Investigating Consumer Comprehension of Drug Information Fact Sheets

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This paper examines comprehension of pharmaceutical drug information sheets based upon reading level. Prescription drug information fact sheets were collected, based upon a high or lower grade-level readability. Subjects were asked to identify what the condition the drug was prescribed to treat, possible side effects and warnings or concerns regarding use of the drug. Results do not indicate that reading grade level at which the fact sheet was written influenced subject comprehension. Recommendations for future research are presented based upon these results.

INTRODUCTION

The Internet has become a mainstream information source for many Americans. Consumers turn to the Internet to answer just about any question they might have, including questions concerning health care. More than ten years ago Fox and Rainie (2000) found 70 percent of consumers searched for information online, reported having made a health care decision on the basis of information they found there. As early as 2001, a Harris Poll estimated that roughly 100 million adults went online to find health related information (Taylor, 2001). A 2002 survey by Diaz et al. (2002) found more than half (58%) of respondents used online websites to research side effects of drugs or complications of medical therapy, while 41% searched for second opinions about medical conditions, complementary, or alternative medicine. The pharmaceutical industry has seen significant change in how it communicates with the consumer. These changes include direct-to-consumer advertising of prescription drugs and sales of medical devises and medications over the Internet. By the end of 2008 the U.S. had become the largest e-market in the world (Fox, 2008), both in numbers of buyers as well as in volume of transactions. Thus, it has become a necessity for the pharmaceutical industry respond to the demand for online information.

HEALTH INFORMATION ONLINE

On a typical day five years ago, about 8 million Americans were going online (Fox, 2006). Eighty percent of those people were online looking for health information. One year later, Choi and Lee (2007) reported that searching for health information (80 percent) had emerged as the third most common activity among on-line users. Another year later, Burns (2008) reported that there were close to 17 million consumers age 62 or older in the U.S., spending an average of 44 minutes per day on the Internet; of those, 38% were searching for health and health-related information. Another researcher (Fox, 2008) cited

The Pew Internet Project that reported between 75-80% of Internet users were online searching for health information, while Harris Interactive also reported similar statistics, 81% of Internet users searched for health-related information online. The Harris Interactive report further estimated two-thirds of all adults found health information online. The same year, another study by Renahy, Parizot and Cahuvin (2008) found that close to 70% of the adult population had Internet access, and 49% of Internet users had previously searched for medical information. In 2009, Burns reported the online population between ages 70-75 had grown the most, from 26% of these users online in 2005, to slightly less than half, 45%, in 2009. In much the vane, Jones and Fox (2009) reported that the third most popular online activity for seniors, was searching for health information. Searching for health-related information is not just limited to seniors and older consumers. These researchers also indicated that 82% of Generation Xers, referred to as the "wired" generation, also searched for health-related information, and were expected to maintain their connection with the Internet as their information source.

Health Literacy

Adult literacy has been a concern for many years, across many professions and industries. Health literacy affects consumers of all ages and walks of life. Ten years ago Cling and Haynes (2001) found more than 70,000 websites that disseminated health information, and that more than 50 million people sought health information online. While the Internet offered widespread access to health information, these authors expressed concern about the ability of consumers to comprehend the information available to them online. Berland, et al. (2001) expressed similar concerns, when they found the reading level of most Web-based material to be well above the average reading level of U.S. consumers. All the health-related sites in their study required at least a 10^{th} grade reading level and more than half of the sites had material presented at the college level. Griffiths, Christensen, and Evans (2002) echoed these same concerns. They found that consumers generally do not have the expertise to effectively and accurately assess the truthfulness of information offered in the online sites. While consumers may lack the needed skill level to evaluate online health-related information, more and more consumers are seeking information from this resource. Therefore, the concern of those providing health information to consumer online should be the literacy level required by consumer to fully understand that information. The average reading level in the U.S. in 2001 was approximately eighth to ninth grade (Solomon, 2001). This study recommended critical information for daily living should be scaled back to the sixth-grade level. That same year, Berland et al. (2001) found the average reading level of health information web sites written at grade 13.2, but findings ranged from 10^{th} grade to graduate school level. They concluded that health information was written at a much higher level than the average consumers possessed. Sagaram, Walji, & Bernstam (2002) examined consumer and alternative medicine online information intended for consumers, and found nearly three-fourths (73%) of the web pages examined had mean overall readability levels written at the eleventh grade, again, far higher than the recommended eighth grade level.

In 2003 health literacy was defined by the National Center for Educational Statistics (NCES) as "the ability to understand and use health-related printed information in daily activities to achieve one's goals and to develop one's knowledge and potential (NAAL, 2003)." That same year, the 2003 National Assessment of Adult Literacy (NAAL) measured American adults' ability to use literacy skills to read and understand health-related information (http://nces.ed.gov/naal/health_dev.asp). Health literacy was assessed using written form, for three categories of tasks: clinical, prevention, and navigating the health system. While this did not directly measure online health information, it did address the ability to determine the correct dose of a prescribed medication from a prescription label; understand the health risks of obesity from written material; or determine the benefits of a health insurance plan. The National Center for Educational Statistics (2006), ("The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy," 2006) reported that the majority of adults (53 percent) had an intermediate level of health literacy, while 12 percent were proficient, 22 percent had a basic understanding, and 14 percent were considered to be below. They also reported that women had higher average health literacy than men; 16 percent of men had below basic health literacy compared with 12 percent of women. Adults who were ages 65 and older had lower average health literacy than adults in

younger age groups, while the percentage of adults in the 65 and older age group who had intermediate or proficient health literacy was lower than the comparable percentage of adults in other age groups. Finally, for adults who had graduated from high school or obtained a GED, average health literacy increased with each higher level of educational attainment. Almost half (49%) of adults who had never attended or did not complete high school had below basic health literacy, compared with 15 percent of adults who ended their education with a high school diploma, and 3 percent of adults with a bachelor's degree. Ownby (2005) reported similar results, indicating 47% of adults aged 60 years or older had only basic reading skills. This was especially true of elders, with few who possessed the reading skills needed to assess and interpret information at higher levels of difficulty. In 2009, a pair of studies (Kunz & Osborne, 2009; Osborne & Kunz 2009) found the readability of consumer pharmaceutical web page information was written at a reading level much higher than the average consumer. In particular, drug information pages on consumer pharmacy web sites were written at or above the eleventh (11^{th}) grade level, while drug information pages posted on pharmaceutical corporate web sites were slightly more readable, but still overall, written far above the average literacy level of US consumers.

PURPOSE OF STUDY

Given the continued interest and concern regarding consumers' ability to understand and comprehend health-related information, and the increased role of the Internet in providing consumer information, the researchers wanted to investigate consumers' comprehension of drug information pages, based upon the reading level of these documents. The purpose of this paper is to examine comprehension and understanding of drug information pages posted on pharmaceutical company web sites and online drug stores. The research question driving this study is: does the readability (grade level) of a drug information page impact consumer comprehension of drug information? It is predicted that drug information sheets written at a lower grade level (more readable) will be better understood, and subjects will answer more questions correctly for the drug information written at a lower reading level.

METHODOLOGY

Following a methodology similar to that used by the two 2009 studies of Kunz & Osborne and Obsorne & Kunz, drug information pages were located and selected from consumer pharmacy sites, and corporate pharmaceutical sites. Two drug information sheets from each source that were analyzed found to have relatively "good" readability scores, and two that were written at a higher reading level were selected. Likewise, four drugs with drug fact sheets posted on pharmaceutical company websites were selected, two easily read, and two written at a higher grade reading level. All the drugs selected for inclusion could be considered relatively familiar across a broad spectrum of the adult US consumer market. After reviewing the drugs and their respective treatments, and know that a convenience sample of university students would be used for the study, an additional three drugs were selected for inclusion in this study based upon their familiarity to young adults. Drug information sheets were retrieved for these three drugs via the website Drugs.com. All eleven drugs, their source and readability level are presented in Table 1.

TABLE 1
DRUG INFORMATION

Company	Drug	Grade Level	Source
eDrugstore.md	Viagra	8.2	Consumer drugstore
WalMart.com	Flomax	9.8	Consumer drugstore
Walgreens.com	Zoloft	12.1	Consumer drugstore
Drugstore.com	Lisinipril	16.1	Consumer drugstore
Glaxo Smith Kline	Coreg	9	Corporate Pharmaceutical
Pfizer	Detrol LA	9.5	Corporate Pharmaceutical
BristolMeyers Squibb	Plavix	16.4	Corporate Pharmaceutical
Sanofi-Aventis	Ambien CR	16.8	Corporate Pharmaceutical
Drugs.com	Yaz	9.9	Young adult
Drugs.com	Ritalin	14.6	Young adult
Roche	Accutane	17.1	Young adult

Survey Development

An online survey was developed, and included three specific questions for each drug: 1) What condition it was prescribed to treat? 2) What were two side effects? and 3) What were two warnings or cautions for individuals taking the drug? All questions were designed in an open-end format, allowing respondents to answer freely, without any prompting or recall aids. Additional demographic questions asked age, gender, and if the individual, or a relative/close friend had or was currently taking any of the drugs included in the survey. A convenience sample of students was recruited to participate in the survey. Students in three undergraduate business classes and two MBA classes at a regional university in the southeast US were given extra credit in their respective class for participation in the study. A learning unit was established, and posted on the online course content management system. This format required the subject to read and review each of the 11 drug information sheets posted in either Word or Adobe PDF format, and then they were taken to the online "quiz" which randomized each of the three questions for the eleven drugs. Students then completed the demographic questions, and questions regarding use of the respective drugs by themselves, or family and friends.

RESULTS

Sample Demographics

A total of 82 usable surveys were completed. Sixty-one percent (50) of the subjects were female, 39% (32) were male. They ranged in age from 20-58. Age was reduced to categorical data: 20-24; 25-34; 36-42, and 46-58, with 33, 33, 9, and 7 in each category respectively. The two upper age categories were collapsed, so the final age grouping or categories used were: 20-24, with 33 subjects, 25-34 with 33 subjects, and 36-58 with 16 subjects. Slightly more than one-fourth (27% or 22) of the respondents indicated they had previously or were taking one or more of the drugs reviewed; while more than two-thirds, (38%, 31) indicated they had a family member or close friend who had previously or was taking one or more of the reviewed drugs. A breakdown by individual drug is presented in Table 2. This information was used to identify familiarity with the individual drug.

TABLE 2
RESPONDENT FAMILIARITY WITH DRUGS

Drug	Personally taken	Family/Friend Take
Accutane	6	7
Ambien CR	3	6
Flomax		2
Lisinopril	1	5
Plavix		7
Ritalin	3	9
Viagra	1	3
Yaz	5	10
Zoloft	7	6

Data Scoring/Coding

Each individual open-ended response was evaluated and scored by the researchers. Answers that were completely incorrect were scored 0, those that were partially correct scored 1, and fully correct responses were scored 2. Scores for individual drugs were totaled across the three questions, with a range of 0-6 possible. If subjects correctly answered each of the three questions, a score of 6 resulted. Table 3 lists the frequency of scores for the individual drugs. It should be noted that only four drugs, had one response score of 0, meaning one individual had no correct answers for the drug. Table 4 indicates the percentage for correct and incorrect responses across each drug, with drugs listed in increasing grade reading level. Observational results show no apparent indication that lower reading grade level (better readability) increased the percentage of respondents correctly answering the questions.

TABLE 3
FREQUENCY SORES BY INDIVIDUAL DRUG

Score	Accutane	Ambien	Coreg	Detrol	Flomax	Lisinipril	Plavix	Ritalin	Viagra	Yaz	Zoloft
0	1	1	1				1		1		
1	1						3				
2	3		3	2	4	1	5		1	1	
3	5	1	5	3	5	1	2	1		3	
4	20	14	14	20	11	8	12	9	8	7	4
5	14	9	10	11	19	10	10	9	6	12	9
6	29	52	62	32	35	48	30	53	57	53	63
Total*	73	77	65	68	74	38	63	72	73	76	76

***** total less than 82 for those with no answer

TABLE 4
ACCURACY OF DRUG RESPONSES BY READING LEVEL

Drug	Avg. Read Level	% Correct	% Wrong
Viagra	8.2	69.5	1.2
Coreg	9	39	1.2
Detrol LA	9.5	39	0
Flomax	9.8	42.7	0
Yaz	9.9	64.6	0
Zoloft	12.1	76.8	0
Ritalin	14.6	64.6	0
Lisinopril	16.1	58.5	0
Plavix	16.4	36.6	1.2
Ambien CR	16.8	63.4	1.2
Accutane	17.1	35.4	1.2

Specific scores by percentage are presented in Table 5, and show that two of the drugs, Coreg and Detrol, with the best readability level (9 and 9.5 grade level) had low percentages of correct (score=6) responses at 39% each. Conversely, two drugs with a high reading level, Lisinipril at 16.1 grade level, and Ambien at 16.8 grade level, had a high percentage of responses at a score of 6, 80.7% and 74.4%, respectively. Further visual review of Table 5 does not provide any specific pattern, nor does this review indicate that lower reading level (more readable) contributes to consumer comprehension and understanding. Thus, more in-depth analysis is called for in order to answer the research question.

TABLE 5
TOTALED SCORES PERCENTAGE BY INDIVIDUAL DRUG

	Viagra	Coreg	Detrol	Flomax	Yaz	Zoloft	Ritalin	Lisinipril	Plavix	Ambien	Accutane
Grade Level	8.2	9	9.5	9.8	9.9	12.1	14.6	16.1	16.4	16.8	17.1
0	1.2%	1.2%							1.2%	1.2%	1.2%
1									3.7%		1.2%
2	1.2%	3.7%	2.4%	4.9%	1.2%			1.2%	6.1%		3.7%
3		6.1%	3.7%	6.1%	3.7%		1.2%	1.2%	2.4%	1.2%	6.1%
4	9.8%	17.1%	24.4%	13.4%	8.5%	4.9%	11.0%	9.8%	14.6%	17.1%	24.4%
5	7.3%	12.2%	13.4%	23.2%	14.6%	11.0%	11.0%	12.2%	12.2%	11.0%	17.1%
6	69.5%	39.0%	39.0%	42.7%	64.6%	76.8%	64.6%	58.5%	36.6%	63.4%	35.4%

Statistical Analysis

Chi-square tests of independence were conducted for readability (reading level), age (by category), gender, and personal knowledge (familiarity) with the drugs. Using a totaled drug "score" to indicate the level of correct responses per drug, chi-square tests of independence found no statistically significant difference based upon the totaled drug scores, and the reading grade level of the drug information document. These results indicate the reading level did not impact the accuracy of respondents answers regarding what the drug was used to treat, side effects, or cautions and warnings. Further analysis was warranted, and it was thought that age might influence familiarity with drugs and respective information. Therefore, chi-square tests of independence were conducted to determine if age influenced accuracy of response. The original age categories were not statistically significant. However, after combining age 36 and over into one category, the chi-square test found statistically significant differences for two drug

variables: warnings for Coreg (χ^2= 12.24, df, 6, p=.057) and the treatment/condition for which Detrol is prescribed (χ^2=12.331, df=6, p =.056). Crosstab analysis of the responses indicate younger subjects were more likely to correctly answer the question regarding cautions or warnings for Coreg, and that subjects age 25-34 were less likely to correctly answer what condition Detrol treats. The results for age and Coreg are not what would be expected, since Coreg is used to treat heart failure and hypertension, and Detrol treats overactive bladder, usually associated with older female patients. The cross-tabs response patterns might be more what one would expect, as older females would be more likely experience over-active bladder, and thus younger respondents less likely to know what the drug treats. Chi-square tests and cross-tab analysis found only one drug variable to be statistically significant, and that was the side effects for Accutane (χ^2= 9.25, df, 3, p=.026). In this instance males were more likely to answer correctly the question on side effects for Accutane. Familiarity with the drugs, i.e. personal or family use, was not statistically significant, but it should be noted that only a small percentage of the respondents had taken, or knew someone who had taken the drugs in the survey.

SUMMARY AND CONCLUSIONS

The results of this study do not support the prediction that drug information sheets written at a lower grade level, (higher readability) would result in better comprehension of the information presented. Overall results of this study might indicate that mid-range readability leads to better comprehension. However, that might not be the case. Many of the drugs in this study have been heavily advertised directly to consumers, on TV as well as in print. The results of this study could be related to the fact sheets information that was almost verbatim from these DTC ads. Perhaps, familiarity with drugs and their respective side effects could be due to repeated exposure to DTC advertising. Therefore, comprehension of drug information may be impacted more by repeated exposure to consumer pharmaceutical advertising, or this advertising in conjunction with online information.

STUDY LIMITATIONS AND FUTURE RESEARCH

This study is limited in scope and subjects. Since a convenience sample of student subjects was used in this study, generalizability to the consumer population is not possible. Furthermore, a limited number of drugs were used in this study, again limiting the generalizability of these results. A blind test applying the same type of procedures using fictitious drugs and their respective information sheets would help control for outside sources and direct to consumer pharmaceutical advertising. Again, a random sample of consumers, rather than a student sample would strengthen the results tool. Finally, an examination of comprehension using simulated television advertising, along with printed information could be used to compare comprehension across different information sources, again controlling for reading level.

SUMMARY

As the Internet continues to play an important role in consumers' lives, and as a major source of information, it continues to behoove pharmaceutical companies to recognize the importance of providing information that is both easy to access, as well as be understood by consumers. Furthermore, as adult literacy and health information literacy continue to be important to both consumers and corporations, determining just how to write information that consumers easily understand will remain at the top of pharmaceutical companies' list of concerns. As the online communication channel becomes more critically integrated into the consumer's decision making processes, companies must pay particular attention to how the information is perceived and used by the consumer.

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