



## Original Research

# Factors associated with intention to engage in self-protective behavior: The case of over-the-counter acetaminophen products

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## Abstract

**Background:** Inappropriate use of acetaminophen products is a concern due to the severe liver damage associated with intentional or accidental overdose of these products. In 2009, the U.S. Food and Drug Administration (FDA) issued more severe organ-specific warnings for the acetaminophen Drug Facts label to improve protective behavior among patients. However, it is not clear how patients react to such interventions by the FDA.

**Objective:** The objective of this study was to evaluate the factors influencing patients' intention to engage in protective behavior while using acetaminophen products after reading the Drug Facts label. The study specifically looked at the relationship between four Protection Motivation Theory-based risk cognition factors and the intention to engage in protective behavior.

**Methods:** An experimental, cross-sectional, field study was conducted using self-administered questionnaires at four community pharmacies in Houston, TX. Two hundred surveys were collected from adults visiting the selected pharmacy stores. Participants were exposed to a simulated label (i.e. Drug Facts label) containing organ-specific warnings for over-the-counter (OTC) acetaminophen products. Risk cognition measures (i.e. measures of perceived severity, perceived vulnerability, response efficacy, and self-efficacy) and measures of intention to engage in protective behavior (always reading warnings, using products with more caution, and consulting a pharmacist/physician) were recorded. Pearson correlation and multiple linear regression analyses, controlling for demographic and behavioral characteristics of the participants, were performed.

**Results:** Bivariate analyses indicated that an increase in perceived severity, perceived vulnerability and response efficacy were associated with a higher intention to engage in protective behavior. Findings from the multiple regression indicated that increase in perceived severity of liver damage, belonging to a non-healthcare occupation, no history of acetaminophen use and no history of alcohol consumption were associated with a higher intention to engage in protective behavior.

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Conflict of interest: None.

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**Conclusion:** Higher risk cognition of liver damage associated with inappropriate use of OTC acetaminophen products leads to greater intention to engage in protective behavior while using such products. Developing interventions targeted towards improving reading and adhering to the Drug Facts label could improve risk cognition, and thus improve patients' intention to engage in protective behavior. Regular acetaminophen users, heavy alcohol consumers and healthcare professionals might need other interventions apart from the Drug Facts label to improve their likelihood to engage in protective behavior. © 2015 Elsevier Inc. All rights reserved.

**Keywords:** Risk cognition; Protective behavior; Acetaminophen; Liver injury; Liver damage; Appropriate use of OTC products

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## Introduction

Over the past few decades increasing efforts are being made to educate patients in healthy behavior, self-care, and preventive care. The earlier practice of unilateral style of health care has shifted over time to increased level of patient involvement in day-to-day management of health. However, a major challenge with the increased participation of a patient in his or her own healthcare is ensuring the use of appropriate healthcare practices and self-protective behavior. Messages and warnings promoting protective behavior such as healthy-eating, adhering to different treatment regimens, methods for avoiding adverse events, and following provider's instructions are expressed routinely to patients via media, at doctors' offices, and at pharmacies. Despite these ubiquitous messages and warnings, patients are often found to engage in potentially harmful or negligent behavior.<sup>1</sup> The ineffectiveness of these healthcare messages and warnings indicate an inability to identify the most effective modes of communicating these messages to the patients. The pathway through which these healthcare messages and warnings affect patients' cognition of the importance of these messages, and patients' intention to eventually engage in the recommended protective behavior is poorly studied in most healthcare situations. This study aims to address this gap, and examine one such pathway of patients' risk cognition when exposed to warning messages, and the effect of this risk cognition on the intention to engage in protective behavior.

Negligent patient behavior is particularly common in the use of over-the-counter (OTC) products, which do not require provider prescriptions or instructions, and are freely available in supermarkets and convenience stores.<sup>2</sup> The ready availability of the OTC products leads to an erroneous perception of their being safe. Although OTC medications help save an average

of \$102 billion annually by aiding self-care for commonly occurring conditions,<sup>3</sup> inappropriate use of such medications often lead to high rates of drug-related emergency department visits and hospitalizations. Since the OTC products do not usually involve prescriptive directions from providers, the Drug Facts label on these products play an important role in providing usage directions and warnings to the patients. However, patients might rely on their own judgment and their prior experience with these OTC products, which might lead to inappropriate product use and associated adverse events.<sup>4</sup> According to an estimate by the Institute of Medicine, 90 million adults in the United States may have difficulty understanding the health information presented to them on the Drug Facts labels.<sup>5</sup> The Food and Drug Administration (FDA) plays an important role in making sure that the information on these Drug Facts labels is easy to comprehend, and conveys important warning messages about these OTC products. This study for the first time uses the case of exposure to the warnings on OTC acetaminophen Drug Facts label to study the effect of risk cognition on the intention to engage in protective behavior.

The case of acetaminophen was particularly picked for this study because it is the most commonly used and "misused" OTC medication among the US adult population.<sup>4,6</sup> Furthermore, the severity of acetaminophen-related side-effects make the drug a suitable case for studying patient risk cognition and intention to engage in protective behavior. An average of about 42,329 emergency department visits per year during the years 2000–2006 were attributable to acetaminophen overdose, of which 51% were unintentional injuries.<sup>6</sup> The average annual projected number of acetaminophen overdose-related hospitalizations was reported to be approximately 37,000 during 2005–2006.<sup>6</sup>

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