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Improving over-the-counter medication safety for older adults: A study protocol for a demonstration and dissemination study

Michelle A. Chui [a, *], Jamie A. Stone [a], Richard J. Holden [b]

[a] Systems Approach to Medication Safety Research Laboratory, Social & Administrative Sciences Division, University of Wisconsin – Madison, School of Pharmacy, 777 Highland Avenue, Madison, WI, 53705, United States
[b] School of Informatics and Computing, Indiana University-Purdue University Indianapolis, 535 W. Michigan Street, IT 475, Indianapolis, IN, 46202, United States

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ABSTRACT

Background: Adverse drug events (ADEs) associated with over-the-counter (OTC) medications cause 178,000 hospitalizations each year. Older adults, aged 65 and older, are particularly vulnerable to ADEs. Of the 2.2 million older adults considered at risk for a major ADE, more than 50% are at risk due to concurrent use of an OTC and prescription medication.
Objectives: To refine the intervention and implementation strategy through diagnostic and formative evaluation; to evaluate the effectiveness of the intervention for preventing misuse of high-risk OTC medications by older adults; and to evaluate the implementation of the intervention in community pharmacies.
Methods: A system redesign intervention to decrease high-risk OTC medication misuse will be tested to reduce misuse by improving communication between older adults and community pharmacists via the following features: a redesign of the physical environment to sensitize older adults to high-risk OTC medications, and the implementation of a clinical decision tool to support the pharmacist when critically evaluating the older adult's health status. The study will be conducted in three phases: a participatory design phase, a beta phase, and a test phase. The test phase will be conducted in three mass-merchandise stores. A total of 144 older adults will be recruited. A pre (control)/post (intervention) test will determine the effectiveness of the intervention. The primary outcome will be a comparison of proportion of older adults who misuse OTC medication from baseline to post-intervention. The process of implementation in the community pharmacy setting will be evaluated using the taxonomy proposed by Proctor et al. The participatory design phase has been approved by the institution's IRB (2016-0743).
Projected impact: It is anticipated that this project, which focuses on achieving systems-based improvement in an underemphasized area of the medication use process, will reduce ADEs associated with inappropriate OTC medication use in older adults.

1. Background

Older adults are at high risk of significant harm associated with over the counter (OTC) medication use. Of the estimated 2.2 million older adults who are at risk of a major adverse drug event (ADE), more than 50% of these interactions involve an OTC medication.[1] Four of the 10 most frequently used drugs are available OTC. They are: ibuprofen, aspirin, acetaminophen, and diphenhydramine. These four drugs also are available in multiple-ingredient preparations, accounting for 45% of acetaminophen and 26% of aspirin use, thus increasing the potential for dangerous overdosing.[2] Older adult use of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and aspirin, results in 80,000 preventable ADEs each year. NSAID use accounts for a larger burden of ADEs (15.4%) than anticoagulants (10.2%), one of the Department of Health and Human Services' top priority drugs in its National Action Plan for ADE prevention.[3,4] Unintentional overdoses of acetaminophen result in 14,000 emergency department visits, and up to 50% of all acute liver failures per year.[5,6] Diphenhydramine has anticholinergic properties which causes dizziness and loss of balance in 25% of

* Corresponding author.
E-mail addresses: michelle.chui@wisc.edu (M.A. Chui), jamie.stone@wisc.edu (J.A. Stone), rjholden@iupui.edu (R.J. Holden).

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older adults, which increases their risk of falling.[7] Of older adults taking diphenhydramine for sleep, 40% were also taking one or more anticholinergic medications concurrently, compounding the risk of ADEs.[8] These four drugs represent a significant ADE burden, and are the focus of this study.

Most older adults are not familiar with the appropriate dosing of OTC medications or how OTC medications interact with their other medications. Compounding the lack of patient knowledge about OTC medications, providers do not know which OTC medications their patients are consuming.[9] Such lack of awareness and documentation about OTC medication use may lead to duplication of therapies and dangerous overdosing. In fact, the Centers for Medicare and Medicaid Services single out diphenhydramine and NSAIDs for review specifically because of their OTC availability and potential for therapeutic duplication.[10,11] Despite the fact that OTC medication misuse is prevalent and costly, this potentially enormous patient safety gap remains relatively invisible. No effective interventions exist to help older adults prevent OTC medication misuse.

The availability of pharmacists at the point of sale of OTC medication has great potential for decreasing OTC medication misuse by older adults. A study found that 57% of elderly patients taking chronic prescription and OTC medications were not taking their OTC safely and required a pharmacist intervention with their OTC medication.[12] Moreover, 80% of Americans report they would purchase (or avoid) a particular OTC medicine based on their pharmacist's recommendation.[13] Unfortunately, the current suboptimal design of community pharmacies and lack of standardized processes contribute to misuse of high-risk OTC medications. OTC medications are displayed to improve profitability,[14] not prevent medication misuse. Older adults, who tend to have more visual and cognitive impairment, can become overwhelmed when faced with poorly designed aisles of confusing OTC choices.[15]

In response to The Affordable Care Act legislation that expands health care coverage, many chain community pharmacy organizations are retooling themselves as a vital part of the health care system, by discontinuing the sale of tobacco, adding primary care health clinics, and redesigning the pharmacy to allow pharmacists to more easily interact with patients.[16,17] Although “health and wellness” is a focus of this nationwide movement, there is no specific emphasis on OTC medication safety. The present study provides a timely opportunity to expand the industry's new initiatives to include system redesign to improve OTC medication use by older adults.

Few interventions have attempted to decrease misuse of high-risk OTC medications in older adults, and none have addressed system barriers.[18] Compared to efforts to improve prescription medication safety,[19,20] efforts to decrease OTC medication misuse in community-dwelling older adults have been practically ignored. To address this alarming and critical gap in medication safety, a system redesign intervention has been developed to mitigate system barriers. This intervention, which is grounded in human factors engineering principles and methods, includes a redesign of the community pharmacy's OTC aisles, and the implementation of a pharmacist clinical decision tool. The intervention will decrease misuse by heightening older adults' awareness of OTC risk, allowing pharmacy staff to see and initiate conversations with older adults in the aisles, and incorporating an efficient standardized process for pharmacists to gather necessary information to make recommendations.

The long term goal is to prevent OTC medication misuse and subsequent harm by targeting system barriers. A three-phase, pre (control)/post (intervention) study design to determine the intervention's effectiveness in decreasing high-risk OTC medication misuse by older adults will be conducted. The hypothesis is that older adults who are more aware of risks and can more easily determine if those risks pertain to their own health situation by speaking with a pharmacist will safely select and not misuse high-risk OTC medications. Specifically, the aims are:

Aim 1. To refine the system redesign intervention and implementation strategy through diagnostic and formative evaluation. The two phase approach will comprise of a participatory design phase, and a beta test and refinement phase to produce a refined intervention and feasible implementation strategy.

Aim 2. To evaluate the effectiveness of a refined system redesign intervention for preventing misuse of high risk OTC medications by older adults. The hypothesis is that communication with a pharmacist, facilitated by the pharmacy redesign and clinical decision tool, will prevent older adult misuse of OTC medications. This hypothesis will be tested by evaluating the potential misuse of OTC medications selected by older adults and comparing results prior to and after the implementation of the intervention.

Aim 3. To evaluate the implementation of a refined system redesign intervention in community pharmacies. By employing summative evaluation and assessing evidence-based implementation outcomes, key intermediate outcomes will be identified and measured,[21] including the intervention's impact on pharmacists' work and older adults' decision making processes. These measures will inform the understanding of the potential feasibility and sustainability of widespread dissemination and implementation of the system intervention.

2. Conceptual model

The conceptual framework for this intervention is adapted from the Systems Engineering Initiative for Patient Safety (SEIPS) 2.0 work system model to improve patient outcomes, a human factors engineering model developed by Holden et al..[22] The SEIPS Model has been applied to frame the design and analysis of many patient safety studies, including research conducted in community pharmacies.[23,24] The SEIPS 2.0 model is appropriate for this study because it emphasizes how work system barriers can impact the “work” conducted by pharmacists and older adults. Work is defined as goal-oriented, effortful activities.[25] For pharmacists, work would include clarifying an older adult's medication list or determining if the older adult should self-treat their stated problem. Older adult work would include determining how often to take an OTC medication or if an OTC medication interacted with prescription medication. This model is also appropriate because it highlights the importance of collaborative work, in which pharmacists and older adults are actively engaged agents, working together to achieve their goals. These work processes in turn affect older adult, pharmacist, and organizational outcomes.

3. Study design overview

In order to assess the effectiveness of the intervention while also understanding the context for implementation, an effectiveness-implementation hybrid design proposed by Curran et al. will be utilized.[26] A hybrid design, which blends design components of effectiveness and implementation research, improves the speed of knowledge creation and increases the usefulness and policy relevance of the research being conducted.[27] In addition to a diagnostic and formative evaluation to refine the intervention (Aim 1), Curran's hybrid Type 2 design will be used in which Aim 2 is to determine the effectiveness of the intervention. An independent aim (Aim 3) is to pilot test an implementation strategy and to