indian or Alaska Native	2	0.7
Asian	2	0.7
Black or African American	57	19.0
Native Hawaiian or Pacific Islander	1	0.3
White	217	72.3
Other	17	5.7
Multiracial	2	0.7
Don't know or prefer not to answer	2	0.7
Education		
Grade school or less	1	0.3
Some high school	19	6.3
Completed high school	88	29.3
Other education beyond high school (e.g., technical degree)	10	3.3
Some college	119	39.7
Completed college	52	17.3
Graduate school or more	11	3.7
	Mean (SD)	Range
Age, y	34.33 (12.93)	18–77
Body mass index, kg/m ²	33.23 (6.95)	19.20–55.09

from format. Second, we examined a linear regression model predicting risk recall from format. Third, we examined a linear regression model predicting risk recall from format and self-efficacy. As an additional way to test the mediational hypothesis, we conducted a Sobel test¹⁸ to determine whether the indirect effect of format on risk recall via self-efficacy was significantly different from zero.

RESULTS

Participants

Three hundred mall visitors who reported that they had been told by a doctor or health care provider that they were overweight and needed to lose more than 15 pounds participated in the study. Half of the participants were women. The majority was non-Hispanic and white, had some college education or more, and was overweight or obese. The mean age was 34 years. See Table 1 for sample characteristics. There were no differences among conditions on BMI or any demographic characteristic ($P_s > 0.05$).

Do Alternative Formats Influence the Comprehension of Major Risks?

The risk recall measure did not differ by format in bivariate analysis (see Table 2). However, in the multivariate analysis, there was a significant difference for format. Contrasts revealed that participants in the drug facts format condition had better recall than did those in the traditional format condition, $P = 0.005$. In addition, log time on the brief summary predicted recall; participants who spent more time viewing the brief summary had better recall, $F(1, 278) = 27.67$, $P < 0.001$. The risk application measure did not differ by format and was not predicted by any of the covariates (see Table 2).

Do Alternative Formats Influence Self-Efficacy?

Self-efficacy significantly differed by format (see Table 2). Specifically, participants in the drug facts format condition reported greater confidence to perform the tasks than did those in the traditional format condition, $P = 0.005$. This did not change

Table 2 Raw Means (Standard Deviations) of Between-Subjects Dependent Variables, by Format

	Total	Traditional	Q&A	Highlights	Drug Facts	Bivariate <i>F</i> (3, 296)	Multivariate <i>F</i> (3, 278)
No.	300	71	78	75	76		
Attitude toward ad	3.76 (0.61)	3.49 (0.58)	3.78 (0.58)	3.71 (0.54)	4.03 (0.64)	10.52 <i>P</i> < 0.001	10.36 <i>P</i> < 0.001
Risk/benefit tradeoff	3.28 (0.81)	3.15 (0.70)	3.33 (0.76)	3.29 (0.77)	3.34 (0.89)	0.88 <i>P</i> = 0.45	0.57 <i>P</i> = 0.64
Behavioral intention	3.36 (1.05)	3.30 (1.06)	3.24 (1.10)	3.46 (0.96)	3.42 (1.09)	0.70 <i>P</i> = 0.55	0.47 <i>P</i> = 0.70
Self-efficacy	7.57 (1.80)	7.19 (1.87)	7.46 (1.84)	7.58 (1.80)	8.03 (1.63)	2.87 <i>P</i> = 0.04	2.57 <i>P</i> = 0.054
Comprehension— risk recall (0–12)	7.22 (1.95)	6.89 (1.98)	7.13 (1.75)	7.24 (2.30)	7.60 (1.70)	1.74 <i>p</i> = 0.16	2.69 <i>p</i> = 0.047
Comprehension—risk application (0–4)	2.48 (1.06)	2.41 (0.95)	2.49 (1.09)	2.51 (1.09)	2.51 (1.09)	0.15 <i>P</i> = 0.93	0.42 <i>P</i> = 0.74
Time on display page (log ms)	9.89 (1.35)	9.86 (1.41)	9.81 (1.40)	9.89 (1.27)	9.99 (1.33)	<i>F</i> (3, 295) 0.47	<i>F</i> (3, 280) 0.56
Time on brief summary (log ms)	9.88 (1.57)	10.05 (1.61)	9.87 (1.70)	9.74 (1.49)	9.88 (1.57)	<i>P</i> = 0.70 <i>F</i> (3, 293) 0.14	<i>P</i> = 0.64 <i>F</i> (3, 278) 0.29
						<i>P</i> = 0.93	<i>P</i> = 0.83

Attitude toward ad and risk/benefit tradeoff were measured on a 1 (*strongly disagree*) to 5 (*strongly agree*) scale. Behavioral intention was measured on a 1 (*definitely will not*) to 5 (*definitely will*) scale. Self-efficacy was measured on a 0 (*not at all confident*) to 10 (*completely confident*) scale. Multivariate analyses included age, gender, race, educational level, and body mass index (BMI) as covariates. Rows 1 to 6 also included log time on the brief summary as a covariate, whereas rows 7 to 8 included log reading speed as a covariate.

when covariates were included in the model. In addition, log time on the brief summary predicted self-efficacy. The more time participants spent viewing the brief summary, the more self-efficacy they reported, $F(1, 278) = 7.50$, $P = 0.007$.

Following Baron and Kenny,¹⁷ we examined 4 criteria to test whether self-efficacy mediated the relation between format and risk recall. First, the direct link from format (drug facts v. traditional) to risk recall was significant, $\beta = 0.16$, $P = 0.03$. As noted above, participants in the drug facts format condition had greater risk recall than did those in the traditional format condition. Second, the link from format (drug facts v. traditional) to self-efficacy (i.e., the mediator) was significant, $\beta = 0.20$, $P = 0.005$. Participants in the drug facts format condition had higher self-efficacy than those in the traditional format condition. Third, the link between the mediator and risk recall was significant when controlling for format, $\beta = 0.19$, $P < 0.001$, such that higher self-efficacy was associated with greater risk recall. Finally, when the mediator was

included in the equation, the direct link from format (drug facts v. traditional) to risk recall became nonsignificant, $\beta = 0.12$, $P = 0.09$ (see Figure 1). In addition, the Sobel test was significant (2.17; $P = 0.03$). This pattern of results supports the mediational hypothesis.

Do Alternative Formats Influence Behavioral Intentions, Risk/Benefit Tradeoff, and/or Time Spent Viewing the Ad?

Behavioral intention, risk/benefit tradeoff, log time on the display page, and log time on the brief summary did not differ by format (see Table 2). However, these dependent variables were related to some of the covariates. Specifically, BMI significantly predicted behavioral intention: Participants with higher BMIs had greater behavioral intentions, $F(1, 278) = 8.57$, $P = 0.004$. White participants felt more positively about the risk/benefit tradeoff than did nonwhite participants, $F(1, 278) = 6.49$, $P = 0.01$. Finally, participants with faster reading speeds spent less time

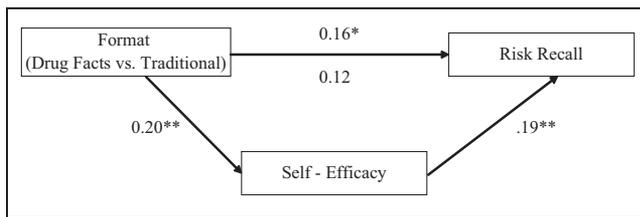


Figure 1. A mediational analysis predicting risk recall. The standardized coefficient above the arrow represents the direct link between format (drug facts v. traditional) and risk recall. The standardized coefficient below the arrow represents the link when the mediator, self-efficacy, was included in the model. * $P < 0.05$. ** $P < 0.01$.

reading the display page, $F(1, 280) = 32.57$, $P < 0.001$, and the brief summary, $F(1, 278) = 54.08$, $P < 0.001$.

Which Format(s) Do Consumers Prefer?

The between-subjects measure of attitude toward the ad differed significantly by format (see Table 2). Contrasts revealed that participants in the drug facts format condition had more positive attitudes toward the ad than did those in the highlights condition and the traditional format condition, $P = 0.001$, $P < 0.001$, respectively. In addition, participants in the Q&A format condition had more positive attitudes toward the ad than did those in the traditional format condition, $P = 0.003$. This did not change when covariates were included in the model. In addition, log time on the brief summary significantly predicted attitude toward the ad; participants who spent more time viewing the brief summary had more positive attitudes toward the ad, $F(1, 278) = 16.76$, $P < 0.001$.

The within-subjects measure of attitude toward the ad differed significantly by format (see Table 3). Contrasts revealed that participants had more positive attitudes toward the drug facts format than any other format, $P_s < 0.001$. In addition, participants had more positive attitudes toward the Q&A format and the highlights format than the traditional format, $P_s < 0.001$.

There was a significant effect for preference (see Table 3). The drug facts format was ranked highest, followed by the Q&A format, the traditional format, and finally the highlights format.

DISCUSSION

We assessed how alternative brief summary formats compared with the traditionally used (“traditional”)

format to explore ways in which the brief summary might be improved. Our primary end point was comprehension (recall and application) of the risk information.

We found that participants who viewed the drug facts format recalled more risk information than those who viewed the traditional format. There were no other significant effects. From this finding, we cannot assert that participants who viewed the drug facts format had better recall than those who viewed the Q&A or highlights format. At the same time, we cannot assert that participants who viewed the Q&A and highlights formats had better recall than participants who viewed the traditional format. In sum, no format decreased recall in relation to the traditional format, and the drug facts format increased recall in relation to the traditional format.

The second comprehension measure examined whether readers could apply the information in the brief summary to novel situations. Format did not appear to influence this measure. In fact, participants in all formats showed an average score of 2.48 on a scale from 0 to 4, indicating that participants correctly answered a bit more than half of the application questions. It is possible that format does not influence the ability to apply knowledge in the case where participants have the brief summary in front of them.

Comprehension, although our most important consideration, was not the only variable we examined. We investigated several supporting variables to determine whether the formats differed with respect to participants’ self-efficacy, preference, behavioral intentions, time spent viewing the ad, and attitudes toward the brief summary. We found significant differences in the amount of confidence participants felt in their ability to use the brief summary, also called their self-efficacy. In this case, participants in the drug facts format felt significantly more confident in their ability to read the brief summary than did those in the traditional format. As with the recall comprehension measure, we cannot say the drug facts format was different from the Q&A or highlights format on this measure or whether the Q&A and highlights formats differed from the traditional format.

We found evidence to support the hypothesis that formats that increase self-efficacy result in better comprehension. Specifically, self-efficacy mediated the relation between risk recall and format (drug facts v. traditional). Although there are limitations to testing mediational hypotheses with cross-sectional data,^{19,20} these results warrant further investigation.

Table 3 Raw Means (Standard Deviations) and Number (%) of Within-Subjects Dependent Variables, by Format

	Traditional	Q&A	Highlights	Drug Facts	Test Statistic	
					Bivariate	Multivariate
Attitude toward ad, mean (SD)	6.14 (2.36)	6.99 (1.74)	7.04 (1.65)	8.22 (1.74)	$F(3, 297) = 56.47$ $P < 0.001$	$F(3, 284) = 2.90$ $P = 0.03$
Preference, No. (%)					$\chi^2(3) = 117.46$ $P < 0.001$	
First	60 (20.0)	40 (13.3)	38 (12.7)	162 (54.0)		
Second	65 (21.7)	96 (32.0)	74 (24.7)	65 (21.7)		
Third	54 (18.0)	120 (40.0)	89 (29.7)	37 (12.3)		
Fourth	121 (40.3)	44 (14.7)	99 (33.0)	36 (12.0)		

Attitude toward the ad was measured on a 1 (*not at all*) to 10 (*very/extremely*) scale. Multivariate analyses included age, gender, race, educational level, body mass index, and log time on the brief summary as covariates.

Conceptually, it makes sense that formats engendering confidence result in better comprehension.²¹ A person who feels that he or she can read and understand a document is more likely to devote cognitive resources to reading the document, which likely increases the knowledge gained from that document.

Preference for a particular format is another variable of secondary interest. All other things being equal, a preferred format may provide an advantage over less preferred formats by, for example, motivating participants to pay attention to the information or improving the “stopping power” of the ad. Participants preferred the drug facts format to all other formats on one measure of preference and preferred the drug facts format to the highlights and traditional formats on another measure of preference. Finally, when asked to rank the formats, the drug facts format scored highest.

Based on the comprehension measure alone, the drug facts format showed an advantage to what exists traditionally, but this was only supported in the recall measure and not in the application measure. When other factors, such as self-efficacy and preference, are taken into consideration, however, it appears that the drug facts format has other advantages over the traditional format. Note, however, that in many cases, the drug facts format was not significantly more favorable than the Q&A format, and in some cases, it was not more favorable than the highlights format. Thus, it is not clear that the drug facts format is the only contender for a revised brief summary.

The finding that the drug facts format scored higher than the traditional format on several important variables is consistent with the research conducted on the OTC drug label.⁸ The OTC label is based in part on

qualitative and quantitative research, and the current research extends it, demonstrating that the principles that were investigated in the OTC research are transferable to another area of research. This may partially explain the recall comprehension superiority. It is also likely that participants’ familiarity with the drug facts format played a large role in preference ratings for particular formats. The OTC label has been in existence since 1999, and the drug facts format that we created for this study was based as closely as possible on that format, including replicating standardized headings. Thus, participants may have responded more positively to it because they recognized it.²² Perhaps that familiarity led to the higher self-efficacy scores for the drug facts format and, through the self-efficacy concept, to greater recall.

The highlights section of physician labeling was placed into effect in 2006 after qualitative testing of the format. Because physicians responded favorably to it, we chose to test a similar version in our examination of nonphysicians. It appears that this format, rated favorably by physicians, may not work well when applied to the brief summary setting. Although the highlights version did not score *worse* than the traditional version in terms of comprehension, participants did not prefer it on any of our measures, and on one measure, they preferred the traditional version more. Our study demonstrates the importance of tailoring testing to the intended audience.

A few study limitations should be noted. First, our sample was collected by recruiting individuals in various malls throughout the United States. Thus, this was a sample of interested volunteers. Although we made attempts to evenly distribute relevant demographic characteristics such as gender

and education across experimental cells and to over-recruit individuals of lower education attainment, we did not weight our sample in such a way as to make it a reasonable extrapolation of the US population as a whole, and so caution must be exercised when generalizing.

Another limitation is that word count was confounded with format. The traditional format had the highest word count, and the drug facts format had the lowest word count. This is the nature of the different formats; one reason to seek an alternative to the traditional format is to find a more succinct way to relay important risk information. From the results of this study, however, it is not clear if participants who saw the drug facts format had better comprehension than those who saw the traditional format simply because there were fewer words or whether it was due to other aspects of the format (such as the box itself). Future research should separate word count from format to determine which aspects of the drug facts format contribute to greater comprehension. For instance, the same information could be conveyed in paragraphs like the traditional format and in a box like the drug facts format.

A difficulty with this kind of research is how to assess comprehension. We created measures based on the information in this particular ad, and therefore these were new measures. This area of research would benefit from measurement development.

This study imposed a limit on the amount of time participants had available to read the ad. Although only 2 participants reached the 4-minute limit and the majority of participants spent 2 minutes or less on the ad, it is still possible that the time limit affected results. It is possible that, knowing there was a time limit, some participants read through the ad faster than they normally would. This may have been a disadvantage for participants who saw the traditional format, which had a higher word count than the other formats. Future research would benefit from unrestricted viewing of the ad.

Participants spent little time reading the brief summary and overall scored only a little better than chance on the comprehension measures. This demonstrates the difficulty in increasing risk comprehension in this setting. However, we did see differences between formats. The results of this study show that there is room for improvement over the traditional format, a format that acceptably fulfills the regulatory requirement for displaying risk information in print media. Although there is some support for the drug facts format specifically, the results do not lead unequivocally to this format. The results

do demonstrate that improvement over the traditional brief summary format is possible and suggest that future research explore these other formats, particularly the drug facts format.

These data provide policy makers and researchers with important information regarding the role of format in consumers' understanding of the brief summary. Policy makers should consider encouraging alternate formats for the brief summary. Researchers should continue to explore ways in which the content and format of the brief summary combine to help consumers understand risk information, ultimately leading to more informed decisions about prescription drug use.

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