Improving Over-the-Counter Medication Safety for Older Adults

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STRUCTURED ABSTRACT

Purpose: This study examines effectiveness of a structural pharmacy design change, called the Senior Section™, on over-the-counter (OTC) medication misuse in older adults.

Scope: This study took place in four Shopko Stores in Wisconsin. Shopko Stores was a mass merchandise chain with multidepartment operations and a pharmacy.

Methods: Participatory design was used to fine-tune the intervention. Next, a beta test of the intervention was conducted in one store. A pre (control)/post (intervention) test was conducted in three stores to determine the effectiveness of the Senior Section™ to decrease OTC medication misuse and understand the process of implementation. Misuse outcomes comprised Drug/Drug, Drug/Disease, Drug/Age, and Drug/Label, with five subtypes.

Results: There were statistically significant reductions in Drug/Disease misuse ($z=-2.09$, $p=0.037$) and Drug/Label misuse subtypes, with reduced Daily-Dosage ($z=-2.42$, $p=0.016$) and Single-Dosage ($z=-5.82$, $p=0.001$) misuse. The Senior Section slightly reduced Drug/Drug misuse. The Senior Section improved the quality of pharmacist encounters with older adults. After implementation, pharmacy staff were more likely to initiate patient encounters, address more topics, provide details about OTC products, discuss appropriateness of OTC use, and discuss medication classes highlighted in the Senior Section.

Key Words: older adult, medication safety, over-the-counter, pharmacy, human factors

PURPOSE

Adverse drug events (ADEs) associated with over-the-counter (OTC) medications cause 178,000 hospitalizations each year,[1] representing a major patient safety concern. Older adults aged 65+, one of AHRQ's priority populations, are particularly vulnerable to ADEs. Of the 2.2 million older adults who are at risk for a major ADE, more than 50% of them are because of concurrent use of an OTC and prescription medication.[2]

Community retail pharmacies, where most older adults purchase OTC medications, are unique healthcare settings characterized by extended hours and access to a pharmacist who can provide free medication guidance. Unfortunately, the design of most community pharmacies is poor and contributes to misuse of high-risk OTCs.

We have developed a system redesign intervention, the Senior Section™, 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. The goal of the intervention is to decrease misuse by heightening older adults' awareness of OTC risk and by allowing pharmacy staff to see and initiate conversations with older adults in the aisles in order to gather necessary information to make recommendations. Our hypothesis was that older adults who are more aware of risks and can more easily determine if that risk pertains to their own health situation by speaking with a pharmacist will safely select and not misuse high-risk OTC medications.

Aim 1. To refine the system redesign intervention and implementation strategy through diagnostic and formative evaluation. We used a two-phase approach using 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 on preventing misuse of high-risk OTC medications by older adults. We hypothesized that communication with a pharmacist, facilitated by the pharmacy redesign, will prevent older adult misuse of OTC medications. We tested this hypothesis 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, we identified and measured key intermediate outcomes, including the intervention's impact on pharmacists' work and older adults' decision processes. These measures informed our understanding of the feasibility and sustainability potential of widespread dissemination and implementation.

SCOPE

Background

Older adults (aged 65+ years) use more OTC medications than any other age group. Despite representing only 16% of the US population,[3] older adults account for approximately 40% of all OTC medication use.[4] The typical older adult uses an average of three OTC medications along with three prescribed medications, and 25% of older adults use a combination of 10 or more OTC and prescription medications.[5]

Older adults are at high risk of significant harm associated with OTC medication use.[6] Of the estimated 2.2 million older adults who are at risk of a major ADE, more than 50% of these interactions involve an OTC medication.[2] Four of the 10 most frequently used drugs are available OTC. They are ibuprofen, aspirin, acetaminophen, and diphenhydramine.[7] 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.[8] Older adult use of nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, and aspirin results in over 100,000 preventable ADEs each year.[9] NSAID use accounts for a larger burden of ADEs (15.4%) than do anticoagulants (10.2%), one of the Department of Health and Human Services' top priority drugs in its National Action Plan for ADE prevention.[10,11] Such outcomes prompted the US Food and Drug Administration to strengthen its warnings regarding non-aspirin NSAIDs associated with stroke or cardiovascular events.[12] Unintentional overdoses of acetaminophen result in 14,000 emergency department visits, and up to 50% of all acute liver failures per year.[13-15] Diphenhydramine, commonly used for sleep,[16] has anticholinergic properties that cause dizziness and loss of balance in 25% of older adults, which increases their risk of falling.[17] Of older adults taking diphenhydramine for sleep, 40% were also taking one or more anticholinergic medications concurrently, compounding the risk of ADEs.[18] These four drugs represent a significant ADE burden and were 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.[19] 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 singles out diphenhydramine and NSAIDs for review specifically because of their OTC availability and potential for therapeutic duplication.[20,21] Despite the fact that OTC medication misuse is prevalent and costly, this potentially enormous patient safety gap remains relatively invisible.

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[22]; 80% of Americans report that they would purchase (or avoid) a particular OTC medicine based on their pharmacist's recommendation.[23] Unfortunately, the current, poor design of community pharmacies and the lack of standardized processes contribute to misuse of high-risk OTCs. OTC medications are displayed to improve profitability,[24] 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.[25] This situation demands a system redesign to reduce older adult OTC medication misuse.

Context

In the pilot study that proceeded this project, we conducted interviews with 20 older adults while they selected an OTC product in a community pharmacy.[26] Older adults were provided with scenarios and asked to navigate through the pharmacy and select an OTC medication. We found surprising levels of misuse among our older adult participants; at least one instance of potential misuse was found in 95% of participants (19 of 20). Forty-five percent and 60% of participants were at risk of having drug-disease or drug-age interactions, respectively. Eighty percent of participants selected an OTC that, if taken with their current medication regimen, could cause a drug-drug interaction. The average number and range of drug-drug interactions for these participants was 3.9 (range 1-8). In total, we documented 87 potential instances of misuse in 19 participants. This was significantly higher than previous reported literature, which cited a 57% incidence of misuse in older adults.[22]

Our initial studies explored factors that affect the quality and effectiveness of the counseling interaction between community pharmacists and older adults.[27,28] We found numerous interacting work system barriers that reduce a pharmacist's ability to provide safe OTC recommendations and the older adult's ability to select a safe OTC product (Table 1).

Table 1. Pharmacist & Older Adult Barriers to Safe OTC Selection

Work System Components	Pharmacist Barriers	Older Adult Barriers
Tools & Technology	• Prescription dispensing system was not mobile • No point of care decision tool	• Difficult to understand OTC labels • Unclear if pharmacist was an information resource
Organization	• Safety culture	• OTC purchase location motivated by price & proximity to home
Person	• Limited knowledge of patient's Rx & OTC history	• Limited knowledge of OTC risk • Cognitive & physical limitations
Tasks	• High demand and time pressure	• Large number of OTCs to choose from • OTC comparison was challenging
Environment	• OTC aisle distant from Rx dept • Difficulty viewing OTC aisles • Lack of private consult area	• OTC aisles distant from Rx dept • Lack of OTC signage

In summary, we found the underlying assumption that self-managing older adults are capable of safely selecting and using OTC medications to be flagrantly wrong. These assumptions have significant ramifications and shed light on a potentially enormous, but invisible, patient safety concern. These barriers informed the initial development of the Senior Section system redesign of the pharmacy OTC aisles.

Settings

This study took place in four Shopko Stores in Wisconsin. Shopko Stores was a chain of mass merchandise stores with multidepartment operations. The company operated over 300 stores located in 20 states, typically in small to mid-sized communities. Most Shopko Stores had a pharmacist available the majority of time that the store was open and stocked several large aisles of OTC products. Unfortunately, during post-intervention data collection, Shopko stores filed for bankruptcy and closed all sites.

The Shopko Stores that participated in the project included four Wisconsin stores. One store served as the beta site, and the other three were the test sites. These stores were selected because they represented a variety of communities that varied by the size of the population, proportion of older adults, and socioeconomic status.

Participants

The patient study population was older adults aged 65+ who had received at least one prescription at one of the Shopko study sites in the last 12 months and indicated that they had considered or would consider

purchasing an OTC medication from one of the following categories: pain, sleep, or cough/cold/allergy. The participants also had to be able to provide written informed consent and speak English.

The pharmacy population that participated included two pharmacists, two technicians, and one store manager per participating store as well as one administrator.

METHODS

Study Design

In order to assess the effectiveness of our intervention while also understanding the context for implementation, we utilized an effectiveness-implementation hybrid design proposed by Curran et al.[29] 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.[30] In addition to a diagnostic and formative evaluation to refine the intervention (Aim 1), we utilized Curran's hybrid type 2 design in which Aim 2 is to determine the effectiveness of the intervention. An independent aim (Aim 3) is to understand the context for widespread implementation through an examination of barriers and facilitators.

The study design included three phases (Figure 1). Aim 1 (to refine the intervention and implementation strategy through diagnostic and formative evaluation) comprised the first two phases. The two phases are a participatory design phase and a beta test and refinement phase. In the first phase, we used a participatory design approach to fine-tune the intervention. This phase utilized a stakeholder group comprised of Shopko pharmacists, technicians, and older adults. The second phase was a beta test of the intervention in one pilot Shopko store. During the beta phase, we pilot tested the intervention with a total of 24 older adult participants. OTC medication selection and reported use information were collected at baseline and post-intervention. Members of the participatory design group convened to discuss results from the beta test. Actionable barriers identified during the beta test were discussed and formative evaluation was used to refine and improve the implementation process and optimize the intervention.[31]

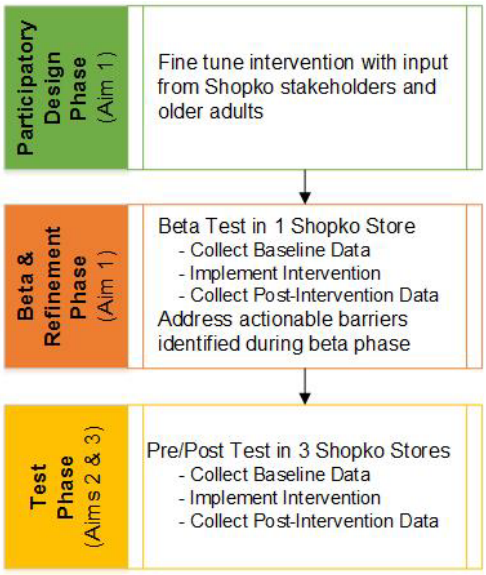

Figure 1. Research Design Overview

In the third phase, we conducted a pre (control)/post (intervention) test to determine the effectiveness of the refined system redesign intervention to decrease OTC medication misuse in older adults (Aim 2) and understand the process of implementation in the community pharmacy setting (Aim 3). The third phase included the collection of baseline data followed by the implementation of the refined intervention and collection of post-intervention data in our test site Shopko stores. Our goal was to collect data on 72 older adults at baseline and 72 older adults post-intervention.

Data sources/collection

Table 2 provides a summary of effectiveness outcomes and data sources. Specific information about the data sources related to our principle findings is provided below.

Older Adult Medical/Demographics Form: This form includes the self-report of disease information using the OAR questionnaire,[32] prescription and OTC medications, and demographic information. Both baseline and post-intervention participants completed the form.

Older Adult Interviews: Each consented older adult participated in a face-to-face "walking" interview. Participants were met by the interviewer near the store entrance. After collecting study materials and answering any participant questions, the participant was asked to choose one of the following symptom scenarios that resonated with them.

Sleep Scenario: Recently, you have been having (more) difficulty falling asleep or staying asleep. You are here at Shopko to look for a medication that can help you sleep.

Pain Scenario: You are having a soreness and muscle aches. It is not bad enough to call your doctor. You have not taken any medication to help with these aches yet. You are here at Shopko to look for a medication that can help you feel better.

Cough/Cold or Allergy Scenario: For the past 3 days you've had a runny nose and sore throat, felt "stuffy," and your head is congested. You don't have a fever and it is not bad enough to call your doctor. You have not taken any medication for your symptoms yet, but you are here at Shopko to look for a medication that can help you feel better.

Table 2. Effectiveness and Implementation Outcomes

Effectiveness Outcome	Definition	Data Source
OTC Medication Misuse	One or more of the following: • Drug-drug interaction • Drug-disease interaction • Drug-age interaction • Reported use exceeds product labeling guidelines	• Older Adult Interview • Older Adult Medical/ Demographics form (disease list, medication list)
Older Adult Decision Making Process	Knowledge and strategies required to select a safe OTC medication	• Older Adult Interview
Recommendation characteristics	Type and confidence of recommendation	• Older Adult Interview • Pharmacist OTC Encounter Form
Implementation Outcome	**Definition**	**Data Source**
Acceptability	Satisfaction with aspects of innovation	• Pharmacist/Technician Tool Acceptance Survey • Pharmacist Interviews • Older Adult Satisfaction Survey
Adoption	Intention to try the innovation	• Pharmacist/Technician Observation • Pharmacist/Technician Tool Acceptance Survey • Pharmacist/Technician/Manager Interviews
Appropriateness	Perceived fit, compatibility, practicability	• Pharmacist/Technician Observation • Pharmacist/Technician Tool Acceptance Survey • Pharmacist/Technician/Manager Interviews
Feasibility	Actual fit; the extent to which an innovation can be successfully used	• Pharmacist/Technician Tool Acceptance Survey • Pharmacist/Technician/Manager Interviews • Pharmacist OTC Encounter Form
Fidelity	Innovation delivered as intended; quality of innovation delivery	• Pharmacist/Technician Observation • Pharmacist/Technician/Manager Interviews • Pharmacist OTC Encounter Form
Cost	Innovation delivery costs, overhead costs	• Shopko Organization Data • Pharmacist OTC Encounter Form

The trained researcher asked the older adult to articulate the medication they were searching for and the decisions involved in making the selection. The researcher elicited this information by asking the participant to "think aloud" and use such probes as "what are you thinking now?" and "are you considering any other options here?" These probes helped us understand the older adult's so-called "work," (goal-oriented effortful activities) as they selected an OTC medication. We also asked specific questions about the information that they used to make their OTC medication decision, such as cost, previous experience with a particular medication, and label warnings.

Following the walking interview, a short, semi-structured interview was conducted to gather information on how the older adult intended to use the medication (e.g., dosing and duration). The entire interview took 30-45 minutes. Additionally, for those older adults participating in the study post-intervention, questions specifically related to the feasibility, usefulness, and acceptance of the intervention were also asked. Interviews were recorded using a GoPro video and audio. After transcription of the interviews, observations that were recorded in the video (e.g., pointing to or picking up medications) were incorporated into the transcripts.

Pharmacist/Technician/Store Manager/Administrator Interviews: Interviews were conducted with two pharmacists, two technicians, and one store manager at each participating site as well as one administrator to elicit descriptions of each respondent's role and how the intervention was implemented in their store. Guided by the components of the SEIPS 2.0 model, we probed for facilitators and barriers related to each implementation outcome.

Pharmacist OTC Encounter Form: The purposes of the OTC Encounter Form were to 1) document the interactions that pharmacists had with consumers (study participants and nonparticipants) regarding OTC medications, 2) provide a reliability check for the data collected during the older adult participant interviews, and 3) pilot-test a quick and simple data collection tool that may be used during a future scaled-up intervention.

The encounter form was used to collect recommendation characteristic outcomes that are in addition to the OTC medication misuse outcome (e.g., referral to a physician, behavioral or medication recommendations). Furthermore, the encounter form was used to quantify the time required to interact with consumers before and after the intervention was implemented. Encounter form data were collected at both baseline and post-intervention times.

Measures

Primary Outcome Measure - OTC Medication Misuse

Misuse Analysis

Three pharmacists with clinical experience working with the geriatric population comprised a misuse analysis team. Prior to the misuse evaluation, information about the participant and OTC medication selected was de-identified and entered into Redcap (HIPAA secure database). This information included participant's self-reported medication list and health conditions, the selected OTC, and reported OTC use (which included direct portions of the interview transcript and use summaries prepared by the research team). Data were extracted from the transcripts in this manner to ensure that the misuse analysis team would be unable to identify whether the interview occurred before or after Senior Section implementation. Also included were photographs of the OTC medication (front, back, and top to capture all product labeling information) as reference for the misuse analysis team. A random number generator was applied to the participant list, which randomly assigned all participants to three different batches for evaluation. The overall process of randomization and blinding ensured that the misuse analysis team would be unable to identify whether the interview occurred pre- or post-implementation. Misuse was first evaluated independently by each reviewer, and responses were then consolidated in preparation for group discussion and discrepancies between reviewers were noted. The misuse study team, supported by study researchers, then met as a group to review independent comments, facilitate discussion about discrepancies (which were commonly the result of misuse analysis team members' interpretation of the drug facts information on the label or what patients meant when describing their use), and achieve consensus about final misuse classifications.

Four misuse outcomes were operationalized by the misuse analysis team through these group discussions:

(1) Drug-Age misuse was identified using the 2015 Beers Criteria list for older adults,[33] in which any selected OTC medication included on the list, except NSAIDs that are only used to temporarily treat acute pain, is considered misuse.

(2) Drug-Drug misuse was measured using LexiComp[34] risk ratings of medication interactions and resulted in the following domains that carried enough risk to be considered misuse: type C (monitor therapy), type D (consider therapy modification), type X (avoid combination).

(3) Drug-Disease misuse was determined by identifying potential interactions between medications and disease states designated as high risk in Beers Criteria, a condition listed in product labeling, or other (e.g., clinical knowledge of the pharmacist).

(4) Drug-Label misuse considered the following deviations from the product labeling recommendations: over daily dosage, exceeds single dose, dose timing/frequency, use duration, and indication.

For Drug-Age, Drug-Disease, and Drug-Label misuse, the final determinations were based on evaluations and agreement by the misuse analysis team and were measured as the frequency of misuse per participant.

Statistical Analysis

When the treatment is not randomly assigned (as for this study), it is expected that the treated and untreated units present very different distributions of their observable characteristics.[35] To account for this assumption, an initial propensity score was estimated based on the treatment condition using a Logit model to compute the predicated probability (π, or pi). Using the pi score, the following weights were constructed: 1/pi for the treated observations, and 1/(1-pi) for the untreated observations. It was then possible to calculate the average treatment effect by comparing the weighted means of the two groups. All estimates were conducted using the "teffects" and "treatrew" routines in Stata v.16.[36] Logistic regression initially was used to determine similarity of patient characteristics at pre-/post-implementation of the Senior Section. These variables then were compiled into a propensity-score matching model to estimate their combined effects on the Senior Section's association with various misuse types.

OTC Decision Process Mapping

Using data from the older adult interviews, a cognitive task analysis[37-39] was conducted to compare the decision-making processes of the older adults at baseline and post-intervention. Our hypothesis was that the intervention would impact the decisions of older adults and predict medication choice appropriateness. This method of analysis serves as a mediator of the effect of the intervention and allows us to identify when the intervention improves decision making (e.g., reduces the number of choices) and when it does not (e.g., information is still hard to process).

Pharmacist OTC Encounter Form: The OTC form is a 10-item tool consisting of fixed-choice response options representing eight content domains relevant to this study, including who initiated each encounter, activities

involved, topics and problems/symptoms discussed, and time spent with the patient. Each pharmacist and/or pharmacy technician involved in a patient encounter completed the OTC form for that encounter, occurring over a week prior to implementing the Senior Section, to allow pharmacy staff to become accustomed to this new activity. The same pharmacists/technicians then used the OTC form to collect information about patient encounters occurring within 2 weeks after Senior Section implementation. One OTC form was completed per patient encounter. To compare data from the pre- and post-intervention OTC forms, frequency distributions were computed for each OTC form item at both points in time.

Qualitative Data Analysis: Qualitative data from interviews were subjected to rigorous qualitative data analysis using techniques employed by the PI in previous pharmacy medication safety qualitative research.[27,40-46] We used deductive content analysis, discovering patterns, themes, and categories in our data, guided by our theory-based approach.[47]

Limitations

The primary limitation of our study is that, during the final period of data collection, it was announced that Shopko was declaring bankruptcy and began closing its pharmacies. As a result, only 15 of the 72 planned post-intervention older adult interviews were collected. This was controlled for during statistical analysis. Pharmacist and technician interviews were completed after the closure of the stores. Although OTC encounter forms were completed both pre- and post-intervention at each test pharmacy, the announcement that the stores were closing came just before or during post-intervention OTC encounter form data collection at two of the three test stores. Therefore, the pre/post analysis of the OTC encounter forms was only conducted on the store for which data collection for the post OTC encounter forms had been completed prior to the closure announcement. After speaking with the store staff and research team, we agreed that the data from the other two sites would have been too profoundly impacted by the bankruptcy announcement to be included in the analysis.

Despite the crucial insights gained from our analyses, various limitations warrant consideration, beyond the limited generalizability of this small sample of community pharmacies. First, a number of patient characteristics were self-reported (e.g., health status, 30-day medication use, and number of prescribers and pharmacies seen), so future data collection efforts should attempt to employ existing health systems databases. Second, the patient sample size was limited (n=87 cumulatively between pre- and post-implementation). However, the statistical approach was chosen specifically to best accommodate this sample size and compute valid results. Third, throughout this study, patients were not randomly selected but rather were chosen through recruitment methods. Fourth, patient interview responses were based on reactions to a hypothetical health scenario and may not represent “real-world” behaviors. Fifth, results could vary based on which scenario the participant selected (i.e., pain, cough/cold, allergy, or sleep). Additional research is necessary on a larger selection of participants to determine the influence of medication category on types of misuse. Finally, as mentioned previously, the Senior Section may not be designed sufficiently to address certain types of misuse, such as Drug/Drug misuse and Drug/Age misuse, and future research should consider the intervention features constructed specifically to reduce a broader array of misuse.

RESULTS

Principle Findings/Outcomes

Utilizing Participatory Design and Beta Testing to Develop the Senior Section[48]

To develop the Senior Section, five pharmacy staff and five older adults were recruited into two separate stakeholder groups. The stakeholder groups met for six iterative participatory design sessions to clarify the problems from their own perspectives, to brainstorm strategies, and to prototype the intervention, which became the Senior Section. Each session was developed to include a variety of active participation activities, targeted for the perspectives of each stakeholder group. Utilizing participatory design provided a framework for incorporating feedback from each session in the preparation of the subsequent session. Participatory design was an effective and necessary approach to understand the needs of end users so that the final intervention fit with the existing work system.

After the participatory design step, the Senior Section was beta tested in one pharmacy. Using Proctor’s implementation outcomes[49] as the guiding framework, we sought formative evaluation from stakeholders. To ensure compatibility and practicability, stakeholders stressed the importance of the intervention having limited impact on routine processes and close proximity to the prescription department. The intervention was perceived as feasible - it minimally affected both workflow and overall OTC consult time.

Prioritizing specific implementation outcomes during the design process allowed us to address these barriers early on and foster buy-in. This formative data collection allowed for rapid cycle improvement of the Senior Section.

The Senior Section Systems Redesign Intervention**:** The Senior Section is a physical redesign of the pharmacy's OTC aisles, grounded in human factors engineering and focused on improving communication with a knowledgeable and accessible pharmacist. The conceptual framework for the Senior Section 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. and shown in Figure 2.[50] The SEIPS model has been applied to frame the design and analysis of many patient safety studies, including research we conducted in community pharmacies.[40,51,52] The SEIPS 2.0 model is appropriate for this intervention, because it incorporates the work system barriers that were identified in our preliminary studies that can impact the "work" conducted by pharmacists and older adults. 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 highlights a key goal of the Senior Section by emphasizing 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.

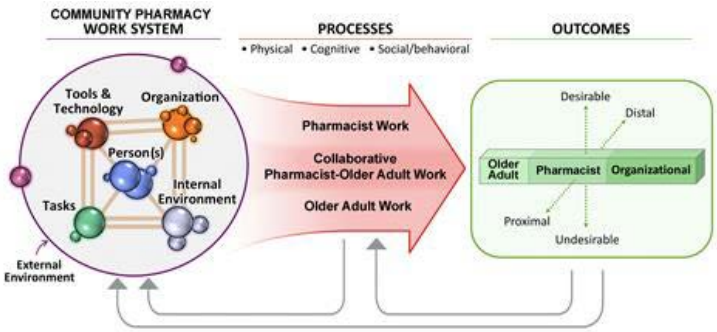

Figure 2. SEIPS 2.0 model adapted for community pharmacy work system

Five Senior Section features facilitate older adults' safe OTC medication selection: (1) dedicated, well-lit, section with a curated list of safe OTC medications for older adults, (2) proximity and sight line to the prescription department to facilitate pharmacist/patient engagement, (3) tools (e.g., countertop and lighted magnifying glass) for reading and reviewing OTC options, (4) strategically placed signage to highlight potential risks and encourage seeking of pharmacist assistance, and (5) shelving height that placed OTC medications between shoulder and knee height to assist visual or physical impairment (Figure 3).

Figure 3. The Senior Section

Effectiveness of Senior Section

Our project required 72 older adult participants pre- and post-implementation in order to be powered for a 45% reduction in OTC medication misuse. The pharmacy organization partner filed for bankruptcy during our post-implementation data collection period. As a result, we were only able to recruit 15 older adult participants in the post-implementation period.

Patient characteristics (age, gender, race, education, number of prescribers, pharmacies, and medications, health status, and total health) revealed few notable differences in patient samples between pre-

and post-implementation times. At pre-implementation, no patient had an educational level below high school, but one patient reported education up to eighth grade at post-implementation. The number of medications that patients reported taking also was narrower at post-implementation (pre-implementation min/max: 1-33 vs. post-implementation min/max: 6-18), but this did not translate into any distinction between means. In addition, over 60% of patients had a total health rating of very good/excellent prior to Senior Section implementation, but only a third of patients had the same rating at post-implementation. Despite these slight differences, no patient characteristic varied significantly between pre- and post-implementation times, and groups were considered homogeneous. Given these descriptive results, it is not surprising that the effect of patient characteristics, when added to the regression models as propensity scores, had little if any adjusting effect on most misuse outcomes.

Even given the limited sample size, there were significant reductions in OTC medication misuse. Drug/Disease misuse significantly lessened over time ($z=-2.09$, $p=0.037$). Drug/Label misuse varied according to the subtype, with reduced Daily-Dosage ($z=-2.42$, $p=0.016$) and Single-Dosage misuse ($z=-5.82$, $p=0.001$).[53]

Impact of the Senior Section on Pharmacist Work

Importantly, the intervention fit with pharmacists' workflow, did not add to pharmacist workload, and facilitated pharmacist-patient communication.[54-56] The Senior Section improved the quality of pharmacist-older adult encounters. After Senior Section implementation, pharmacy staff were more likely to initiate (and be involved in) patient encounters, address more topics or problems/symptoms, provide details about OTC products, discuss appropriateness of OTC use, and discuss medication classes highlighted in the Senior Section. Because of the proximity to the prescription department, pharmacy staff were less likely to need to leave the prescription department for extended periods and had fewer prolonged encounters. Pharmacy staff noted no barriers that would reduce Senior Section utilization.

Cognitive Task Analysis of OTC Decision Process

Using data from a sample of older adult interviews (n=9 pre- and n=3 post-implementation), we conducted a cognitive task analysis[37-39] to compare the effect of Senior Section implementation on shoppers' decision-making processes (Figure 4). Cognitive task analysis (specifically hierarchal task analysis, because it provides significant insight into a task being analyzed by describing the specific goals, subgoals, operations, and plans of that task[57]; it allows determination of whether the intervention improves decision making (e.g., reduces the number of choices) and when it does not (e.g., information is still hard to process). Our hypothesis was that the intervention would influence older adult decisions and would predict medication choice appropriateness.

Analysis showed that decision making did not differ between shoppers who use the Senior Section and those who use the normal OTC aisles to select a product. However, a closer examination of the way these two groups assess a product and consider alternatives provides unique insight about the Senior Section's impact. As expected, decisions involved a multitude of factors, all of which are indicated in steps 5.1 to 5.10 in Figure 4; some factors related to product safety (steps 5.4, 5.5, 5.7, 5.8, and 5.10), and others indicated shopper preferences (steps 5.1, 5.2, 5.3, 5.6 and 5.9) (Table 3).

After Senior Section implementation, the average number of factors that older adults used to make a decision reduced from 6.3 to 3.3; two thirds of shoppers considered the appropriateness of the OTC for their symptoms (step 5.8) (compared with 56% pre-implementation). When shopping from the Senior Section, older adults no longer considered the form of the medication (step 5.3), generic versus name brand (step 5.9), and ingredients (step 5.10), and they were less likely to consider steps 5.1, 5.2, 5.4, 5.4, 5.5, and 5.7.

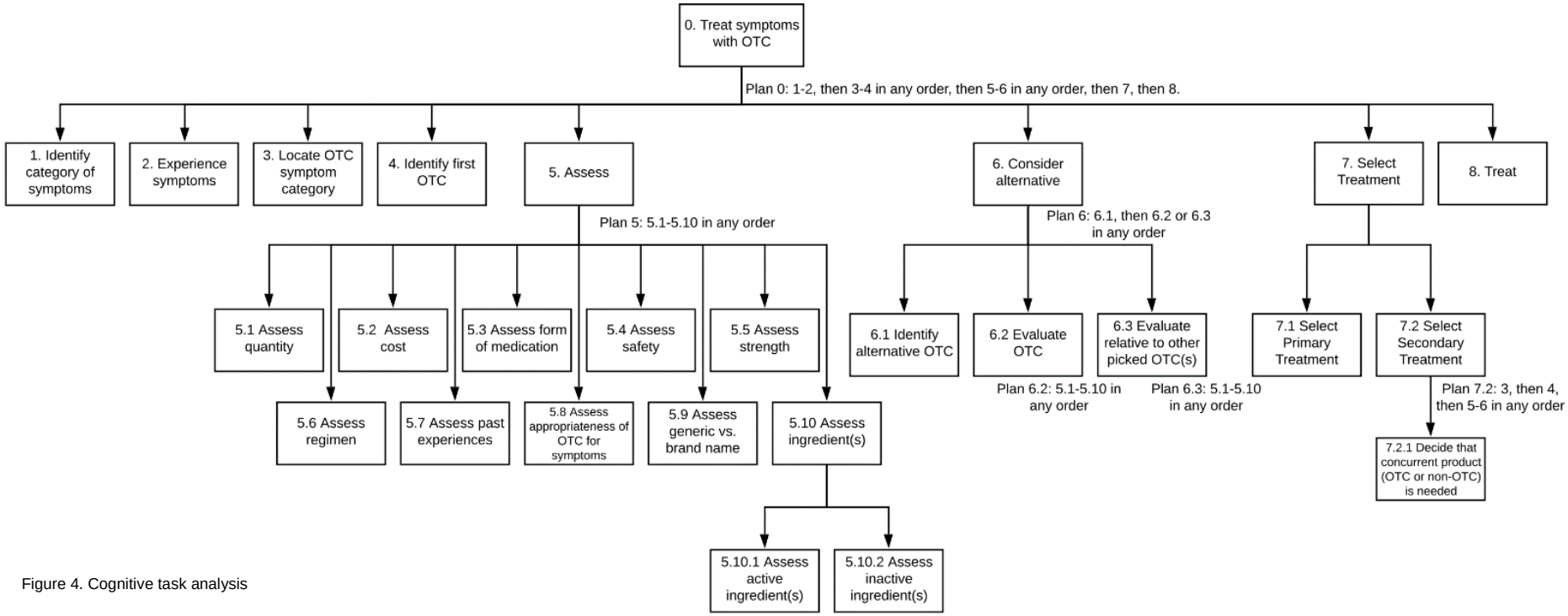

Figure 4. Cognitive task analysis

Table 3. Comparison of steps 5.1 and 5.10 prior to pre and post intervention.

Assess Step	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	5.10	5.10.1	5.10.2	Average number of factors considered in decision process
PRE	78%	78%	56%	44%	44%	67%	67%	56%	67%	56%	22%	0%	6.3
POST	33%	33%	0%	33%	33%	67%	33%	67%	0%	0%	0%	33%	3.3

Intention to Adopt Senior Section by Advocate Aurora Health pharmacists

In January 2020, our research team submitted an AHRQ proposal (PA 20-028) to expand the implementation of the Senior Section at Advocate Aurora Health Pharmacies. In order to prepare for this submission and to understand how pharmacists outside of Shopko may perceive the Senior Section, we conducted a short survey with AAH pharmacists.

In the survey of AAH community pharmacists, 84% indicated they would consider implementing the Senior Section in their pharmacy. Eighty-two percent of pharmacists indicated that the Senior Section would help older adults select OTC medication safely, and 73% indicated the Senior Section would fit into current pharmacy workflow.

Discussion

Results suggest that a simple but well-conceived redesign of the OTC aisles in a small number of community pharmacies can reduce some categories of older adult OTC medication misuse. Comparing data from homogenous samples over time, these analyses suggest that the Senior Section influenced the prevalence of misuse, with the degree of change depending on the specific type of misuse and patient characteristic effects. The two misuse categories that seemed most responsive to the system redesign were Drug/Disease misuse and Drug/Label misuse. Drug/Disease misuse, Drug/Label misuse (Exceeds Daily-Dosage), and Drug/Label misuse (Exceeds Timing/Frequency) became significant only after the patient demographic covariate was added to the models; the covariates comprising the patient demographic propensity score had an adjusting impact, making the effect of the intervention more sensitive. However, Drug/Label misuse (Exceeds Timing/Frequency) challenged expectations by being more frequent after Senior Section implementation. Despite this single significant finding, almost 70% of all misuse comparisons (from all models, excluding or including the propensity score) trended in the direction of anticipated effects, with lower frequencies occurring post-implementation.

Although it was originally hypothesized that the Senior Section would diminish all misuse types, in retrospect, there are clear reasons that may undermine this expectation. Drug/Age misuse, based on the Beers Criteria list, likely did not change statistically because of two factors. First, ibuprofen remained in the Senior Section inventory because of its benefits for treating a variety of symptoms, even though the Beers Criteria contains a recommendation to avoid its chronic use for pain management. Second, it was often difficult to ascertain Drug/Age misuse occurrence, because a patient's acute or chronic use determination was required. Alternatively, for Drug/Drug misuse, the Senior Section's cautionary signage did not include warnings about specific drugs or potential interactions. When implementing the Senior Section in a broader network of pharmacies, which is being planned, modifications will be necessary to determine the best approach to address a greater variety of misuse types.

Findings from both the OTC encounter forms and the pharmacy staff interviews supported the benefits of using the Senior Section. Although patients initiated a majority of OTC encounters, and did so throughout the project, pharmacy staff initiation of these encounters increased after the Senior Section. Importantly, engagement between pharmacy staff and patients was accomplished without an apparent burden on pharmacy staff workload. Overall, there were fewer prolonged OTC encounters and a greater number of encounters not requiring the pharmacy staff to leave the pharmacy department. Pharmacy staff feedback confirmed that activities prompted by the Senior Section fit into existing workflow. The proportion of both topics discussed and pharmacy staff tasks during encounters increased in the post-intervention period, and medication recommendations (e.g., providing product details and self-care appropriateness) also became more frequent, suggesting a growing occurrence of clinically relevant discussions. Accompanying patients to a product's location also occurred to an even greater extent after Senior Section implementation, as questions about product location diminished slightly (likely due to medication proximity and visibility).

Conclusion

This study provides initial insights into the extent that a pharmacy system redesign reduced potential patient uses of OTC medications that were indicative of misuse (e.g., selecting an OTC that was contraindicated with existing health conditions or that differed from product labeling). That is, increased opportunities for pharmacy staff engagement with patients around medication safety issues, along with more visible cautionary signage and an OTC inventory comprising lower-risk medications, decreased the occurrences of some types of misuse. More frequent encounters, while also being shorter in duration, covering a greater

number of topics per encounter, and focusing on issues related directly to the Senior Section medications, all point to increased efficiency of OTC encounters facilitated through the Senior Section implementation. Again, enhanced efficiency in pharmacy staff/patient encounters was an anticipated objective when formulating the intervention design. Additional research and adopting the Senior Section in more pharmacies of various sizes and layouts, in collaboration with system engineers, architects, and workflow enhancement technicians, will establish a needed evidence base supporting broader implementation and an understanding of suitable size-to-space ratios.

Significance

Because of the proven effectiveness of our intervention, as well as the minimal impact to pharmacist workload, the Senior Section can be scaled up to the vast majority of community pharmacies in the United States. The potential impact of such a widespread implementation could be profound.

Evidence suggests that over 1 million at-risk older adults may experience an adverse drug event (ADE) associated with an OTC medications. Our work shows a 27% decrease in overall OTC medication misuse after implementation of the Senior Section, potentially safeguarding 270,000 older adults from an adverse drug event if our Senior Section were implemented nationwide.

Older adult use of nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, and aspirin results in over 100,000 preventable ADEs each year. We found a 55% decrease in NSAID misuse after Senior Section implementation (i.e., the Senior Section may protect 55,000 older adults from an ADE associated with NSAID use).

The 2019 AGS Beers Criteria strongly recommends avoiding OTC antihistamine products (diphenhydramine, phenylephrine, doxylamine) due to their highly anticholinergic effects that present as cognitive problems, urinary retention, blurred vision, and dizziness. It also strongly recommends avoiding chronic use of NSAIDS (ibuprofen, naproxen, aspirin) due to the increased risk of gastrointestinal bleeding, high blood pressure, and kidney injury. One third (approximately 16 million) of US older adults have these medications in their home. Our Senior Section reduced the purchase of these products by 37%, which could shield close to 6 million older adults from these significant harms.

Implications

This intervention, if more broadly implemented in other pharmacy corporations, would create new permanent structures and processes that could improve the quality and availability of information for older adults as they approach the OTC aisles. Such information could lead to greater risk awareness and help older adults more easily determine their own risk levels and select safer OTC medications with confidence. Additional research must evaluate the generalizability of the intervention's results and the sustainability of post-implementation improvements in different pharmacy environments. Physically redesigning OTC aisles may also be tested in different vulnerable populations, such as pediatric patients. Taken together, these preliminary outcomes support the Senior Section as a valuable tool for pharmacy staff to improve patients' safe OTC medication use through heightened awareness and education efforts.

In summary, these results suggest that a well-conceived, pharmacy-based OTC aisle redesign, which has been informed by a human factors engineering framework and structured stakeholder engagement and supported by a strong partnership with organization leadership and frontline pharmacists, can reduce older adult OTC medication misuse. Furthermore, the Senior Section has the potential to increase quality and effectiveness of engagements between pharmacy staff and patients without significantly impeding practice workflow. Our study suggests a signal of effectiveness, but only in three homogenous pharmacies in predominately White, educated patient populations. Scaling intervention implementation across heterogeneous community pharmacies and demonstrating effectiveness with diverse patient populations is the clear next step to advance the development of sustainable medication safety strategies.

PUBLICATIONS AND PRODUCTS

Products

https://pharmacy.wisc.edu/chui-research-group/chui-research/otc-use/senior-section/

A website with an overview of the project, the research team, tools/methods, results, and publications.

Publications in Preparation

- "Understanding factors influencing older adults' decision-making about their use of over-the-counter medications"
    - Target journal: Pharmacy – Special issue on "Medication Experiences"
- "Characterizing and Operationalizing Misuse of Over-the-Counter Medications among Older Adults"
    - Target Journal: Journal of Gerontology in the social science domain
- "Using Hierarchical Task Analysis to Describe Older Adults' Over-the-Counter Medication Decision-Making Processes while Shopping in the Senior Section™ versus the Regular Community Pharmacy Aisle"
    - Target Journal: Journal of Cognitive Engineering and Decision Making
- "Using Persona Analysis to Understand Older Adults' Behavior when Shopping for Over-the-Counter Medications in a Community Pharmacy"
    - Target Journal: Research in Social and Administrative Pharmacy

Publications Under Review/Submitted

1. Gilson A, Stone J, Morris A, Brown R, Xiong K, Jacobson N, Holden R, Albert S, Phelan C, Walbrandt Pigarelli D, Breslow R, Welch L, Chui MA. Impact of a pilot community pharmacy system redesign on reducing over-the-counter medication misuse in older adults. Submitted to Journal of Patient Safety. Preprint available at medRxiv https://doi.org/10.1101/2019.12.19.19014886.
2. Gilson AM, Xiong KZ, Jacobson N, Stone JA, Chui, MA. Pharmacy-based intervention to improve safe over-the-counter (OTC) medication use in older adults: qualitative assessment of a pilot to determine effectiveness and implementation. Under minor revisions at *Res Social Adm Pharm.*
3. Xiong KZ, Shah S, Jacobson N, Stone JA, Chui MA. Using a Scenario-Based Hybrid Approach to Understand Participant Health Behavior. Submitted to Sage Research Hub.

Published (articles available through links in citations)

4. Gilson A, Xiong KA, Stone JA, Jacobson N, Phelan C, Reddy A, Chui MA. Improving Patient-Pharmacist Encounters with Over-the-Counter Medications: A Mixed-Methods Pilot Study. *Innovations in Pharmacy.* 2020; 11(11). https://doi.org/10.24926/iip.v11i1.2295
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Peer-Reviewed Research Podium/Oral Presentations and Abstracts

10. Chui MA, Bix L, Holden RJ, Albert S. “Optimizing OTC Medication Use: Packaging, Human Factors, Pharmacy Redesign.” The Gerontological Society of America, November 2018
11. Reddy A, Stone JA, Chui MA. “How do health literacy and risk perception impact older adult misuse of over-the-counter medications?” Midwest Social & Administrative Pharmacy Conference, August 2018

Peer-Reviewed Research Posters and Abstracts

12. Shah SR, Morris AO, Stone JA, Chui, MA. “Older Adult Shopping Persona Types and its Impact on Over-the-Counter Medication Misuse.” Accepted to International Symposium on Human Factors and Ergonomics in Health Care, March 2020 (conference canceled).
13. Chui MA, Gilson A, Stone JA, Morris AO, Brown R, Holden RJ, Jacobson N, Albert S, Xiong KZ, Phelan C, Walbrant-Pigarelli D, Breslow, R. “Impact of a community pharmacy system redesign on reducing over-the-counter medication misuse in older adults.” Accepted to American Pharmacist Association Annual Meeting and Exposition, March 2020 (conference canceled).
14. Reddy A, Lester CA, Stone JA, Phelan C, Chui MA. “Using invisible design to engage stakeholders in health system intervention implementation.” Academy Health Dissemination & Implementation Conference, December 2019
15. Reddy AC, Chui MA. “The Relationship Between Health Literacy, Risk perception, and Over-the-Counter Medication Misuse.” Presented at Wisconsin Health Literacy Summit, April 2019.
16. Reddy AC, Chui MA. “Impact of Health Literacy and Risk Perception on Over-the-Counter Medication Misuse.” Presented at Translational Science, March 2019
17. Flynn B, Xiong KZ, Stone JA, Chui MA. “A Comparison of Patient Encounters Prior to and After an OTC Safety Intervention in a Community Pharmacy Setting.” American Pharmacists Association Annual Meeting, March 2019
18. Reddy A, Stone JA, Chui MA. “Utility of Invisible Design in Developing a Pharmacy System Intervention.” Human Factors & Ergonomics Health Care Society Symposium, March 2019
19. Xiong KZ, Reddy A, Stone JA, Lester CA, Chui MA. “Using Implementation Outcomes to Guide Stakeholder Engagement in an Over-the-Counter Medication Safety Intervention.” Academy Health Annual Conference on the Science of Dissemination and Implementation, December 2018
20. Reddy A, Stone JA, Lester CA, Holden RJ, Chui MA. “Developing a System-level Medication Safety Intervention for Older Adults: The Utility of Participatory Design.” National Academy of Engineering, May 2018
21. Reddy A, Stone JA, Lester CA, Holden RJ, Chui MA. “Using Participatory Design to Develop a Pharmacy-Based Intervention to Improve Over-the-Counter Medication Safety for Older Adults.” American Pharmacists Association Annual Meeting, March 2018
22. Lester CA, Reddy A, Jamie Stone, Holden RJ, Chui MA. “Participatory Design: An effective approach to designing a patient-centered intervention to Improve Over-the-Counter medication safety for older adults.” Academy Health Annual Research Meeting, June 2017

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