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# Factors to Consider in Improving Prescription Drug Pharmacy Leaflets

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## Abstract

Today, when consumers receive prescription drug pharmacy leaflets (also known as 'consumer medication information' or CMI), they often appear in small font size, with cluttered layouts, and distracting information.

This problem has attracted the attention of the U.S. Food and Drug Administration in advocating for more comprehendible, accurate, and easy-to-access CMI formats. Our study of four different CMI prototypes shows that an expanded Over-the-Counter (OTC) Drug Facts prototype is the best for improving comprehension accuracy, and is especially effective for those with lower health literacy and health motivation. A simpler OTC prototype did not aid accuracy scores due in part to its lack of complexity; whereas the most complex prototype (the revised medication guide – similar to most CMI today) reduced leaflet likability and usage intentions. Finally, continued leaflet availability improved accuracy scores for lower health literacy and health motivation respondents. Implications for marketing and public health policy are offered.

## Keywords:

prescription drug labeling, pharmacy leaflets, health literacy, health motivation

## Introduction

What do most consumers do with prescription drug pharmacy leaflets, also known as consumer medication information (CMI)? The short answer is that many usually just throw them away, often without even reading the information (cf. Plummer 2009). Who can blame them? As can occur with many marketing disclosure efforts (Andrews 2011), CMI routinely appears in extremely small font size, cluttered layouts, and with distracting information, such as ads and store coupons that can contribute to clutter and miscomprehension. Moreover, when consumers receive *any* type of prescription drug information beyond that from their health care provider, it is often in the form of a wide array of potentially confusing and complex labeling information, including (1) patient package inserts (PPIs), (2) medication guides (MGs) – if there are serious adverse events, risks, or directions for use, (3) direct-to-consumer (DTC) prescription drug advertising, and/or (4) the previously mentioned, consumer medication information (i.e., pharmacy leaflets or CMI).

As a result, the U.S. Food and Drug Administration (FDA) has planned to offer guidance in assessing the effectiveness of different pharmacy leaflet prototypes to (hopefully) result in more comprehendible, accurate, and easy-to-access CMI (FDA 2009a; *Federal Register* 2009; 2010). Redesigning CMI is an important effort for consumer researchers, as there are over 750,000 adverse events each year in the USA reported to the FDA due to the misuse of prescription and over-the-counter (OTC) drugs and biologic products (FDA 2013a). (An 'adverse event' is any undesirable experience associated with the use of a drug, OTC, or biologic product in a patient. This includes death, life-threatening events, hospitalizations, disability, birth defects, permanent impairment or damage, etc. (FDA 2013b). In addition, over 38,000 deaths are due to drug overdoses each year in the USA, with 60% (22,134) of those involving prescription drugs (CDC 2013a). As category expenditures are substantial in this category and approximately 74% of US adults currently take at least one prescription drug, the rise in the number of adverse medication events and deaths from medication use reveals serious problems with communication, comprehension, and use of prescription drugs (Cheong and Kim 2014). In addition, prescription drug abuse is the fastest growing drug problem in the USA. Since 2003, a greater number of overdose deaths involving opioid analgesics (at 16,651 per year) have occurred than overdose deaths from heroin and cocaine combined (CDC 2013a; 2013b; Paulozzi 2011). Although most consumers receive CMI with their prescriptions, many CMI formats are found to be illegible and unreadable (Kimberlin and Winterstein 2008; Winterstein et al. 2010).

In 2010, the FDA originally planned to study several label prototypes to aid readability and use of CMI (FDA 2009a; Federal Register 2010). The result of this study under a Research Triangle Institute contract showed that people reporting higher self-literacy had a greater ease of understanding the label protoypes, but not actual comprehension (Boudewyns et al. 2013). Also, a paper format aided recall to a greater extent over an online format and some prototype formats were better than a more comprehensive MG format.

Importantly, however, beyond testing of different formats and content, academic researchers clearly have shown the *moderating effects* of health literacy and health motivation in the processing of health and nutrition information. For example, it is estimated that approximately 48% of US adults either do not have or have only very basic literacy skills impacting their understanding of basic medical information (Davis et al. 1998; see also Wolf 2011). Thus, the key purpose of this study is to examine the effects of different levels of objective health literacy and health motivation on the accurate evaluation, attitudes, and the intended use of prescription drug label (CMI) prototypes by consumers. In addition, prototype availability (always available, withdrawn from view) will be assessed to examine the realistic processing of pharmacy leaflet information. That is, some patients may always consult the leaflet information when taking their prescription, whereas others may not look at it after their first use, if at all. Also, the prototypes tested reflect a range of increasing complexity of prescription drug information. The study of these issues should contribute to understanding not only how consumers process complex information, such as for prescription drugs, but also help enhance the format and conditions under which this information can be best conveyed. Such objectives are important outcomes for not only prescription drug companies and pharmacies, but also for consumers, the health care industry, the FDA, and public health research in general.

# Background and hypotheses

## Communication of prescription drug information and CMI

Patient understanding of prescription drug information had *not* always been a priority in the early days of the FDA, as drug labeling was recommended to be written 'only in such medical terms as are *not* likely to be understood by the ordinary individual' [emphasis added] (Federal Register 1938). Today, much has changed, as patients receive information on prescription drugs from a multitude of sources beyond their health care provider, including: DTC ads (e.g., television, websites); 'brief summary' information in print media and online; FDA-approved labeling, such as PPIs and MGs; as well as non-FDA-reviewed CMI received by patients from the dispensing pharmacy. For DTC ads with product claims, a fair balance of risks and benefits is required, and if all risks are not offered, a major statement of risks and access to approved 'labeling' (i.e., the 'brief written summary') is necessary (Huh and Becker 2005; Ostrove 2008; Huh, DeLorme, and Reid 2012). However, more information is not necessarily better and such DTC and brief summary ad information has been criticized as not always adequately conveying the relative numerical efficacy of the prescription drugs (Schwartz et al. 2007). DTC prescription drug TV ads also have been found to contain 'competing modality' in that audio risk information can be masked by the simultaneous presentation of video benefit distracters (Hoy and Andrews 2004). Moreover, limitations in processing such advertising information are apparent with detrimental effects on memory, comprehension, persuasion, and use of coping strategies for vulnerable populations, such as older adults, children, low literacy, and minority populations (cf. Bonifield and Cole 2007; Davis et al. 1998; Federal Register 2009; Wolf et al. 2004; Wolf 2011).

In the case of prescription drug labeling, PPIs are currently required by the FDA for two prescription drug medications, estrogen and oral contraceptives, yet are usually offered voluntarily by manufacturers for many prescription drugs. Research shows that while a great majority say that they receive and read the PPIs, many cannot recall specific major risks with use (cf. Morris 1980). Also, MGs are required by the FDA for over 150 prescription drugs that pose either severe adverse effects, serious risks, or for which there are problems with patient directions. In a study of antidepressant users, over 46% indicated that they 'never' or 'just sometimes' read the MGs before use (Plummer 2009). Recently, given the importance of the product category, the FDA (2013c) developed a one-page, 'consumer-friendly' MG for long-acting opioid analgesics.

Finally, CMI is written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing (FDA 2006).

Although not under direct control of the FDA, Congress had set minimum criteria for its effectiveness (Kimberlin and Winterstein 2008; Winterstein et al. 2010), and the FDA has the authority to offer guidance to the industry in the form of new formats and prototypes to increase CMI usefulness. In a report commissioned for the FDA, Kimberlin and Winterstein (2008) conducted a consumer shopper and content analysis study of CMI for lisinopril (high blood pressure) and metformin (type 2 diabetes) using data from 420 pharmacies. Although 95% of shoppers received CMI with their prescriptions, only 75% of the CMI tested met minimum criteria for usefulness, a figure that falls short of the 95% goal set by Congress for 2006. Primary reasons cited for reduced usefulness were the illegible and unreadable formats often found in CMIs. In addition, Raynor et al. (2007) found that CMI leaflets from the USA had significant shortcomings on content and format in comparison with Australia and the UK. In sum, there are serious issues of information overload, redundancy, and miscomprehension of prescription drug labeling information in trying to communicate important risk, benefit, and usage information for CMI to consumers.

## Communication of risk information for prescription drugs

Beyond initiatives at the FDA regarding new prototypes, there are many potential reasons for prescription drug miscommunication, miscomprehension, and usage deficits. For example, risk type (e.g., electing *not* to treat a condition) can impact consumer perceptions and beliefs (Kees et al. 2008). Also, framing and format effects of warnings and risks play an important role in comprehension and use of information (cf. Andrews 2011; Bettman, Payne, and Staelin 1986; Slovic, Fischhoff, and Lichtenstein 1980; Stewart, Folkes, and Martin 2001). For example, shorter and more organized information improves processing due to decreased cognitive load and processing capacity required by consumers (Bettman, Payne, and Staelin 1986). In addition, comprehension is enhanced when there is a logical and expected presentation order and risk and benefit information is grouped to aid processing. Of importance to the current study, and based on consumer research, Kanouse and Hayes-Roth (1980) argue for an expected hierarchical order of information in designing prescription drug leaflets (e.g., product name and description, uses and indications, risks and benefits, directions for use, side effects, and what to do if side effects occur). Although we do not test order variations, the general order of information recommended by Kanouse and Hayes-Roth (1980) is followed in the CMI prototypes tested in the current study.

## Processing increasing complexity of information

The FDA proposed to study whether one of three CMI prototypes (Drug Facts, Minimal Column, and Column Plus) and order (warnings before uses, uses before warnings) affected patients' evaluation of the CMI prototypes (Federal Register 2010; see also Boudewyns et al. 2013). They also planned to prescreen for literacy (with oversampling for low literacy) and prior medical conditions. Our study adds to the proposed FDA study in many ways, including testing different prototypes of increasing complexity, examining the role of key *moderating* variables (e.g., objective health literacy, health motivation, information availability), and focusing on the expected order of information for consumers. Thus, based on the proposed FDA formats, we focus on the increasing complexity of information (e.g., word amount/complexity, presentation format) as evidenced by readability scores (Bettman, Payne, and Staelin 1986). (We do not test other graphical aids, such as symbols, colors, etc.) To accomplish this added complexity, we test simple OTC, expanded OTC, ‘bubbles,’ and revised med guides formats that expand the OTC drug facts with either a version that reduces the complexity of words presented (simple OTC) or one that presents the same information in an expanded format (expanded OTC). The ‘bubbles’ format has the exact same information as the OTC format, yet appears in two columns and grouped in ‘bubbles.’ Finally, the most complex prototype (‘revised med guide’) is based on the existing FDA medication guide format, a very detailed series of questions and answers expanding on the same information found in the other prototypes. Although not technically classified as CMI, the revised medication (Med) guide prototype is used as a comparison for other prototypes. These CMI prototypes appear in Appendices 1–4, along with their Flesch–Kincaid readability scores showing the increased complexity of information from the simple

OTC format (6.6) to the expanded OTC format (6.8) to the 'bubbles' format (7.3) to the revised med guide format (8.9). As the largest difference in readability was from the bubbles to the revised med guide format (i.e., an increase of 1.6), as opposed to only an increase of 0.7 across the other three formats, our hypotheses presented below compare the most complex leaflet prototype (i.e., revised med guide) with simpler prototype versions (i.e., simple OTC, expanded OTC, and bubbles formats).

Also, with respect to the expected order of information, we follow Kanouse Hayes-Roth (1980) in always presenting the uses before warning information. Finally, based on the research below, we manipulate information availability (always available, drawn from view) and include high/low measures of both objective health literacy and health motivation – potentially key moderators of the processing of the CMI prototypes. Based on previous research, and the relative and increasing complexity of the different prototypes, it is predicted that:

H1:

Those exposed to more complex pharmacy *leaflet prototypes* (revised MGs) will have (a) less accurate medication scores, (b) less favorable attitudes toward the pharmacy leaflet, and (c) less favorable intentions to use the drug than those exposed to simpler pharmacy leaflet prototypes (expanded OTC, simple OTC, bubbles format).

## Motivation, ability, and opportunity to process information

In general, the Elaboration Likelihood Model, containing one's motivation, ability, and opportunity to process information, provides a valuable theoretical framework to assess outcomes related to the processing of prescription drug information (Petty and Cacioppo 1986; see also Andrews 1987; Batra and Ray 1986; Chaiken 1980; MacInnis, Moorman, and Jaworski 1991). When applied to prescription drug information, this includes special attention to patient health literacy (affecting one's ability), their motivation/interest in obtaining health information (motivation), and information availability (opportunity) when making medication decisions. Under high motivation, ability, and opportunity, higher elaboration and scrutiny of the CMI details are likely resulting in more accurate comprehension of the information and (correctly held) attitudes and intentions toward using the prescription drug (cf. Petty and Cacioppo 1986, p. 5). Higher elaboration of CMI should aid in processing the increasing complexity of formats tested.

### Health literacy

Health literacy represents one of the major challenges in the US health care system today (Carmona 2006; Wolf 2011). It is an important consideration in the design of PPI, MG, and CMI brochures, as well as with OTC drug labels (Lokker et al. 2009). It is estimated that 48% of Americans are either functionally illiterate or have marginal literacy skills (Davis et al. 1998). Deficits in health literacy can limit one's ability to process medical information, leading to worse self-care and poor health conditions (Wolf 2011). For example, Davis and colleagues (2006a; 2006b) find that those adults with limited literacy skills had greater rates of confusion and misunderstanding of medication directions provided by either physicians or pharmacists. Moreover, Wolf and colleagues (2011) show that those with lower literacy over-complicate multi-prescription drug regimens, taking medicines a greater number of times daily than required. Thus, based on theoretical background and previous research reviewed, we predict that:

H2:

*Health literacy* will moderate the impact of the leaflet prototypes on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with greater health literacy skills will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflet, and (c) more favorable intentions to use the drug when exposed to more complex pharmacy leaflet prototypes (revised MGs) than those with fewer health literacy skills. Such interaction effects will be attenuated for the simpler pharmacy leaflet prototypes.

### Health motivation

In general, one's motivation to search for information also is an important variable that can affect the processing of message arguments presented to consumers (Chaiken 1980; Petty and Cacioppo 1986). Prior findings indicate that more motivated consumers tend to acquire and utilize nutrition information to a greater extent than those not as motivated (Moorman 1990; 1996). Also, health motivation is found to positively influence consumers' preventive health behaviors (Moorman and Matulich 1993). Those with higher nutrition consciousness are found to have significantly more favorable product attribute and purchase intention scores for a product with front-of-pack nutrition labeling than those with lower nutrition consciousness (Andrews, Burton, and Kees 2011). Therefore, it is expected that:

H3:

*Health motivation* will moderate the impact of the leaflet prototypes on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with greater health motivation will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflets, and (c) more favorable intentions to use the drug when exposed to more complex pharmacy leaflet prototypes (revised MGs) than those with less health motivation. Such interaction effects will be attenuated for the simpler pharmacy leaflet prototypes.

### Information (leaflet) availability

Having available and accessible information can positively affect brand evaluation and choice decisions (Biehal and Chakravarti 1983; Lynch 2006; Tybout et al. 2005). As applied to the processing of health information, there is evidence that the use of visual aids (e.g., pictographs, patient-centered icons) can aid memory, especially for those with lower literacy levels (Houts et al. 2006; Wolf et al. 2010). Similarly, if the health information is available (versus only examined once), it may aid the realistic processing and comprehension of the information, as well as intended use of the prescription drug in question. Also, as noted previously, some patients may always consult the leaflet information when taking their prescription, whereas others may simply throw it out or misplace it. Therefore, it is expected that:

H4:

*Information (leaflet) availability* will moderate the impact of the leaflet prototypes on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with greater information availability will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflets, and (c) more favorable intentions to use the drug when exposed to more complex pharmacy leaflet information (revised MGs) than those with less information availability. Such interaction effects will be attenuated for the simpler pharmacy leaflet information.

Finally, as health literacy is a major limiting factor in one's ability to process medical information (Wolf 2011), having the leaflet available should aid in this processing. Thus, we expect that information (leaflet) availability will be moderated by health literacy in the following manner:

H5:

*Health literacy* will moderate the impact of information (leaflet) availability on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with fewer health literacy skills will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflet, and (c) more favorable intentions to use the drug with greater information (leaflet) availability than those with less information (leaflet) availability. Such interaction effects will be attenuated for those with greater literacy skills.

# Research methodology

## Sample and general procedure

The study sample consisted of 807 US adults recruited through a major online marketing research service and who possessed the target condition for the prototype labels (arthritis/chronic joint symptoms (CJS)). This condition was first screened and a 60/40 split was made on gender based on the higher incidence levels of arthritis in women (Hootman et al. 2006). (Overall, approximately 33% of the US population suffers from either arthritis and/or CJS; Bolen et al. 2002.) An expert firm in online ad surveys for over 20 years administered the survey. Three age quotas (i.e., 18–44, 45–64, 65+) based on U.S. Bureau of the Census data and arthritis/CJS incidence levels (Bolen et al. 2002) were set to help ensure representative samples in all age groups of 18 and older. The methodology and presentation of labeling treatments and measures online followed generally accepted procedures for copy testing (cf. Pechmann and Andrews 2011). This was pretested with a sample of 40 consumers from the targeted population to ensure that the stimuli and measures were presented correctly to respondents.

For the main study, and after successful screening for minimum age (18), gender, disease incidence (arthritis/CSJ), age quotas, and consent to the study, respondents were randomly assigned to one of four prescription drug label (CMI) treatment conditions and then responded to the study measures. The study first applied a 4 (pharmacy leaflet prototype: simple drug facts, expanded drug facts, 'bubbles,' revised MG) × 2 (information (leaflet) availability: always available, withdrawn from view) between-subjects design. Then, health literacy (high, low) and health motivation (high, low) were each substituted in place of information availability. For the analyses, cell sizes ranged from 92 to 113. Appendices 1–4 display the extended drug facts and other prototypes. The extended drug facts prototype is based on the existing OTC Drug Facts box with bullet points (see FDA 2009a; Federal Register 2009, 2010). A column format is suggested for testing by the FDA (FDA 2009a; Federal Register 2009, 2010), and contains the same information as the extended drug facts prototype, yet appears in 'bubbles' in two columns in our study. The simple drug facts prototype contains the same general information as the previous two, yet it is redesigned by one of our authors (a prescription labeling expert) to reduce the complexity of words presented. The most complicated prototype ('revised MG') that we present is based on the existing med guide format, a very detailed series of questions and answers expanding on the same information found in the other prototypes. This format is similar to the current pharmacy leaflets or CMI; however, we have revised it to follow the same sequence of information in the others (i.e., product name, uses, warnings, tell you doctor before using, stop use if, common side effects, directions for use). Thus, these basic sequence sections appear in all prototypes with the same general information. The simple drug facts prototype contains less complicated versions of the same words in the expanded drug facts and bubbles formats, and the revised med guide simply expands the basic information provided by the others. The information (leaflet) availability format randomly assigned half of the respondents to the context in which the prototype is always available for reading and reference, whereas the other half saw it once before removal for the study questions. (This is a common procedure in copy testing; cf. Pechmann and Andrews 2011). The target product ('Rheutopia') is a very realistic, yet fictitious prescription drug, as presented on the prototypes by the FDA (Federal Register 2010). Again, prototype readability scores (e.g., Flesch–Kincaid Grade Level) were calculated based on total words/total sentences and syllables/word ratios, and appear on the appendices' pages. The scores show increased information complexity from the simple drug facts format through the revised med guide format.

## Study measures

The questionnaire follows generally accepted procedures for copy testing, funneling from questions on customer understanding of targeted prescription drug pharmacy leaflet content to attitudes toward the pharmacy leaflet to intentions to use the prescription drug (given medical condition, availability, insurance, etc.). Specifically, a series of seven medication accuracy questions were presented after respondents were instructed to ‘read the questions carefully… and chose the best answer for each statement.’ For example, based on the prototype leaflet content, respondents were asked to complete the statement, ‘I should call my doctor right away when using Rheutopia if I have ___,’ with response options of (1) foot odor [incorrect], (2) numbness or tingling skin [correct], (3) acne that spreads [incorrect], (4) color changes in my toenails or fingernails [incorrect], or (5) don't know or not sure. As another example, respondents were asked, “How would I get Rheutopia?” with response options of (1) as an injection (a shot) [correct], (2) as a pill you take by mouth – once a day [incorrect], (3) as a pill you take by mouth – twice a day [incorrect], (4) breathing it into your lungs (inhaled) [incorrect], or (5) don't know or not sure. The seven items then were summed into an overall medication accuracy score, ranging from 0 to 7 (mean = 5.32).

Attitudes toward the pharmacy leaflet consisted of three, semantic differential items that were summed: unfavorable – favorable, negative – positive, and bad – good (coefficient $\alpha = 0.97$). Instructions for measuring intentions toward using the Rheutopia prescription drug told respondents (who all had arthritis/CJSs) to assume that (1) they were diagnosed with a disease Rheutopia treats, (2) there was a choice of medications or treatments for the problem, and (3) insurance covered the cost. Intentions consisted of four items measuring the likelihood of (1) talking to your doctor about Rheutopia, (2) asking your doctor for a sample of Rheutopia, (3) looking for more information about Rheutopia, and (4) asking your doctor to prescribe Rheutopia (coefficient $\alpha = 0.94$).

Also, an attention filter check was administered to avoid ‘click-throughs’ that may result in online surveys (cf. Oppenheimer, Meyvis, and Davidenko 2009). Health literacy was measured by the reliable and valid, eight-item, S-TOFHLA instrument – the Short Test of Functional Health Literacy in Adults (Baker et al. 1999). The S-TOFHLA is one of the two leading measures of health literacy (Wolf 2011), is objective (as opposed to self-report), and is related to the other commonly-used measure (REALM: Rapid Estimate of Adult Literacy in Medicine, $r = .80$; Baker et al. 1999). The S-TOFHLA consists of 36 Cloze reading completion statements (each multiplied by 2) and 4 numeracy items (each multiplied by 7) for a total score out of 100 (Baker et al. 1999, p. 37). A two-item measure of health motivation, ‘I usually am interested in reading information affecting my health’ and ‘I would like to see additional information affecting my health’ was used in our study ($r = .82$). Both items are measured on seven-point scales and based on prior reliable and valid measures of nutrition motivation (Andrews, Netemeyer, and Burton 2009). A median split was applied to separate higher and lower health literacy (median = 35) and motivation (median = 6). The mean score for higher health literacy was a 35, whereas it was 30.8 for lower health literacy. In the case of higher health motivation, the mean score was 6.69. For lower health motivation it was 5.14.

## Results

Table 1 shows the results of analysis of variance (ANOVA) tests for the independent variables of leaflet prototype, health literacy, health motivation, and leaflet availability. Mean values for medication accuracy, leaflet attitudes, and intentions to use the prescription drug are shown in Table 2. As shown in the tables, there are several main and interaction effects, which are discussed below. Hypothesis 1 examines the effects of the *pharmacy leaflet prototype* (i.e., CMI prototype) across the three dependent variables. Results show that there is a significant main effect of leaflet prototype on leaflet attitude ($F = 2.13$, $p < .05$) and intentions to use the prescription drug ($F = 3.01$, $p < .05$). As predicted, the more complex prototype condition (‘revised med guide’) resulted in less favorable attitudes and lower intentions to use than some of the simpler prototypes. Specifically, as shown in Table 2, the revised med guide ($M = 4.38$; $SD = 2.01$) resulted in less favorable consumer attitudes than the simple OTC ($M = 4.86$, $SD = 1.89$; $t = 2.69$, $p < .01$) and bubbles ($M = 4.87$, $SD = 1.70$; $t = 2.70$, $p < .01$) formats. The revised med guide format ($M = 3.67$, $SD = 2.01$) resulted in lower intentions to use than all three of the simpler formats ($M_s = 4.20–4.36$, $SD_s = 1.86–1.96$; $t_s = 2.35–3.14$, $p_s < .05$). These findings provide some support for H1(b) and H1(c). There was a marginally significant main effect of leaflet prototype on medication accuracy (*F* = 1.87, *p* < .10). Follow-up contrasts show that the more complex med guide format (*M* = 5.18, *SD* = 1.75) resulted in marginally significant lower accuracy scores than the simpler expanded OTC format (*M* = 5.44, *SD* = 1.67; *t* = 1.55, *p* < .10). This finding offers some support for H1(a).

Table 1. Effects of leaflet prototype, health literacy health motivation, and leaflet availability on medication accuracy, leaflet attitudes, and intentions to use.

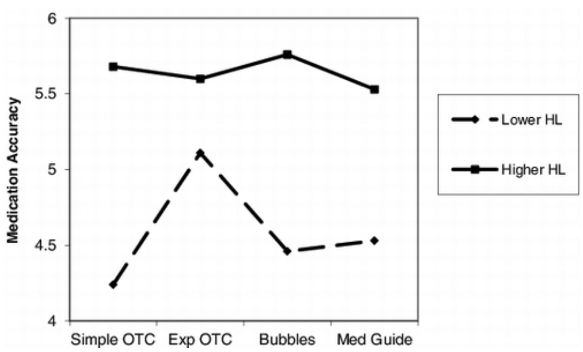
| **ANOVA results** | | | |
|---|---|---|---|
| | **Univariate *F*-values** | | |
| **Independent variables** | **Medication accuracy** | **Leaflet attitude** | **Intentions to use** |
| Main Effects | | | |
| Leaflet prototype (LP) | 1.87[c] | 2.13[b] | 3.01[b] |
| Health literacy (HL) | 70.60[a] | 1.05 | 0.30 |
| Health motivation (HM) | 13.75[a] | 17.24[a] | 27.25[a] |
| Leaflet availability (LA) | 714.20[a] | 3.17[b] | 1.22 |
| Interaction effects | | | |
| LP*HL | 2.77[b] | 0.68 | 0.22 |
| LP*HM | 1.91[c] | 1.78[c] | 0.40 |
| LP*LA | 1.72[c] | 1.97[c] | 2.25[b] |
| HL*HM | 8.47[a] | 0.03 | 0.63 |
| HL*LA | 3.55[b] | 0.10 | 4.31[b] |
| HM*LA | 0.93 | 0.48 | 0.04 |

Table 2. Effects of leaflet prototype, health literacy health motivation, and leaflet availability on medication accuracy, leaflet attitudes, and intentions to use.

| **Means** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Leaflet prototype** | | | | **Health literacy** | | **Health motivation** | | **Leaflet availability** | |
| **Cell means** | **Simple OTC (a)** | **Expanded OTC (b)** | **Bubbles (c)** | **Med guide (d)** | **Low literacy (a)** | **High literacy (b)** | **Low motivation (a)** | **High motivation (b)** | **Leaflet not available (a)** | **Leaflet available (b)** |
| Medication accuracy | 5.26[b] (1.67) | 5.44[a,d] (1.61) | 5.42 (1.67) | 5.18[b] (1.75) | 4.56[b] (2.11) | 5.70[a] (1.28) | 5.18[b] (1.79) | 5.47[a] (1.53) | 5.16[b] (1.76) | 5.50[a] (1.56) |
| Leaflet attitude | 4.86[d] (1.89) | 4.79 (1.69) | 4.87[d] (1.70) | 4.38[a,c] (2.01) | 4.62 (1.93) | 4.77 (1.80) | 4.44[b] (1.71) | 5.03[a] (1.93) | 4.83[b] (1.85) | 4.62[a] (1.83) |
| Intentions to use | 4.20[d] (1.96) | 4.23[d] (1.86) | 4.36[d] (1.87) | 3.67[a,b,c] (2.01) | 4.19 (1.95) | 4.11 (1.94) | 3.79[b] (1.82) | 4.50[a] (2.01) | 4.24 (1.88) | 4.02 (2.00) |

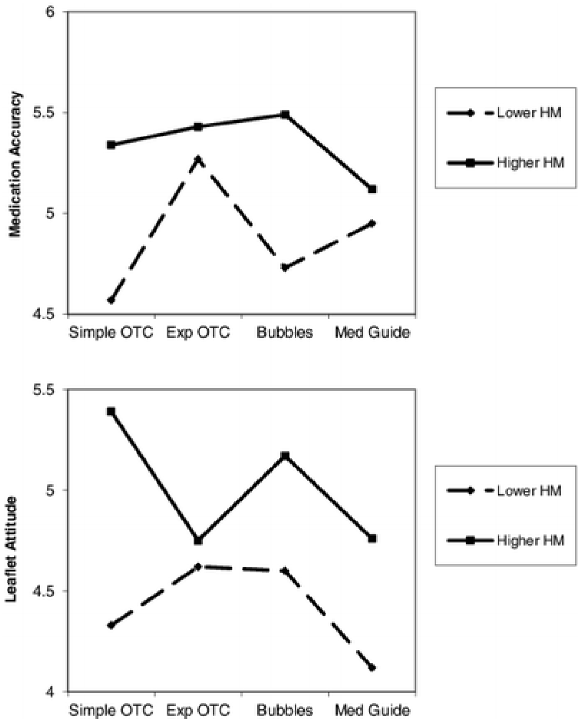
Hypothesis 2 predicts that *health literacy* will moderate the main effects of leaflet prototype shown above. As shown in Table 1, evidence for this predicted interaction is found for medication accuracy ($F = 2.77$, $p < .05$), but not for leaflet attitudes or intentions to use the drug. A plot of this interaction is shown in Figure 1. As predicted, participants with higher levels of health literacy were more accurate with their medication accuracy estimates when exposed to the revised med guide prototype ($M = 5.53$, $SD = 1.45$) versus participants with lower levels of health literacy ($M = 4.51$, $SD = 2.08$; $t = 3.64$, $p < .01$). Yet, this also occurred for those exposed to the simple OTC (high literacy: $M = 5.66$, $SD = 1.23$; low literacy: $M = 4.21$, $SD = 2.16$; $t = 4.83$, $p < .01$) and bubbles prototypes (high literacy: $M = 5.74$, $SD = 1.35$; low literacy: $M = 4.52$, $SD = 2.14$; $t = 3.77$, $p < .01$). However, as predicted, this effect was attenuated for the expanded OTC prototype (high literacy: $M = 5.60$, $SD = 1.37$; low literacy: $M = 5.02$, $SD = 2.07$; $t = 1.92$, $p > .05$). Also, for the expanded OTC prototype, those with lower health literacy levels had higher levels of medication accuracy ($M = 5.11$; $SD = 2.07$) versus the other prototype conditions ($M_s = 4.24$-$4.53$, $SD_s = 2.07$-$2.16$; $t_s = 1.74$-$2.68$, $p_s < .05$). These overall findings provide some support for H2(a). However, H2(b) and H2(c) were not supported.

Figure 1. The impact of leaflet prototype and health literacy (HL) on medication accuracy.



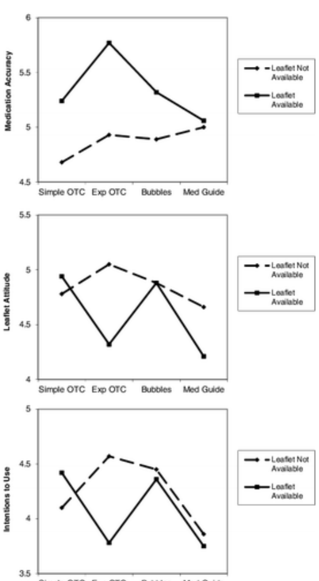

In Hypothesis 3, it is expected that the leaflet prototype effect demonstrated in H1 will be moderated by *health motivation*. As shown in Table 1, there is a marginally significant leaflet prototype × health motivation interaction for medication accuracy ($F = 1.91$, $p < .10$) and leaflet attitude ($F = 1.78$, $p < .10$). Plots of these interactions are shown in Figure 2. Those with higher levels of health motivation ($M_s = 5.12$-$5.49$, $SD_s = 1.26$-$1.81$) outperformed those with lower levels of health motivation ($M_s = 4.57$-$5.62$, $SD_s = 1.70$-$1.91$; $t_s = 1.94$-$3.32$, $p_s<.05$) on medication accuracy for the simple OTC and bubbles prototype conditions. Similar to the pattern of results for health literacy, the expanded OTC resulted in the most accurate estimates for the low motivation group ($M = 5.27$, $SD = 1.66$) versus the other formats (versus simple OTC: $t = 2.62$, $p < .01$; versus med guide: $t = 1.36$, $p < .10$), and which was similar to the estimates for the high motivation group ($M = 5.43$; $SD = 1.57$). Not surprisingly, the more complex, revised med guide format resulted in greater negative attitudes for the low health motivation group ($M = 4.12$, $SD = 1.90$); yet this effect also occurred for the high health motivation group as well ($M = 4.76$, $SD = 2.05$). For the low motivation group, leaflet attitudes were the highest for the expanded OTC ($M = 4.62$, $SD = 1.52$) and bubbles ($M = 4.60$, $SD = 1.49$) prototypes which were significantly higher than the revised med guide ($p_s < .05$) and marginally significantly higher than the simple OTC ($p_s < .10$). These findings provide partial support for H3(a) and H3(b).

Figure 2. The impact of leaflet prototype and health motivation (HM) on medication accuracy and leaflet attitude.




Next, H4 predicts that leaflet availability (i.e., extended exposure to the leaflet prototype during the study) will moderate the effects of the leaflet prototype across the dependent variables. As shown in Table 1, this interaction effect is significant for intentions to use the drug ($F$ = 2.25, $p$ < .05) and marginally significant for medication accuracy ($F$ = 1.72, $p$ < .10) and leaflet attitude ($F$ = 1.97, $p$ < .10). As depicted in Figure 3, the availability of the leaflet for the extended period of time ($M_s$ = 5.06–5.77, $SD_s$ = 1.70–1.92) resulted in higher levels of medication accuracy across the prototype conditions as compared to conditions when the leaflet was only seen once at the beginning of the study ($M_s$ = 4.68–5.00, $SD_s$ = 1.81–1.99). Contrary to expectations, this difference was attenuated for the revised med guide condition in which medication accuracy was similar for the leaflet available ($M$ = 5.06; $SD$ = 1.93) and the leaflet not always available ($M$ = 5.00; $SD$ = 1.85) conditions.

Figure 3. The impact of leaflet prototype and leaflet availability on medication accuracy, leaflet attitude, and intentions to use.



Finally, in H5, it is expected that health literacy will moderate the impact of leaflet availability on medication accuracy, leaflet attitudes, and intentions to use the drug. As noted in Table 1, this interaction is significant for medication accuracy ($F = 3.55$, $p < .05$) and intentions to use the drug ($F = 4.31$, $p < .05$), offering support for H5(a) and H5(c). As shown in Figure 4, medication accuracy scores were significantly stronger for lower literacy respondents when the leaflet was available for an extended period of time ($M = 4.94$; $SD = 2.01$) versus when it was not ($M = 4.23$; $SD = 1.88$; $t = 2.81$, $p < .01$). This effect was attenuated for higher literacy respondents. Similarly, intentions to use the drug were higher for the lower literacy respondents when the leaflet was available for an extended period of time versus when it was not. For high literacy respondents, it was the exact opposite effect. Table 3 provides a summary of hypotheses tested and findings.

Figure 4. The impact of leaflet availability and health literacy on medication accuracy and intentions to use.

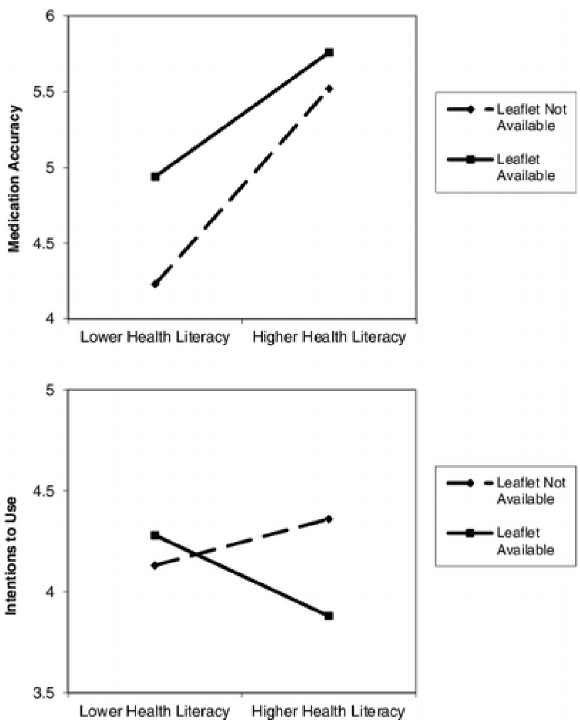



Table 3. Summary of hypotheses and findings.'

| Hypotheses | Findings |
|---|---|
| H1: Those exposed to more complex pharmacy leaflet prototypes (revised medication guides) will have (a) less accurate medication scores, (b) less favorable attitudes toward the pharmacy leaflet, and (c) less favorable intentions to use the drug than those exposed to simpler pharmacy leaflet prototypes (expanded OTC, simple OTC, bubbles format). | Partial support for H1(a)–(c) |
| H2: Health literacy will moderate the impact of the leaflet prototypes on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with greater health literacy skills will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflet, and (c) more favorable intentions to use the drug when exposed to more complex pharmacy leaflet prototypes (revised medication guides) than those with fewer health literacy skills. Such interaction effects will be attenuated for the simpler pharmacy leaflet prototypes. | Partial support for H2(a); H2(b) and H2(c) not supported |
| H3: Health motivation will moderate the impact of the leaflet prototypes on medication accuracy, leaflet attitudes and intentions to use the drug. Specifically, those with greater health motivation will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflets, and (c) more favorable intentions to use the drug when exposed to more complex pharmacy leaflet prototypes (revised medication guides) than those with less health motivation. Such interaction effects will be attenuated for the simpler pharmacy leaflet prototypes. | Partial support for H3(a) and H3(b); H3(c) not supported |
| H4: Information (leaflet) availability will moderate the impact of the leaflet prototypes on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with greater information availability will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflets and (c) more favorable intentions to use the drug when exposed to more complex pharmacy, leaflet information (revised medication guides) than those with less information availability. Such interaction effects will be attenuated for the simpler pharmacy leaflet information. | H4(a)–(c) not supported |
| H5: Health literacy will moderate the impact of information (leaflet) availability on medication accuracy, leaflet attitudes, and intentions to use the drug. Specifically, those with fewer health literacy skills will have (a) more accurate medication estimates, (b) more favorable attitudes toward the pharmacy leaflet, and (c) more favorable intentions to use the drug with greater information (leaflet) availability than those with less information (leaflet) availability. Such interaction effects will be attenuated for those with greater high literacy skills. | H5(a) and H5(c) supported; H5(b) not supported |

# Discussion

## The role of moderators in pharmacy leaflet comprehension, attitudes, and intentions

With over 750,000 adverse events and 38,000 deaths in the USA each year due to medication misuse (CDC 2013a; FDA 2013a), better options are needed in the effective communication of prescription drug risks and usage information. One viable alternative is to offer more comprehendible, accurate, and easy-to-access prescription drug pharmacy leaflets, also known as CMI. Currently, such pharmacy leaflets or CMI often appear in extremely small font size, cluttered layouts, and with distracting information (e.g., ads, coupons). Moreover, only 75% of the CMI tested have met the minimum criteria for usefulness, a figure that falls short of the 95% goal set by Congress for 2006 (Kimberlin and Winterstein 2008; Winterstein et al. 2010). Although a variety of CMI prototypes have been proposed, assessing key *moderators* – such as one's motivation, ability, and opportunity to process leaflet information – provides a more in-depth, theoretical understanding of exactly how consumers comprehend and are persuaded by the leaflet information (Batra and Ray 1986; Chaiken 1980; MacInnis, Moorman, and Jaworski 1991; Petty and Cacioppo 1986). For example, patient health literacy (affecting one's ability), patients' interest in obtaining health information (motivation), and information availability (opportunity) when making medication decisions are all key potential factors affecting whether one leaflet prototype (e.g., expanded OTC) might be more effective than another format (e.g., revised med guide). Opportunity to process (via pamphlet availability) also served to enhance those with limited ability (literacy) skills. Thus, the key purpose of this study was to examine the effects of different levels of objective health literacy and health motivation on the accurate evaluation, attitudes, and intended use of prescription drug label (CMI) prototypes. In addition, prototype availability (always available, withdrawn from view) was assessed to examine the realistic processing of pharmacy leaflet information.

## Leaflet comprehension

Our results clearly show the importance of the moderating conditions on the correct comprehension of the leaflet prototypes, as measured by medication accuracy scores. First, as found in Table 2, higher (versus lower) health literacy, higher (versus lower) health motivation, and leaflet availability (versus not always available) all increased the medication accuracy scores. More specifically, the expanded OTC prototype was the best overall for improving comprehension, as well as for those with lower literacy and lower motivation. This prototype is similar to the 'Drug Facts' box (a variant of the OTC Drug Facts box) that has been advocated by some researchers (Schwartz, Woloshin, and Welch 2007). It turns out that the simple OTC prototype did not perform as well as the other prototypes on medication accuracy scores, perhaps by not being specific enough to help with a deeper understanding of the medication. However, on the other end, the revised MGs were not as well comprehended for lower health literacy and lower motivation respondents. As this prototype was lengthy and detailed (and similar to current leaflets), it was not comprehended as well as the expanded OTC prototype. Finally, providing the continued availability of the leaflet helped improve the medication accuracy scores for the expanded OTC prototype, as it did well for lower literacy and lower motivation subjects. This mirrors the real context in which some patients may keep the leaflet and always consult it, whereas others may not look at it after the first time that it is received. Thus, health care provider–patient education emphasizing the need to refer to CMI when taking prescription drugs may be especially beneficial for this with lower health literacy and motivation. In addition, although comprehension scores improved for the expanded OTC prototype, it was not as well liked and reduced drug-use intentions (see Figure 3) when its availability was continuous during the study. In general, however, having access to the prototypes through the study was a positive aspect, as this improved comprehension scores and prescription drug-use intentions for those with lower (versus higher) health literacy.

## Leaflet persuasion: attitudes and intentions

Leaflet attitudes and intentions to use the (Rheutopia) drug were the worst for the revised MGs. Interestingly, even though respondents did not like the revised med guides, and preferred the simple OTC prototype better, it did not help comprehension accuracy scores for lower literacy and lower motivation subjects (as noted above). The expanded OTC prototype was the best on attitudes for lower motivation subjects (Figure 2), yet having it always available reduced its likability and intentions to use the drug. In general, however, having the leaflet available helped to increase Rheutopia usage intentions for lower literacy subjects.

## Recommendations and implications for marketing communications and public health policy

Based on our findings, one major recommendation for researchers is to make sure to assess the possible motivational (e.g., health motivation), ability (e.g., health literacy), and opportunity (e.g., leaflet availability) moderators in the study of the comprehension and persuasiveness of health information, such as the pharmacy (CMI) leaflets. Prototypes that may be effective for high health literacy individuals may not be the best for those with lower health literacy. Overall, our findings do indicate that the current CMI leaflets (closer to revised med guide prototype) *can* be improved by reducing the complexity of information to a point. Yet, the ultimate measure of effectiveness is their impact on patient understanding and persuasion, especially for key vulnerable populations. The expanded OTC prototype (similar to the 'Drug Facts' box) may be an especially beneficial format, given its improved comprehension scores for lower health literacy and lower health motivation respondents.

Obviously, in the assessment of different labeling formats, there can be different processing outcomes – as likeability and intent do not always translate into accurate comprehension (cf. Andrews, Netemeyer, and Burton 2009). For example, although the simple OTC prototype was better liked, and led to relative high intentions to use the prescribed drug, it did not fare well on medication accuracy scores – a key policy outcome measure.

There certainly is an educational component to the understanding and use of CMI, as pharmacists and doctors should consider the 'teach back' method with revised (and simpler) CMI versions (Wolf 2011). Also, further testing of information availability is warranted for different literacy levels such that a respondent could be provided an option to examine the leaflet again after it is taken away. The idea is that those with lower literacy levels may benefit by such repetition and be encouraged by health professionals to review the information. In addition, visual aids and graphics (e.g., pictures of pills, colored warnings) and other format improvements might further help with CMI communication especially in lower literate populations (Houts et al. 2006; Kees et al. 2010; Wolf et al. 2010). Other innovative ideas include the possibility of offering *customized* patient information in CMI based on personal medical history (e.g., through electronic medical records; apps) and *tiered levels* of information based on patient literacy skills (e.g., highlighted context – similar to 'quick start guides,' deep online links; Winterstein et al. 2010; see also Boudewyns et al. 2013). Also, an improvement in pharmacy leaflet information for consumers can provide a competitive advantage for those pharmacies willing to make the initial changes. Finally, we encourage the FDA and public health researchers to continue with further testing of CMI prototypes, including the consideration of possible moderators and mediators, as well as with larger samples of consumers and patients. Particular attention is needed for those with very low health literacy skills in gauging their understanding of different CMI formats (cf. work by Davis et al. [2006a] with prescription drug warnings). Such continued efforts may help improve the comprehension and accurate use of consumer medication information in helping to reduce the tragedy of prescription drug misuse and mortality in the USA and throughout the world.

## Disclosure statement

No potential conflict of interest was reported by the authors.

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