The Drug Facts Box: Providing Consumers with Simple Tabular Data on Drug Benefit and Harm

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The Drug Facts Box: Providing Consumers with Simple Tabular Data on Drug Benefit and Harm

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Context. *Direct-to-consumer drug ads have been criticized for providing inadequate and misleading information. Requiring ads to include a table with data on drug benefits and side effects (derived from clinical trials) could help, provided that consumers understand such tabular information.* ***Objective***. *To determine if people could understand and use a 9-row × 2-column "study findings table" presenting expected outcomes (both beneficial and harmful) with and without a drug.* ***Subjects***. *A convenience sample of 274 participants: 186 recruited from alumni of Dartmouth's "Community Medical School" public lecture series and Dartmouth Hitchcock's Center for Shared Decision Making and 88 veterans and their families recruited from waiting rooms in the Veterans Affairs outpatient clinic, White River Junction, Vermont.* ***Design***. *Cross-sectional survey. Participants were tested on their comprehension of the study findings table about the drug tamoxifen used for the primary prevention of breast cancer—with no instructions on how to use the table.* ***Main outcome measure***. *Five comprehension questions testing how well participants could read and use the table with drug benefits and side effects data.* ***Results***. *On average, participants correctly answered 4 of the 5 table comprehension questions: 89% correctly used the table to determine the percentage of women given tamoxifen who got a blood clot in their legs or lungs, and 71% were able to use data in the table to calculate the absolute difference in the proportion of women who got breast cancer in the tamoxifen v. the placebo group. Most participants were also able to use the table to make comparisons.* ***Conclusion***. *Most participants—even those with lower formal educational attainment—were able to understand and use the tabular data.* ***Key words:*** *risk communication; decision aids; pharmaceutical decision making.* ***(Med Decis Making 2007;27:655–662)***

Direct-to-consumer pharmaceutical advertisements have been criticized for how they present data on drug benefit and side effects.[1,2] Drug benefit is rarely quantified, and when quantitative data are provided, they are typically provided in a format that tends to exaggerate perceptions of the effect size—namely, a relative change with no base rate (e.g., "lowers heart risk by 40% v. placebo," without stating the risk in the placebo group).[2] Although side effect data often appear in ads, they are generally found in long, hard-to-read lists that fail to distinguish between clinically important and unimportant problems.

To improve the educational value of direct-to-consumer ads, we developed a presentation format called the "drug facts box"—a 1-page summary of the drug that includes descriptive (e.g., the drug's indication) and quantitative information (Figure 1). The quantitative information at the heart of the box is presented in the "study findings table." The table summarizes drug benefit and side effect data from published trials used in the Food and Drug Administration's (FDA's) drug approval process. The table

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Drug Facts: TAMOXIFEN (Nolvadex)

What is this drug for?	To reduce the chance of getting breast cancer
Who might consider taking it?	Women at high risk of getting breast cancer (1.7% or higher risk over 5 years). You can calculate your breast cancer risk at http://bcra.nci.nih.gov/btc.
Who should not take it?	Women who are pregnant or breastfeeding
Recommended testing	Have a yearly checkup that includes a gynecological examination and blood tests
Other things to consider doing	No other medicines are approved to reduce breast cancer risk for women who have not had breast cancer

TAMOXIFEN STUDY FINDINGS TABLE

13,000 women at high risk of getting breast cancer were given TAMOXIFEN or a sugar pill for 6 years. Here's what happened:

What difference did TAMOXIFEN make?	Women given a sugar pill	Women given TAMOXIFEN (20 mg a day)
Did TAMOXIFEN help?		
Fewer women got invasive breast cancer	2.7%	1.4%
Fewer women died of from breast cancer	0.09%	0.05%
Did TAMOXIFEN have side effects?		
Life-threatening side effects		
More women had a blood clot in their leg or lungs	0.4%	0.8%
More women had a stroke	0.4%	0.6%
More women got invasive uterine cancer	0.2%	0.5%
Symptom side effects		
More women had hot flashes	69%	81%
More women had vaginal discharge	35%	55%
More women had cataracts needing surgery	1.1%	1.7%
Other things to know		
Dying for any reason	1.1%	0.9%

How long has the drug been in use?

Tamoxifen was first approved by the FDA in 1982 - Studies show that most serious side effects or recalls of new drugs happen during their first 5 years of approval.

Figure 1 Tamoxifen drug facts box.

includes 2 columns of numbers: the chance of various outcomes for people who do or do not take the drug.

Although the drug facts box concept is intuitively appealing,[3] some have expressed concerns about how well consumers would be able to understand and make use of the tabular data, citing studies that highlight problems that many Americans have in working with numbers.[4-6] At the FDA's suggestion, we conducted a study to address these concerns. We found that consumers understood and valued data presented in the drug box; almost all said the data were easy to understand, and more than 90% rated the data as "very important" or "important" to include in drug ads.[7]

Nonetheless, the study had 3 important limitations. Our evaluation was done under highly controlled circumstances: an interviewer took participants through a training task to familiarize them with how to navigate the box. Second, the box was simple: it included just 2 rows of 2 columns of data (about drug benefit only). Finally, the comprehension task was not demanding—participants simply had to extract 2 numbers from the table.

We conducted the following study to more fully evaluate how well people could understand and use tabular data under less artificial circumstances. Specifically, we gave participants a more complex drug facts box (the table included 9 rows of 2 columns of data on benefit and side effects, i.e., a 9×2 table)—but no instructions or training—and tested how well they could navigate the table, extract specific data, and use the data to do calculations and make comparisons.

METHODS

Drug Facts Box

This 1-page presentation format is meant to provide consumers with basic drug information (and was designed to replace the "brief summary" page that now accompanies direct-to-consumer drug ads). The format includes descriptive information about drug indication, how the drug should be used, what monitoring needs to be done, and the date of FDA approval. The central feature of the drug facts box is the "study findings table," a table quantifying drug efficacy and side effects using 2 columns of data—the absolute risks of outcomes for people who do or do not take the drug. The drug facts box created for this study appears in Figure 1; it summarizes information about the drug tamoxifen (Nolvadex) used for the primary prevention of breast cancer. The data for the box are from the FDA-approved label[8] and the randomized trial cited in the FDA approval documents.[9]

Study Sample

We recruited English-speaking subjects aged 35 to 79 from 3 sources. First, we mailed letters to past attendees of the Dartmouth Community Medical School,[10] an annual public lecture series about a variety of health and medical topics taught by Dartmouth faculty and guests. We also mailed letters to individuals who visited the Center for Shared Decision Making at the Dartmouth Hitchcock Medical Center, a resource for patients interested in learning how to participate more fully in medical decisions. Finally, we recruited veterans and their family members at the Veterans Administration (VA) Medical Center in White River Junction, Vermont, by placing advertisements in the outpatient clinic waiting areas.

All recruitment letters and advertisements explained that we were conducting a study to learn better ways to present health information to patients and that participants who returned surveys would be given their choice of a $20 gift certificate to a local bakery, restaurant, Borders bookstore, or Wal-Mart. Dartmouth's Committee for the Protection of Human Subjects approved this project.

Study Design and Protocol

Individuals interested in participating contacted a research assistant, who verified eligibility and then mailed the tamoxifen drug facts box. Subjects were also asked to complete and return an enclosed survey within 2 weeks (we provided a stamped self-addressed return envelope). Subjects were not provided with any instruction on how to read or use the drug facts box. Reminder letters were sent to nonresponders. Of the eligible participants, 274 of 295 (93%) mailed back a completed survey.

Outcome Measures

The survey tested how well participants could read and use the information in the drug facts box. The exact text of all questions is presented in the results tables.

Primary outcome: table comprehension. Five questions focused on the study findings table and involved using and interpreting the tabular data on drug benefit and side effects. These questions tested a variety of skills: 2 questions tested the ability to

Table 1 Participant Characteristics

n	274
Mean age (range), y	59 (40–79)
Women, %	57
Education, %	
High school graduate or lower	11
Some college	19
College graduate	38
Postgraduate degree	31
Race/ethnicity, %	
White	97
Black	0
Hispanic	1
Other	2
Health status, %	
Excellent	16
Very good	45
Good	24
Fair	13
Poor	2
Medical conditions, %	
Heart/vascular disease	13
Chronic obstructive pulmonary disease	5
Diabetes	13
History of cancer (not skin)	17
Smoking history, %	
Never smoked	51
Former smoker	43
Current smoker	7

find specific data items in the 9×2 table; 1 question asked subjects to use data from the table to calculate an absolute risk difference (i.e., subtraction); and 2 questions asked subjects to make comparisons between tamoxifen and hypothetical drugs with different benefits.

Secondary outcomes: text comprehension. We tested text comprehension with 2 questions about how well participants could find information in the descriptive parts of the drug facts box (i.e., find the date of FDA approval and length of follow-up in the clinical trial) and 3 questions about how well participants could apply information; specifically, we tested whether they could use the information provided in the "who might consider taking it" and "who should *not* take it" sections in deciding whether tamoxifen was appropriate for various patients.

Analysis

To compare findings across education categories and the effect of age, we used chi-square tests, linear regression, and tests of trend from regression. All comparisons were 2-sided and were considered statistically significant at $P < 0.05$. We used Stata 9.1 (StataCorp, College Station, TX) for all analyses.

RESULTS

As described in Table 1, participants had an average age of 59 years (range, 40–79), 57% were women, and educational attainment ranged as follows: high school graduate or lower (11%), some college (19%), college graduate (38%), and postgraduate degree (31%).

Primary Outcome: Table Comprehension

The mean (and median) number correct for the 5 table comprehension questions was 4 (Table 2). Most participants were able to find specific data from the study findings table; for example, 89% correctly identified the percentage of women given

Table 2 Primary Outcome: Table Comprehension

	% Correct Answer ($n = 274$)
What percentage of people given TAMOXIFEN get a blood clot in their leg or lung?	
Wrote in "0.8%"	89
What percentage of women NOT given TAMOXIFEN get invasive breast cancer?	
Wrote in "2.7%"	89
Which statement is correct about how TAMOXIFEN changes the chance of getting breast cancer?	
Answered "Lowers chance by 1.3%"	71
NEWDRUG is identical to TAMOXIFEN (e.g. the same side effects, etc.) except NEWDRUG does not lower the chance of dying from breast cancer. Which drug should Mrs. Jones take?	
Answered "TAMOXIFEN"	86
OTHERDRUG is also identical to TAMOXIFEN (e.g. the same side effects, etc.). In the study, 1% of the women taking OTHERDRUG got breast cancer over the 6 years. Which drug should Mrs. Jones take?	
Answered "OTHERDRUG"	69
Mean (median) number correct out of 5	4 (4)

tamoxifen who got a blood clot in their legs or lungs from the data table. In addition, 71% were able to use data in the table to calculate the absolute difference in the proportion of women who got breast cancer in the tamoxifen v. the placebo group (i.e., they could find the appropriate data and do the subtraction). Most participants were also able to use the data table to make comparisons. For example, 86% recognized that tamoxifen was a better choice than a hypothetical drug described as similar in all respects except that it did not lower the chance of breast cancer death. To complete this task, participants had to recognize that, according to the study findings table, tamoxifen did lower this risk. And 69% correctly judged that another hypothetical drug worked better than tamoxifen. This task entailed comparing 2 percentages—one in the question text and one in the relevant cell of the tamoxifen study findings table.

Figure 2 shows that the mean number correct on the 5 data interpretation questions differed somewhat according to participant educational attainment: 3.4 correct (high school graduate or lower), 4.0 (some college), 4.2 (college graduates), and 4.1 (postgraduate degree) ($P_{trend} = 0.02$). Another way to look at the effect of education is to examine the distribution of high scores (i.e., getting at least 4 of the 5 questions correct). Forty-eight percent of participants with a high school degree or lower achieved a score of 4 or 5 compared to 66% of those with some college, 81% of those who graduated college,

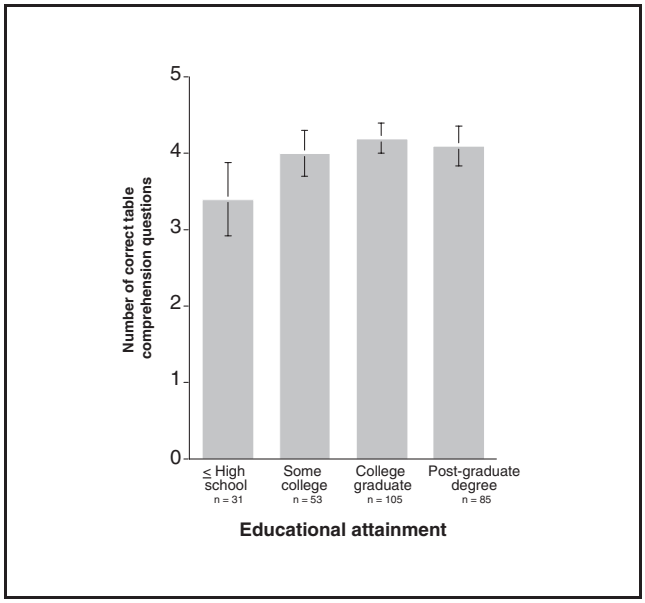

Figure 2 Effect of educational attainment on the number of the 5 table comprehension questions answered correctly. The height of each column is the mean number correct, and the error bars indicate the 95% confidence interval. $P_{trend} = 0.02$; of 6 pairwise comparisons, 2 were statistically significant: high school or lower v. college graduate ($P = 0.01$) and high school or lower v. postgraduate ($P = 0.01$) degrees.

and 75% with a postgraduate degree ($P_{trend} = 0.004$) In a multiple linear regression, both age (coefficient −0.0170969, 95% confidence interval [CI]: −0.0320469 to −0.0021469) and educational

Table 3 Secondary Outcome: Text Comprehension

	% Correct Answer ($n = 274$)
Find basic drug facts	
When was TAMOXIFEN approved by the FDA? Wrote in "1982"	92
How long were the people in the TAMOXIFEN study followed? Wrote in "6 years"	92
Apply drug indication information	
According to the Drug Facts Box, should a 50-year-old woman whose risk of getting breast cancer is 1.4% in the next 5 years consider taking tamoxifen? Answered "No"	68
According to the Drug Facts Box, should a 40-year-old woman whose risk of getting breast cancer is 2% in the next 5 years consider taking tamoxifen? Answered "Yes"	83
According to the Drug Facts Box, should a healthy 30-year-old woman who is pregnant consider taking tamoxifen? Answered "No"	91

attainment (+0.1791, 95% CI: 0.0368 to 0.3214) were independent predictors of the number of correct answers. Adjusting for age did not change the estimates for the effect of educational attainment (see online appendix).

Secondary Outcomes: Text Comprehension

Almost all participants were able to *find the basic drug facts* in the descriptive section of the drug box; each question was answered correctly by 92% of respondents, and 89% of respondents got both answers right (Table 3). Most participants were also able to correctly *apply the drug indication information* provided in the box in deciding whether tamoxifen was appropriate for various patients. Sixty percent answered all 3 indication questions correctly.

Text comprehension also varied by education (but the differences were not statistically significant). The proportion answering 4 or 5 of the text comprehension questions correctly was 71% for those with a high school diploma or lower compared to 83% with some college, 86% who graduated from college, and 80% of those with a postgraduate degree ($P_{trend} = 0.47$).

COMMENT

Without prior training, most participants were able to find, understand, and use the information provided in the drug facts box. Although finding basic drug facts (e.g., the date of drug approval by the FDA)—or applying them (e.g., recognizing who should or should not consider the drug)—is not especially difficult, it does entail the ability to navigate the format. Participants' performance on the study findings table comprehension questions, however, is noteworthy, particularly given the complexity of the 9×2 table in which many of the 18 data points involved decimals. These 5 questions cover a broad set of skills that range from comparing percentages, calculating absolute risk differences, and integrating data to make comparisons across drugs—tasks that are far from trivial.

That our findings varied to some extent across educational attainment is not surprising. What is surprising—and encouraging—is that even people at the lower end of the range of educational attainment in our sample, did fairly well. Our table comprehension questions were not easy; nonetheless, half of those with only a high school diploma (or less) and two thirds of those with only some college (i.e., did not graduate) answered 4 of the 5 questions correctly. This suggests that a substantial portion of the population is capable of reading and interpreting tabular data without specific training.

Our study should be interpreted in light of several limitations. First, we tested the box in a convenience sample of participants in a single US community that did not reflect the full range of racial and

ethnic variation and of socioeconomic status of the general US population. Second, volunteer bias may have resulted in a sample of participants with somewhat better than average quantitative skills compared to others with similar socioeconomic status. Third, it is important to note that the format used to represent data in the box probably matters. We used percentages (e.g., "2.7%"). Others have argued that a frequency format (e.g., "27 out of 1000") might be more accessible to readers.[11] This is probably most important for low-probability events (e.g., 0.1%), where the percentage format may be especially confusing.[6] It will be useful to see in subsequent work whether use of frequency formats (or a combination of percentages and frequency formats) further improves comprehension of tabular data. The other data formatting issue not addressed in this version of the box is statistical significance. Because we wanted to focus on the more basic issues like correctly judging the direction and magnitude of effects, we did not address significance (in fact, the effect of tamoxifen on breast cancer mortality in the box was not significant). This is also clearly an important issue for future work. Finally, because the goal of the drug facts box is to make informed decision making possible (by ensuring the availability of key information), we focused our testing on comprehension rather than on how the box affected actual decisions. However, the skills tested—including the ability to correctly judge which was the better drug—are necessary prerequisites to informed decision making.

We hope that our findings will encourage the FDA to reconsider data requirements in direct-to-consumer ads. Currently, there are no requirements for efficacy data in ads or any presentation standards for side effect data. More complete, balanced information is in the public interest and would help give substance to drug company assertions that the ads serve an educational function.

Clearly, not everyone will be able to make use of such tabular data. For this reason, we believe that more should be done than simply providing drug facts boxes. To enhance the accessibility of drug information, some training would be useful. To this end, we have developed[12] and tested[14] a general educational primer to teach people (at all levels of education) how to make sense of medical data.

Finally, although tables are routinely used to communicate data in medical journal articles, there seems to be a hesitancy to use them in communicating with the general public. For example, none of the major medical journals' "patient summary" pages include tables, nor are tables regular elements in most news stories reporting on medical research. Moreover, some in the risk communication research community believe that numeric data—in any format—may be too difficult for even highly educated members of the general public.[13] This is unfortunate because tables are the most efficient and practical way to look at and compare a series of numbers: that is why tables are ubiquitous in the scientific literature. Presenting the 9×2 study findings table in prose, for example, would require many sentences with numbers and would result in a paragraph that few would want to read.

We believe our study supports the broader use of simple tabular displays to communicate the benefits and side effects of drugs or other medical interventions to the public. We hope that our findings will encourage medical journal editors, journalists (and their editors), and authors of patient decision aids to routinely use tables to communicate data to the public. Although editors and writers may worry that readers would not understand the data, our findings suggest that most would.

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