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Research Briefs

Reducing drug self-injection errors: A randomized trial comparing a "standard" versus "plain language" version of Patient Instructions for Use

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Abstract

Background: Many American adults struggle to use and interpret medical-related instructions. Plain language materials have been shown to improve patient understanding and adherence.
Objective: The study objective was to compare the effectiveness of a "standard" Patient Instructions for Use (PIFU-standard) with a "plain language" Patient Instructions for Use (PIFU-PL) by testing user comprehension and ability to administer a biologic agent with an auto-injector ("pen").
Methods: A trained research assistant administered sociodemographic items and the Rapid Estimate of Adult Literacy in Medicine to study participants ($n = 50$). Next, using a priori random assignment, participants received either PIFU-PL or PIFU-standard. Participants' knowledge of preparation (6 steps) and pre-injection (3 steps) procedures, and demonstrated correctness of self-administration (15 steps) were then evaluated.
Results: Participants receiving the PIFU-PL were more likely to correctly describe a greater number of both preparation (4.5 ± 1.3 versus 3.1 ± 1.5, $P = 0.01$) and pre-injection steps (2.4 ± 0.8 versus 1.6 ± 0.6, $P = 0.01$), and demonstrated more correct self-injection steps (13.1 ± 2.1 versus 10.8 ± 4.4, $P = 0.05$) as compared to participants receiving the PIFU-standard.
Conclusion: Participants given "plain language" instructions had a significantly better understanding of how to prepare for and self-administer medication with a pen and were consistently more accurate in demonstrating how to self-inject.

Keywords: Comprehension; Drug labeling; Health literacy; Patient education as topic/methods; Prescription drugs/administration; Risk reduction behavior; Medication errors

Introduction

Minimizing the occurrence of medication mal-administration has been identified by the Institute of Medicine as an important objective for improving healthcare delivery in the United States.[1,2] A commonly used tool for minimizing

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medication maladministration is a written instructional guide, often referred to as Patient Instructions for Use (PIFU). Such information is typically distributed with the medication at the time of dispensing by the pharmacy.

PIFUs are deemed to be part of drug labeling and, as such, both their content and format are regulated by the United States Food and Drug Administration (FDA).[3] Labeling regulations, however, may not always incorporate "best practice" educational design principles for written consumer information.[4] In fact, most patient medication materials require advanced reading skills (i.e., equivalent to post-graduate school education), while the average American adult has reading skills ranging between the 6th and 8th grade level.[2] Similarly, quantitative information included within medication instructions, such as dose measurement or injection angle, requires numeracy and/or quantitative literacy skills exceeding those of the average American adult as well.[5]

Nearly half of all adults in the United States have only below basic or basic health literacy skills.[6] Unfortunately, it is not uncommon for patient education materials to be plagued by not only exceedingly high literacy demands, but also poorly designed layout features as well (e.g., small font point sizes, lack of white space).[7–10] Importantly, replacing standard patient educational materials with plain language materials has been strongly associated with knowledge gains in relation to patients' understanding of medical procedures[11,12] and medication administration[13] and prompting discussion of screening during the clinical encounter.[14]

While the difficulties faced by patients using medical devices such as respiratory inhalers have been examined,[15] to our knowledge no studies have assessed whether patients can self-administer. The purpose of this study was to compare the effectiveness of a "standard" Patient Instructions for Use (PIFU-standard) with a "plain language" Patient Instructions for Use (PIFU-PL) by testing user comprehension and ability to administer a biologic agent with an auto-injector ("pen"). This study addresses the U.S. Department of Health and Human Services goal of developing and disseminating health and safety information that is accurate, accessible, and actionable as highlighted in the *National Action Plan to Improve Health Literacy*.[16]

Methods

The Crescent City Institutional Review Board approved all procedures employed in this study.

Development and pilot testing of "plain language" Patient Instructions for Use (PIFU-PL)

In accordance with recognized best design practices for patient education materials,[4,17,18] study investigators created two PIFU-PL versions for an existing product. Key principles included: defining the main learning goal, using plain language to explain essential steps, minimizing text, increasing the number of graphics, and information in discrete "chunks" sequentially in accordance with the desired behaviors. The first version included very detailed medication information and step-by-step administration instructions in booklet format. The second version was shorter (4-sided fold-out) and contained only the most pertinent information and instructions (i.e., "quick" guide). Both PIFU-PL versions included high quality graphics accompanied by a large amount of white space and $\geq$12-point font throughout.

Upon creation of both PIFU-PL versions, the second author conducted pilot tests using structured one-on-one cognitive interviews with 25 adult chronically ill patients, aged $\geq$30 years or older, to obtain their input regarding the design and readability of the materials. Specifically, patients were asked to review the materials and provide feedback regarding layout features. They were also asked how information could be best presented to facilitate patient understanding. The second author took detailed notes during each one-on-one interview and revised both sets of materials based on the cumulative feedback of pilot test participants. Lastly, both authors reviewed and agreed upon final formatting features of both sets of materials to be used in the randomized clinical trial described below.

Study and participant eligibility criteria

A convenience sample of 50 patients was recruited from an outpatient primary care clinic in both Loudon and Knoxville, Tennessee during September–November, 2009. To be eligible for the study, participants had to be 18 years of age or older, English-speaking, and have at least one chronic illness, including but not limited to the adult disease conditions for which the study medication was indicated (Crohn's disease and rheumatoid arthri-