Original Research

User testing as a method for identifying how consumers say they would act on information related to over-the-counter medicines

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Abstract

Background: User testing evaluates written medicine information (WMI) usability by examining participants' ability to find and understand information. It can also be an effective method to determine how consumers say they will act on information on an over-the-counter (OTC) label.
Objective: To examine consumers' proposed behaviors regarding dosage and storage as a measure of a medicine label's usability and consumers' functional health literacy.
Material and methods: User testing of 5 diclofenac OTC labels (by 50 subjects; 10 per label) measured consumers' ability to find and understand key points of information using a 13-item questionnaire. Consumers were required to elaborate on their behavior in regard to 2 additional questions: 1) when they would take diclofenac if they had constant back pain from 8 am (dosage-related) and; 2) where they would store it in their home (storage-related). Responses were transcribed verbatim, and coded by 2 pharmacists.
Results: Appropriate dosing for constant back pain was reported by 29 consumers. However, dosing intervals shorter than the specified 8 h were often reported ($n = 19$), due to adjusting intervals to accommodate up to the maximum of 8 tablets in 24 h, desire for pain relief, and/or pragmatic dosing (e.g. around bedtime). Only 29 consumers stated completely appropriate storage location examples (e.g. medicine cabinet).
Conclusions: Consumers may act inappropriately on OTC label information about dosage and/or storage, which could potentially adversely impact medication use. User testing can contribute to the development of high quality WMI and help identify where label wordings are inappropriate for the health literacy levels of consumers.
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Introduction

The importance of health literacy is clear within the context of health care. Health literacy can be defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[1(p32)] Health literacy can be further conceptualized within a three-tiered model of health literacy, consisting of functional (level 1), interactive (level 2), and critical health literacy (level 3), where functional health literacy is the foundation level upon which the other levels can be developed.[2] Functional health literacy is related to a person's capacity to utilize literacy skills in the context of health and medicine-related information.[3]

Suboptimal health literacy has been associated with a number of negative outcomes for individuals.[4–6] Thus, adequate health literacy levels are important, and have been associated with written medicine information (WMI) understanding.[7] A number of health literacy screening tools exist, but not all measure functional health literacy.[8] Those which require individuals to apply a range of skills inherent in functional health literacy include tools such as the Test of Functional Health Literacy in Adults (TOFHLA), and the Newest Vital Sign (NVS).[8] In relation to written information, a wide range of tools exist for use in health and medicines information evaluation; however, most only assess readability and/or design.[8]

Suboptimal health literacy is widespread,[9] and there are a number of strategies that can be implemented to help improve the ease with which health and/or medicines information can be understood, with one such strategy being user testing.[10] Therefore, in light of the universal precautions approach to health literacy, where strategies to support patients in managing their health are underpinned by the premise that everyone may have problems understanding health-related information,[11] user testing can help to achieve this in relation to WMI.[12] User testing, developed by Sless and colleagues,[13] can be regarded as the gold standard method in evaluating the performance or usability of WMI.[14] User testing is recommended[15] in the European Union, where the usability of leaflets must be assured via consultation with consumers.[16] Similarly, in Australia, user testing has been incorporated into guidelines on the development and testing of over-the-counter (OTC) labels,[17] and leaflets.[13]

The process of user testing involves measuring the usability of WMI by indirectly utilizing consumers' functional health literacy,[3] as demonstrated by their interaction and understanding of the WMI being evaluated.[15] A range of demographics such as education, age, factors regarding occupation, amongst others, are considered when recruiting participants,[15,18] to potentially include a range of health literacy levels within the study population. Individuals are required to demonstrate their ability to find and understand key points of information, which are the primary outcome measures in performance evaluation, which is followed by a qualitative, semi-structured interview where feedback is obtained on the information that was user tested.[15] Therefore, the questionnaire developed specifically to user test the WMI has a key influence over what is measured in terms of understanding. The strength of user testing lies in its iterative nature, whereby necessary changes are made to the information to address any identified shortcomings from the initial round of user testing, with the revised information then subject to further testing to ensure it is fit-for-purpose.[12]

User testing as a process exists at the interface of both: (a) ensuring WMI caters for the health literacy needs of the target patient population, and (b) as an indirect way to examine how an individual's functional health literacy influences both perceived and actual WMI usability. However, user testing has not been previously used as a method to help provide further insight into participants' functional health literacy via the examination of proposed behaviors, as an extension of the user testing process in response to information read on a medicine label. Therefore, the aim of this study was to examine participants' proposed behaviors regarding dosage and storage as a measure of a medicine label's usability and consumers' functional health literacy.

Methods

This study forms part of a larger international research project, which aimed to develop and user test alternative OTC label formats that could be considered for implementation as part of an OTC label standardization strategy.

Four alternative OTC label formats were developed for the study medicine diclofenac. Two label formats were developed based on existing and proposed standardized label formats