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# Influence of patient medication information format on comprehension and application of medication information: A randomized, controlled experiment

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ABSTRACT

*Objective:* To examine patients' comprehension and application of alternative versions of patient medication information handouts for a fictitious drug, and whether patient characteristics influence patients' ability to understand the handouts.
*Methods:* A web-based experiment was conducted in which 1397 adults with rheumatoid arthritis, ankylosing spondylitis, or plaque psoriasis were randomly assigned to one of three conditions: (1) a one-page "Bubbles" format; (2) a one-page "Over-The-Counter" (OTC) format; and (3) a four-page document modeled after MedGuides used in 2009 which served as the control arm. Comprehension and application of information in the handouts were the key outcomes of interest.
*Results:* Participants who viewed either the Bubbles or OTC formats had greater comprehension than participants who viewed the MedGuide, but did not have better application scores. No significant differences were noted between the Bubbles and OTC formats. Patient characteristics did not moderate the results.
*Conclusion:* Both formats resulted in better comprehension than the MedGuide format used in the study.
*Practice implications:* Results provide valuable information on how to design patient information to improve patients' understanding of the risks and benefits of the drugs they are prescribed. Results could be extended to inform the content of other types of patient education materials.


## 1. Introduction

According to the 2012 report on the health status of Americans, nearly half of the United States population and 90% of Americans over the age of 65 used at least one prescription drug in the past 30 days [1]. Unfortunately, many prescription medication users struggle to understand the written information provided with their prescription medications [2–4]. This written information is found in the format of patient information leaflets, written for patients to provide information about their prescription medication. Past research has shown patient information leaflets to be difficult to read and not useful for the intended audiences [2,4–6]. One type of patient information leaflet dispensed to patients in the United States (U.S.) is a Medication Guide (MedGuide). MedGuides are developed by the pharmaceutical industry and are reviewed and approved by the U.S. Food and Drug Administration (FDA); these paper-based handouts contain information that can help patients avoid serious adverse events. As of 1998, FDA regulations required that pharmacies distribute MedGuides to patients for certain prescription medications that possess serious and significant public health concerns [7]. In recent years, the number of drugs required by the FDA to have a MedGuide increased ten-fold (from a total of 40 in 2006 to over 400 as of May 2014) [8].

MedGuides can be complex and difficult to understand [6,9]. For example, Wolf et al. [6] conducted a suitability assessment of materials (SAM) analysis [10] to assess the comprehension and readability of MedGuides developed from 2006 to 2010 for lower-literate adults and found that only 1 out of the 185 MedGuides evaluated was suitable. According to the SAM criteria, the authors found that MedGuides often failed to limit the scope of content and formatted the information poorly (e.g., not using visual cueing

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devices, presenting pages that appear cluttered). They also found that participants' comprehension of three available MedGuides was poor, especially among those with lower health literacy.

The continued recognition of the complexity of current patient information has led to the development of new prototypes that exemplify different approaches to conveying prescription drug information. Specifically, in 2009, FDA convened a Risk Communications Advisory Committee [11] and a subsequent public workshop [12] that addressed the shortcomings of patient information format and developed new handouts based on evaluation of scientific literature, expert opinion, and stakeholder input. The refined handouts differed from the existing patient information formats in the amount and type of content and how the information was formatted. Research on reading and human cognition suggests that presenting information in a more organized or chunked structure may enhance processing and recall because it decreases cognitive load and is more likely to be stored and processed [10,13–15]. As such, these content and formatting changes are expected to result in better comprehension; however, little specific empirical evidence exists to support these changes.

Using a randomized, controlled trial design, we evaluated patients' comprehension of information from three patient medication information handouts for a fictitious drug for rheumatoid arthritis that FDA had developed in past outreach exercises. One handout, modeled on MedGuides used in practice in 2009, was used as a starting point for developing new materials. We also examined patient characteristics as potential moderators of patients' comprehension and application of the handouts.

## 2. Materials and methods

### 2.1. Design overview

We conducted the study between November 2012 and January 2013, with all study procedures approved by RTI International's Institutional Review Board and FDA's Research Involving Human Subjects Committee.

### 2.2. Settings and participants

All participants were required to be 18 years of age or older and have self-reported rheumatoid arthritis (RA), ankylosing spondylitis (AS), or plaque psoriasis (PP), conditions treated by the fictitious drug under study. Individuals were ineligible if they or someone in their household worked as a healthcare professional, or if they participated in a health-related research interview in the past 6 months.

Using random-digit-dialing and address-based sampling, we recruited participants from a professional survey firm (GfK) research panel consisting of about 50,000 U.S. adult members. Because too few panel members met the eligibility criteria, GfK supplemented the sample with an opt-in panel from sample vendor Survey Sampling International.

An a priori power analysis was conducted to determine the sample size needed for this study to test various continuous outcome measures, such as comprehension and application. The following assumptions were made in deriving the sample size: (1) 0.05 alpha and 0.95 power and (2) a small effect size. Based on this analysis, it was determined that our sample size of 1300 would be likely to detect effects as small as $f = 0.10$.

### 2.3. Randomization and intervention

Two authors, in collaboration with FDA staff, developed the two "Rheutopia" handouts used in this study (the Bubbles and Over-the-Counter [OTC] formats) through an iterative process that involved input from risk communication experts from academia, government, and industry attending a Risk Communication Advisory Committee meeting in February, 2009 [11]; a public workshop held in September, 2009 [12]; and from public stakeholders through Federal Register procedures [16,17]. Plain language principles were used in the development of these handouts where possible. Rheutopia was modeled after an existing injectable drug indicated for RA, AS, or PP. The two final handouts used in this study were further selected through qualitative research with patients who had one of these medical conditions [18]. The handouts for Rheutopia contained

| Characteristic | MedGuide | OTC | Bubbles |
|---|---|---|---|
| **Page length** | 4 pages | 1 page | 1 page |
| **Format** | Follows the Medication Guide's model, Part 208 requirements; paragraph format | Similar to OTC drug facts labeling; information about serious infections shaded in gray | Bubbles in two columns; information about serious infections shaded in gray |
| **Bulleted points** | Yes | Yes | Yes |
| **Use of white space** | Minimal | Moderate | High |
| **Headings framed as a question or phrases** | Questions | Phrases | Phrases |
| **Information presented first in the handout** | Introduction to the Guide; summary of most important information | What is Rheutopia and its uses | What is Rheutopia and its uses; when to call doctor right away or stop using |
| **Reading level** | Flesch reading ease: 54.6<br>Flesch-Kincaid reading level: 8.8 | Flesch reading ease: 60.9<br>Flesch-Kincaid reading level: 6.1 | Flesch reading ease: 60.9<br>Flesch-Kincaid reading level: 6.1 |
| **Content included in MedGuide but *NOT* in the OTC and Bubbles formats** | | | |
| • Introduction to the Guide<br>• Pregnancy risk<br>• Detailed information about how to store Rheutopia<br>• Ingredients | | | |

**Fig. 1.** Side-by-side handout comparison. Comparison of handout characteristics across the three patient medication information handouts.