BRIEF REPORT

Primary Care Physicians' Use of FDA-Approved Prescription Drug Labels

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Background: **In 2006, the US Food and Drug Administration reorganized the approved label format and content for prescription drugs —also known as the prescribing information (PI). This research examines primary care physicians' use of the new PI and how it may influence their perceptions about prescription drugs.**

Methods: **A total of 500 physicians responded to an Internet survey that displayed an interactive PI for a fictitious combination pain relief/heart attack–reducing drug. The physicians answered questions about perceived risk, perceived benefit, and intention to prescribe that focused on either the treatment indication or the prevention indication.**

Results: **Physicians viewed PI sections in order, most often viewing sections relevant to safe use, such as Warnings and Precautions and Dosage and Administration. When asked to think about the drug's efficacy, many viewed the Clinical Studies section. Viewing certain PI sections was associated with greater perceived risk and lower perceived benefits and intention to prescribe.**

Conclusions: **These results suggest that the information in the PI could affect physician decision making and do not support further reorganization of the PI. (J Am Board Fam Med 2014;27:694–698.)**

Keywords: **Drug Labeling, Prescription Drugs**

Each successful prescription drug application to the US Food and Drug Administration (FDA) results in FDA-approved product labeling, known as prescribing information (PI). The PI details pertinent information about the drug, such as contraindications, and contains essential information for the practice of medicine. It accompanies the product, is available online—including on the FDA's website (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm) and the Physician's Desk Reference website (http://www.pdr.net)—and forms the basis for information found in other physician platforms, such as Epocrates.

Based on research and public input, the FDA reorganized the PI in 2006 to make it more user friendly.[1,2] The PI for many products (and all new products' PI) now follow the new format. It includes a table of contents and a highlights section, which provides an overview of the PI. Studies of physicians' use of PI predate these changes.[3–6] Because the PI is the basis for many sources of physician information, it is critical to understand how physicians process the revised PI. This study is designed to examine how physicians search for medical information[7–9] by assessing physicians' use of the PI and how it may affect physicians' perceptions of the drug.

Methods

Procedure

Participants were recruited from an opt-in internet panel of more than 100,000 physician members of the American Medical Association. To be included, their primary area of specialization had to be family practice, general practice, or internal medicine and they had to report spending 50% or more of their time on direct patient care.

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We created a PI for a fictitious drug, Gilarix, indicated to reduce chronic pain (treatment indication) and the risk of heart attack (prevention indication). Participants viewed the PI twice: First, they were asked to attend to the PI to help the FDA improve its presentation (task 1). Second, they were asked to focus on the drug's efficacy (task 2). For both tasks, participants first saw the Contents page, with a hyperlink for the title of each section and subsection (eg, Contraindications). Within each section, participants could move back to the previous section, move forward to the next section, or go to the Contents or Highlights pages to choose another section to view. After viewing the PI for as long as they liked, participants completed a questionnaire. Participants were randomly assigned to answer questions about the treatment or prevention indication. Participants also completed an independent task, reported in another article.[10]

Measures

PI Viewing

For tasks 1 and 2, we recorded which PI sections participants viewed, the order in which they viewed them, and for how long they viewed them. View time variables were calculated and adjusted for the word count in each section. Because the timing variables were positively skewed, we used log transformations in analyses.

Perceived Benefit

After task 1, participants rated how well the drug would work for patients and how effective it would be (scale of 1 [not at all effective] to 7 [very effective]). They also rated how effective the drug was compared with other drugs for the same medical problem (scale of 1 [much less effective] to 7 [much more effective]). We combined these 3 items to form 1 measure of task 1 perceived benefit.

To reduce repetition for participants, after task 2 we asked a different set of perceived benefit questions. Participants reported how much this drug would reduce symptoms of pain or heart attack risk (scale of 1 [not much] to 7 [a great deal]). They reported how many patients out of 100 they thought would experience less pain (or have a heart attack) with and without the drug.

Perceived Risk

After task 1, participants rated how safe and risky (scale of 1 [not at all risky/safe] to 7 [very risky/safe]) they thought the drug was. They rated how safe the drug was compared with other drugs for the same medical problem (scale of 1 [much less safe] to 7 [much safer]).

Intention

After task 1, participants rated how likely they would be to prescribe the drug to their patients if it were real (scale of 1 [very unlikely] to 4 [very likely]).

Participant Characteristics

Participants reported their age, sex, race, ethnicity, medical training, and practice details. We measured numeracy by summing the number of correct responses to 3 math questions.[11]

Analyses

We calculated descriptive statistics for the PI viewing measures. We tested whether the perceptions and intention of participants who viewed and did not view each PI section differed using 17 *t* tests for each task, with a Bonferroni-adjusted *P* value $<.003$. We tested whether the time spent viewing each section was correlated with perceptions of and intention in each task ($P < .003$). Significant analyses were conducted again with participant characteristics included in the model using analysis of covariance and partial correlations. All significant effects remained except where noted.

Results

Participants

A total of 3000 panelists were invited to participate. Of those, 775 clicked the link and 596 consented to and completed the study. Because of a programming error, data for tasks 1 and 2 were recorded for only 500 participants. Table 1 describes participant characteristics.

PI Viewing

Table 2 shows the number of visits to each section. Most participants completed their review after 18 viewings (task 1: 90.0%; task 2: 96.6%), and about half completed their review after 9 viewings in task 1 (49.2%) and 4 viewings in task 2 (49.8%). Many did not look at any sections after viewing the Contents page (task 1: 20.8%; task 2: 24.6%).

For task 1, most participants looked through the sections in the order they appear in the PI. This was also true for most participants in task 2; how-

Table 1. Characteristics of 500 Primary Care Physician Participants (n = 500)

Characteristics	Number	Percentage
Sex		
Male	375	75.0
Female	125	25.0
Ethnicity		
Hispanic or Latino	26	5.2
Non-Hispanic or non-Latino	474	94.8
Race		
American Indian or Alaska Native	1	0.2
Asian	104	20.8
Black/African American	10	2.0
Native Hawaiian or Pacific Islander	1	0.2
White	343	68.6
Other	15	3.0
Multiracial	9	1.8
Prefer not to answer	17	3.4
Numeracy		
0 Correct	16	3.2
1 Correct	40	8.0
2 Correct	142	28.4
3 Correct	302	60.4
Primary area of specialization		
Family practice	229	45.8
General practice	27	5.4
Internal medicine	244	48.8
	Mean (SD)	Range
Age (years)	47.6 (10.4)	26–78
Years in practice	16.6 (9.2)	1–48
Patients per week	116.3 (51.5)	30–350
Time per week for patient care (%)	95.5 (8.1)	50–100
Patients treated for cardiovascular risk factors (%)	40.1 (21.4)	0–100
Patients treated for chronic pain (%)	13.3 (11.3)	0–55

SD, standard deviation.

ever, several participants began with Clinical Studies when asked to focus on efficacy. For instance, 61 participants (12.2%) visited Clinical Studies first.

Perceptions and Intention

Treatment Indication

Viewing several sections in task 1 was associated with greater perceived risk of the drug (Table 3). Spending more time viewing several sections in task 1 was associated with lower intentions, perceived benefit, and perceived safety after task 1 (Table 4). All other associations were nonsignificant.

Prevention Indication

Viewing Use in Specific Populations (t[248] = −3.20; P = .002) and Nonclinical Toxicology (t[248] = −3.11; P = .002) was associated with greater expected reduction in heart attack risk from the drug. Spending more time viewing Warnings and Precautions and Adverse Reactions in task 1 was associated with lower perceived comparative safety (r = −0.30; P < .001 for both sections). All other associations were nonsignificant.

Discussion

When asked to review the PI generally, physicians were most likely to view sections that had practical utility for how to prescribe the drug, including Indications, Dosage and Administration, and Contraindications. Physicians generally viewed sections in order of appearance. When asked to view the PI thinking specifically about efficacy, physicians viewed

Table 2. Total Number of Visits for Each Section in Tasks 1 and 2*

Section	Task 1	Task 2
Contents†	806	691
Highlights	193	152
Indications and usage	448	272
Dosage and administration subsection: Considerations for patient and product selection	35	21
Dosage and administration	318	221
Dosage forms and strengths	296	214
Contraindications	269	206
Warnings and precautions	252	199
Adverse reactions	254	196
Drug interactions	247	193
Use in specific populations	238	181
Overdosage	236	177
Description	221	179
Clinical pharmacology	217	183
Nonclinical toxicology	211	176
Clinical studies	207	282
How supplied	220	175
Patient counseling	202	145
Adverse reactions subsection: clinical trials	—	18
Clinical pharmacology subsection: mechanism of action	—	14

*Task 1 was a general review of the prescribing information. Task 2 was an efficacy-focused review of the prescribing information.

†All participants started on the Contents page; thus 500 of these visits were by default. Participants could visit a section multiple times.

Table 3. Viewing Selected Sections in Task 1 Was Associated with Greater Perceived Risk in the Treatment Condition

	Perceived Risk	
Section	*t(248)**	*P* value
Dosage and administration	3.90	<.001
Dosage forms and strengths	4.14	<.001
Contraindications	4.00	<.001
Warnings and precautions	4.22	<.001
Adverse reactions	3.78	<.001
Drug interactions	3.73	<.001
Use in specific populations	3.56	<.001
Overdosage	3.41	.001
Description	3.41	.001
Clinical pharmacology	3.41	.001
Clinical studies	3.32	.001

*t-test (degrees of freedom)

many of the same sections, with the addition of Clinical Studies. This suggests that although many physicians consider information from clinical studies when thinking about efficacy, their conceptualization of efficacy may encompass the entire risk–benefit profile of the drug.

In the treatment condition, viewing and spending time on several sections during task 1 was associated with greater perception of risk and lower intentions and perceived benefit, similar to other studies that have found an inverse relation between perceptions of benefits and risks.[12,13] It is possible that the information in these sections affected participants' perceptions of the drug. This supports the idea that the information in the PI can influence physicians' decision making. However, it is also possible that participants who were more skeptical about the drug were more likely to view these sections, perhaps to learn about risks or benefits about which they had doubts.

It is important to note that there were fewer associations in the prevention condition. Reducing the risk of heart attacks has larger and deeper long-term consequences, perhaps leading to a different benefit–risk analysis. Also, there were no associations with task 2 viewing patterns, perhaps because of the targeted nature of that task.

Limitations

The study was administered online, limiting us to American Medical Association members who self-selected into the panel. This allowed us to gather data from a large sample of physicians despite the relatively low response rate to the survey (which is typical for online surveys).

For task 1, perceived benefit and risk measures, we asked how the drug compared with others without specifying the comparator drug. Participants may have been thinking of different comparator drugs, which would introduce variability into these measures.

We examined responses to PI for only one drug. We attempted to account for this by using a combination product with treatment and prevention indications. Finally, approximately 20% to 25% of physicians chose not to look at any sections beyond the Contents page in tasks 1 or 2. This may reflect physicians' preference for obtaining medical information from sources other than the PI.[14] However, it is possible that this was simply noncompliance with the study procedure.

Conclusions

This study investigated how primary care physicians process the revised PI. Our findings demonstrate that physicians who view the PI find it useful

Table 4. Time Spent Viewing Selected Sections in Task 1 Was Associated with Lower Intention, Perceived Benefit, and Perceived Safety in the Treatment Condition

	Outcome Measures	
Section	*r*	*P* value
Intention		
Warnings and precautions	−0.39	<.001
Adverse reactions	−0.39	<.001
Drug interactions	−0.36	<.001
Use in specific populations	−0.39	<.001
Overdosage	−0.34	<.001
Description	−0.44	<.001
Clinical studies	−0.33	.001
Perceived benefit		
Warnings and precautions	−0.28	.002*
Adverse reactions	−0.28	.002*
Description	−0.36	<.001
Perceived safety		
Warnings and precautions	−0.32	<.001
Adverse reactions	−0.32	<.001
Description	−0.34	<.001

*These associations were no longer significant with covariates in the model ($r = -0.25$; $P = .007$).

primarily for practical information likely to be of use in a prescribing situation. The Clinical Studies section emerged as a section of interest when physicians were asked specifically about drug efficacy. Together, these results do not support further reorganization of the PI. In addition, viewing certain sections of the PI was associated with perceptions and intentions, suggesting that the PI could affect physicians' decision making. Because there is little research on physicians' interpretation of the PI, future research should explore the factors that influence these perceptions.

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