Older Adult Misuse of Over-the-Counter Medications: Effectiveness of a Novel Pharmacy-Based Intervention to Improve Patient Safety

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Objectives: Older adults' (ages ≥65) inappropriate over-the-counter medications (OTC) use is prevalent, comprising Drug-Age, Drug-Drug, Drug-Disease, and Drug-Label types. Given that pharmacies sell many OTCs, structurally redesigning pharmacy aisles for improving patient safety (Senior Safe) was conceived to mitigate older adult OTC misuse, using Stop Signs and Behind-the-Counter Signs for high-risk OTCs. This study determined whether Senior Safe reduced high-risk OTCs misuse, while secondarily evaluating misuse changes for all OTCs.

Methods: A randomized controlled trial design matched and randomly allocated 20 health system community pharmacies to control or intervention groups. All 288 study participants completed an OTC choice task in which they chose a hypothetical symptom scenario (pain, sleep, cough/cold/allergy), selected an OTC, and described how they would use it at symptom onset and if symptoms persisted or worsened. Reported OTC use was evaluated for each misuse type. Intervention and control sites were compared for each misuse type using multivariate modeling.

Results: For high-risk OTCs, Drug-Age and Drug-Drug misuse were more likely in control sites (OR = 2.752, *P* = 0.004; OR = 6.199, *P* = 0.003, respectively), whereas Drug-Disease and Drug-Label misuse had too few occurrences in intervention sites for statistical comparisons. For all OTCs, only Drug-Age misuse was more likely for control sites (OR = 5.120, *P* = 0.001). Adults aged 85+ years had the greatest likelihood of all misuse types.

Conclusions: Results demonstrated that older adults frequently reported multiple misuse types, highlighting safety concerns. Senior Safe reduced

high-risk OTC misuse, especially for older adults younger than 85 years. Cumulatively, these findings provide insights into practice recommendations supported through regulatory guidance.

P ast research demonstrates that misusing over-the-counter (OTC) medications is more widespread than expected among adults 65 years or older (older adults).[1] Such misuse can be classified into 4 categories[2]: (1) Drug-Age misuse—using medications having increased risks for older adults, (2) Drug-Drug misuse—interacting with concurrent OTC medications, (3) Drug-Disease misuse—exacerbating health conditions, and (4) Drug-Label misuse—deviating from recommended product usage instructions. Although adverse events associated with a single type of misuse can have deleterious health consequences,[3] harm potential is worsened when a person engages in multiple misuse behaviors. Indeed, OTC-related harms from misuse contribute prominently to older adult emergency hospitalizations.[4] Misuse potential also increases when people use an OTC to begin treating initial symptoms but those symptoms persist, often leading them to take the OTC in larger doses, for longer durations, or in combination with other products.[5,6] It is critical, therefore, to consider OTC misuse as comprising different, but often overlapping, behaviors that are often unintentional. Evaluating different OTC misuse types can provide important insights into interventions that may differentially affect their occurrences.

Given this situation, minimizing older adult OTC medication misuse rates is important, especially because types of misuse are often difficult to identify and address within a primary care setting. This difficulty stems from patients typically not disclosing their OTC medication use to their health care practitioners,[7] and from patients' OTC medications not being included in electronic health records.[8] Exacerbating this clinical issue, patients are unfamiliar with the safety issues of the OTC medications they take.[9] It seems warranted to consider integrating OTC misuse mitigation interventions into health care settings. Pharmacies represent an ideal environment, because they are a common setting for selecting and selling OTC products while benefiting from pharmacists' expertise with medication safety issues.[10]

To develop a pharmacy-based intervention to reduce older adults' OTC misuse, participatory design[11] and human factors engineering[12] frameworks were used to redesign a structural layout of pharmacy aisles.[13,14] Pharmacy aisles were redesigned for older

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adults due to their more prevalent misuse risks,[15] with the primary purpose of reducing Drug-Age misuse by increasing older adults' awareness of OTC medications that are best avoided.[16] The intervention targeted OTC medications related to 3 symptom categories—pain, sleep, and cough/cold/allergy—identified in the Beer's Criteria[16] as having higher morbidity and mortality prevalences.[17–19] Another intervention function was to facilitate pharmacy staff involvement with older adults during decisions to select and use an OTC medication to treat symptoms. Central to the pharmacy aisles redesign was its curated selection of lower-risk OTC medications for the relevant symptom categories. Although Drug-Age misuse was the principal focus, decreasing Drug-Drug, Drug-Disease, and Drug-Label misuses were also objectives.

A small-sample study of community pharmacies within a large mass merchandiser chain organization yielded encouraging effectiveness signals relating to OTC misuse in the 3 medication classes.[2] Introducing the pharmacy redesign significantly reduced certain Drug-Label misuse types but no other misuse, including Drug-Age misuse. However, intervention design features could have undermined its success at diminishing misuse broadly, such as high-risk medications also being available in other pharmacy areas.[2] Clearly, implementing the aisles redesign into different pharmacy environments required modifying design features to better achieve mitigation effects for Drug-Age misuse and other misuse types. This purpose led to a revision of the structural redesign into a related, but distinct, pharmacy-based intervention.

SENIOR SAFE

Researchers conceptualized a refined structural redesign of pharmacy OTC aisles (called Senior Safe) to reduce older adults' OTC misuse by increasing risk awareness associated with certain OTCs while also promoting product-related interactions with pharmacy staff.[13,14] The revised intervention's design avoided product duplication by representing all pain, sleep, and cough/cold/allergy medications were represented only in the Senior Safe area.[14] Pain, sleep, and cough/cold/allergy OTC products determined to be generally safe for older adult use were designated with a Green Senior Safe Banner and relocated on the shelves at about shoulder height to enhance their accessibility (see Fig. 1).

Another central feature of Senior Safe involved signage to delineate OTC products containing ingredients considered high risk for older adult use, which were relocated to the bottom shelves or out of easy reach (Fig. 1). Stop Signs instruct older adults to consider safer products by pointing to alternative medications indicated with the Green Senior Safe Banner, thus serving as a "soft barrier" to selection.[20] In addition, Behind-the-Counter (BTC) signs, located in place of the actual products, distinguished particularly high-risk OTCs for older adults when used chronically. Stop Sign/BTC products are brompheniramine, chlorpheniramine, diphenhydramine, doxylamine, and triprolidine. BTC signage similarly encourages older adults to talk to pharmacy staff to inform OTC use decisions, serving as a "forcing function" to stop selection of a particular product.[21] These product categorizations were meant to encourage safe OTC selection and promote communications with pharmacy professionals. In fact, a foundational intervention component was pharmacy staff training for effectively engaging with older adult patients around medication safety issues.

This study's objective was to determine Senior Safe's effectiveness at influencing the occurrence of all misuse types related to OTC products designated with Stop Signs or BTC signage for high-risk OTCs, as determined in uncontrolled real-world pharmacy environments. A secondary research question addressed Senior Safe effects on each misuse type for all OTC products and was guided by the same hypothesis.

METHODS

A posttest-only randomized controlled trial (RCT) design was used to evaluate differences in misuse for older adult participants from control and treatment sites who were recruited from a matched and randomized sample of community pharmacies and remote dispensing sites (i.e., locations that dispense medications

FIGURE 1. Adopted Senior Safe intervention in a pharmacy site. The figure provides an example of Senior Safe adoption into a pharmacy study site, as well as highlighted instances of the intervention's analysis-relevant features—the Green Senior Safe Banner, the Red Stop Signs, and the Behind-the-Counter (BTC) Signage.

without a pharmacist on site but available through a tele-health system) within a single pharmacy organization.

Recruitment

Study Sites

Ten community pharmacies and 10 remote dispensing sites were selected for participation from a large Midwestern health system. Sites were matched to the extent possible according to physical size (e.g., OTC linear footage), urban/rural location, Area Deprivation Index,[22] and percent of African Americans in the community,[23] and randomly assigned to either treatment (implementing Senior Safe) or control groups.

Older Adult Participants

Older adults were recruited in person or from distributed informational flyers from the participating study sites. A table was set up outside of each participating study site, offering an opportunity for researchers to talk to all patients visiting that site. Solicitations for study participation occurred when an older adult either approached the table directly or responded to verbal salutations when passing, which allowed the researcher to engage with potential participants about their interest in the study. In addition to the recruited participants, 74 additional patients sat down with the researchers to inquire about the study but ultimately decided to not participate due to such issues as not meeting age requirements, time restrictions, or a general lack of interest. No information was collected for nonparticipants. Participation eligibility criteria involved older adults who would consider treating health symptoms with an OTC product, and who passed a brief cognition screening assessment derived from the Mini-Mental State Examination.[24] Recruitment occurred June–October, 2022.

Data Collection

Once recruited and given informed consent, all study participants chose one hypothetical symptom scenario (pain, sleep, or cough/cold/allergy) with which they have the most experience. Instructions for each symptom scenario are in Table 1. Participants then selected at least one OTC that they would use to treat their chosen symptom. Participants were provided a faux credit card to "purchase" their selected product in the pharmacy, during which time they could interact with pharmacy staff, if desired, for as long as necessary. Pharmacy staff were instructed to interact with study participants as they would with any customer.

Selecting the OTC was followed by a 15-minute interview with a research team member, when the participants described how they would use the medication, such as dose, duration, and frequency of medication use. OTC use was described for 2 scenarios:

(1) at symptom onset (called the "typical scenario"), when symptom severity did not warrant seeing a health care practitioner, and (2) if symptoms persisted or worsened after initial treatment (i.e., "extreme scenario"). The interview was designed to capture when participants indicated that they would persist with using one or more medications (including OTC products not initially selected), while describing their use, including how multiple products would be used in combination. Alternatively, for the extreme scenario, no further information was collected if participants reported that they would use a nonpharmacological treatment option or reach out to a health care practitioner. Participant interviews were audio recorded, and the "purchased" OTC products were photographed.

Following the in-person interview, a 20-minute telephone interview typically was scheduled for within a week. During this time, participants reported their demographic information, health literacy (i.e., Brief Health Literacy Survey), a single overall health status question developed for this study, their health condition (using questions based on the Older Americans Resources Survey checklist),[25] and a list of OTC (including herbal and alternative products) and prescription medications used during the last 30 days. The name, dosage, and frequency were documented for each medication. Phone interviews were audio recorded. Each older adult received $40 after completing the phone interview. Both in-person and phone interviews were conducted June–November, 2022. The university's Institutional Review Board approved this research project.

Data Analysis

Research team members entered into REDCap[26] all collected participant data, including their OTC selections, interview responses, and OTC and prescription medications. Researchers excluded, as out of project scope, any mentions of using a prescription medication to treat a symptom scenario. Also, if a participant was unable to provide a medication's exact name, that medication was excluded due to insufficient data. All qualifying OTC medications were then evaluated to determine their status related to the 4 misuse types (see Table 2). Misuse frequencies comprised the study's unit of analysis.

Sample Size/Power Calculation

Sample size calculations were based on prior estimates of OTC medication misuse, determined from the authors' prior findings that safe OTC medication usage by 5%–26% of a study population used medications safely and that, following the implementation of a prior intervention, safe OTC medication usage rose to 53%.[2] These findings led to an estimate that, conservatively, the proportion of older adults who safely use OTC medications will increase from 26% to 53% as a result of Senior Safe. Using the

TABLE 1. Instructions for the Hypothetical Scenarios for Each Study Symptom

Scenario 1: Sleep	Over the last couple of days, you have been having some difficulty falling asleep or staying asleep. you have not taken any medication to help with this sleep problem yet and it's not bad enough to call your doctor. so, you're here at the pharmacy to look for a medication that can help you sleep better.
Scenario 2: Pain	Over the last couple of days, you have been having soreness and muscle aches from an activity like snow shoveling, gardening, or hiking. You have not taken any medication to help with these aches yet. And it's not bad enough to call your doctor. So, you're here at the pharmacy to look for a medication that can help you feel better.
Scenario 3: Cough/Cold/Allergy	Over the last couple of days, you have been having symptoms related to a cold or allergies, like a runny nose, stuffy nose, cough, or congestion. You have not taken any medication for your symptoms yet. And it's not bad enough to call your doctor. So, you're here at the pharmacy to look for a medication that can help you feel better.

TABLE 2. Assessment Criteria for the 4 Misuse Categories

Misuse Categories	Assessment Criteria	Contextual Considerations

Drug-Age misuse	Selected medication was contained on the 2019* Beers Criteria list,[16] most notably:
	1. NSAIDs[†]
	  • Aspirin (>325 mg/d)
	  • Ibuprofen, magnesium salicylate tetrahydrate, and naproxen (self-reported use >90 d)
	2. Anticholinergics (i.e., brompheniramine, chlorpheniramine, diphenhydramine, doxylamine, and triprolidine)
		Magnesium salicylate tetrahydrate was included because it is an NSAID, although it is not from the Beers Criteria

Drug-Drug misuse[‡]	LexiComp risk ratings identified medication interactions[27] between the selected medication(s) and self-reported, comprising 3 domains with a risk for urgent clinical responsiveness: 1. Type C (monitor therapy) with "Moderate" or "Major" severity rating, indicating a more clinically actionable situation 2. Type D (consider therapy modification) 3. Type X (avoid combination)	Medications were evaluated for potential interactions using the following steps: • Brand equivalents were used in place of generic medications because LexiComp does not include entries for generic products with multiple ingredients • If a brand equivalent was unavailable, the medication's individual ingredients were the focus • If no potential matches were found in Lexicomp, a medication was excluded from classification • Cases with multiple Drug-Drug interactions were evaluated separately
Drug-Disease misuse[§]	Contraindications between medications and disease states were identified from: 1. Diseases or syndromes designated as high-risk in the 2019* Beers Criteria[16] 2. Conditions contained in a product's labeling 3. According to the clinical judgment of misuse classification team members	• Misuse was not automatically assumed if the participant was taking any medications or had any health conditions • Cases with multiple Drug-Disease interactions were evaluated separately
Drug-Label misuse[§]	Patients reported using an OTC medication differently from its product labeling in these ways: 1. Inappropriate indication (used to treat symptoms that the product is not intended to treat) 2. Use duration (taken longer than the maximum number of days) 3. Dose timing/frequency (subsequent doses taken earlier than the recommended time between doses) 4. Exceeding single dose (exceeds the maximum recommended single-dose amount) 5. Over daily dosage (exceeds the use amount over 24 h)	• For participants reporting a range of amounts for dose or frequency, the higher dose or lower frequency was chosen for review • Each participant was evaluated for the presence of the 5 Drug-Label misuse categories, and it was possible for participants to fulfill multiple misuse categories

* The Beers Criteria were updated[28] during this project, but changes did not affect misuse classifications.

[†] NSAIDs were assessed for chronic use by 3 PharmD students, supervised by a pharmacist researcher, using the patient-reported duration of use from the in-person interview.

[†] Three PharmD students, supervised by a pharmacist researcher, verified all medication risk ratings of all medication interactions.

[‡] A misuse classification team, consisting of 3 pharmacy faculty members, each with residency training involving geriatric health care, reviewed deidentified participant information obtained during data collection, photos of the OTC products, and drug label facts information. The review process involved (1) independent evaluations and (2) reviewing others' evaluations and having the opportunity to change their answers if warranted. Final misuse classifications were determined either through complete concordance or majority agreement.

score test for the intervention indicator variable from a 2-level (subjects nested within pharmacies) logistic regression model, a sample size of 14 older adults from each study site will provide 80% power to detect the hypothesized difference using a 2-sided 5% level test.

Statistical Analysis

Frequency distributions were used to assess treatment/control differences among older adult participant characteristics to determine a need for propensity score matching. To estimate binary treatment effects, the cumulative frequency of all misuse types, including the 5 different Drug-Label misuse categories, were compared between treatment and control pharmacies. IBM SPSS Statistics v.28.0.1.0[29] was used to calculate frequency distributions and statistical comparisons using Generalized Linear Mixed Model (GLMM) bivariate logistic regression analysis. For the analysis of each misuse type, parsimonious models were created containing both fixed and random effects. Fixed effects related to the experimental group (treatment or control sites), site type (traditional pharmacies or remote dispensing sites), the symptom scenario (pain, sleep, or cough/cold/allergy), OTC use scenario (typical use or extreme use), and the older adult age classification (65–74, 75–84, and 85 years or older). Random effects related to the specific site (individual participating sites) and the specific participant (each participating individual, since they could involve multiple OTC medications). The same modeling approach was used to examine misuse of both high-risk OTCs and all OTCs.

RESULTS

A total of 288 participants were recruited for this study, conforming to power and sample size calculations. Frequencies and differences in patient demographic and health factors revealed no notable differences in older adult participant samples based on treatment/control group assignment (Table 3). As a result, a propensity score matching approach was not required to control for group variability.

Primary Research Question: Senior Safe Effect on High-Risk OTC Products

Frequency Results

Total frequency of occurrence for the different misuse types involving high-risk OTC medications is contained in Table 4. Table 5 provides the misuse frequencies for the fixed-effects variables that occurred in treatment sites compared to control sites.

Effectiveness Results

Calculated GLMM parameters for Drug-Age misuse are shown in Table 6. Drug-Age misuse was significantly higher for control participants than those in treatment sites ($P = 0.004$). In addition, Drug-Age misuse was less likely to involve OTC pain medications when compared to OTC cough/cold/allergy medications ($P = 0.002$). Finally, Drug-Age misuse reduced as older adults' ages decreased ($P = 0.041$; $P = 0.009$), being more likely in the oldest age category. Similarly, Drug-Drug misuse was more likely for participants in control sites (OR = 6.199, $P = 0.003$), and less likely for the lowest age categories (OR = 0.096, $P = 0.017$; OR = 0.112, $P = 0.034$) and for pain products in relation to cough/cold/allergy products (OR = 0.039, $P < 0.001$).

The very low occurrences of Drug-Disease and the individual Drug-Label misuses in treatment sites did not allow for statistical evaluations that would yield interpretable parameters. Overall, though, there were consistently lower frequencies in treatment sites compared to control sites without Senior Safe.

Secondary Research Question: Senior Safe Effect on All OTC Products

Frequency Results

Again, in Table 4, the overall frequencies varied considerably across the misuse types involving all OTC products, ranging from a low of 2.4% for Drug-Label misuse, use for inappropriate indications, to a high of 58.0% for Drug-Drug misuse.

Effectiveness Results

Table 7 reveals the significant difference in the occurrence rate for Drug-Age misuse involving all OTCs in sites implementing Senior Safe compared to control sites ($P = 0.001$). Drug-Age misuse also was less likely for OTC pain medications in relation to cough/cold/allergy medications ($P = 0.015$) and less likely for adults in the 2 younger age categories ($P = 0.002$; $P < 0.001$).

GLMM bivariate logistic regression analysis models for other misuse types were not as robust and did not yield many notable findings. For Drug-Drug and Drug-Disease misuse, only the younger age category was significantly lower than the oldest age category ($P = 0.05$; $P = 0.025$, respectively). However, Drug-Drug misuse—the most frequent of all misuse types—was more prevalent for participants in control sites.

No modeling of Drug-Label misuse evidenced significant frequency differences when participants in treatment sites were compared to those in control sites. However, the low prevalence of Inappropriate Indication misuse did not warrant GLMM modeling. Three of the remaining Drug-Label misuse types yielded a single significant effect each. Drug-Label misuse related to Over Daily Dosage ($P = 0.001$) and Exceeds Recommended Single Dose ($P = 0.041$) was more likely for the extreme OTC use scenario rather than the typical scenario. Finally, OTC sleep products were more involved in Inappropriate Duration of Use misuse than cough/cold/allergy products ($P = 0.040$).

DISCUSSION

Senior Safe, a simple but well-conceived pharmacy OTC aisles redesign, was created with a conviction that the intervention could influence older adult medication misuse, with the degree of treatment and control participant differences depending on the misuse type. These RCT results support this belief—Senior Safe had a notable effect on drug-related misuse for homogenous samples. Compared to participants from matched facilities with no intervention, those in sites implementing Senior Safe evidenced statistically less likelihood of Drug-Age and Drug-Drug misuse for high-risk OTC products, as well as for Drug-Age misuse for all OTC products. These findings are particularly important since the intervention was conceptualized specifically to reduce selection and use of medications determined to be a higher risk for older adults (i.e., NSAIDs used chronically and anticholinergics). A recent example of evidence-based pharmacy decisions is CVS Health's announcement to voluntarily stop selling certain phenylephrine-containing oral OTC decongestants,[30] reacting to an FDA advisory panel conclusion about phenylephrine outcomes.[31] Evidence-informed pharmacy-based activities are warranted to better assure safe and effective OTC product use, including for older adults prone to OTC product-related adverse events.

Importantly, when examining only high-risk OTC products, experimental group effects could not be statistically examined because Drug-Disease and all types of Drug-Label misuse had treatment group sizes that were too small to yield valid results. In fact, no Drug-Disease misuse was identified for participants in treatment group sites or in 3 of 5 Drug-Label subtypes, and occurred only once in the other 2 Drug-Label subtypes. When comparing

TABLE 3. Difference in Participant Demographic and Health Characteristics Between Control and Treatment Sites

	Control Sites (n = 144)	Treatment Sites (n = 144)
Age	72.82 ± 6.142 (min/max: 65–91)	73.45 ± 6.811 (min/max: 65–91)
Gender		
Female	84 (58.3%)	81 (56.3%)
Male	57 (39.6%)	56 (38.9%)
Missing*	3 (2.1%)	7 (4.9%)
Race		
Non-White	5 (3.5%)	9 (6.3%)
White	134 (93.1%)	126 (87.5%)
Missing	5 (3.5%)	9 (6.3%)
Hispanic ethnicity		
Non-Hispanic	140 (97.2%)	135 (93.8%)
Hispanic	0 (0%)	2 (1.4%)
Missing	4 (2.8%)	7 (4.9%)
Where purchase OTC medications		
Non-Aurora involved	115 (79.9%)	112 (77.8%)
Aurora-involved	26 (18.1%)	25 (17.4%)
Where purchase prescription medications		
Non-Aurora involved	85 (59.0%)	65 (45.1%)
Aurora-involved	56 (38.9%)	72 (50.0%)
Confidence in filling out medical forms yourself		
Not at all	2 (1.4%)	0 (0%)
A little bit	2 (1.4%)	3 (2.1%)
Somewhat	7 (4.9%)	10 (6.9%)
Quite a bit	30 (20.8%)	43 (29.9%)
Extremely	100 (69.4%)	81 (56.3%)
How often does someone help you read hospital materials		
Always	4 (2.8%)	5 (3.5%)
Often	3 (2.1%)	6 (4.2%)
Sometimes	14 (9.7%)	17 (11.8%)
Occasionally	24 (16.7%)	22 (15.3%)
Never	96 (66.7%)	87 (60.4%)
How often do you have problems learning about your medical condition because of difficulty understanding written information		
Always	2 (1.4%)	0 (0%)
Often	5 (3.5%)	4 (2.8%)
Sometimes	11 (7.6%)	21 (14.6%)
Occasionally	33 (22.9%)	25 (17.4%)
Never	90 (62.5%)	87 (60.4%)
How would you rate your overall health		
Poor	4 (2.8%)	5 (3.5%)
Fair	32 (22.2%)	15 (10.4%)
Good	44 (30.6%)	52 (36.1%)
Very good	45 (31.3%)	47 (32.6%)
Excellent	16 (11.1%)	18 (12.5%)

TABLE 3. *(Continued)*

Asthma or wheezing		
No	109 (75.7%)	111 (77.1%)
Yes	32 (22.2%)	26 (18.1%)
Allergies or sinus problems		
No	58 (40.3%)	73 (50.7%)
Yes	83 (57.6%)	64 (44.4%)
Bronchitis/emphysema/COPD		
No	113 (78.5%)	117 (81.3%)
Yes	28 (19.4%)	20 (13.9%)
Kidney disease		
No	123 (85.4%)	117 (81.3%)
Yes	18 (12.5%)	20 (13.9%)
Other urinary tract disorders (including prostate trouble)		
No	108 (75.0%)	106 (73.6%)
Yes	33 (22.9%)	31 (21.5%)
Diabetes		
No	106 (73.6%)	100 (69.4%)
Yes	35 (24.3%)	37 (25.7%)
Alzheimer's disease or dementia		
No	140 (97.2%)	136 (94.4%)
Yes	1 (0.7%)	1 (0.7%)
Thyroid or other gland disorders		
No	106 (73.6%)	107 (74.3%)
Yes	35 (24.3%)	30 (20.8%)
Cancer or leukemia		
No	129 (89.6%)	120 (83.3%)
Yes	12 (8.3%)	17 (11.8%)
Seizures or epilepsy		
No	140 (97.2%)	136 (94.4%)
Yes	1 (0.7%)	1 (0.7%)
Unsteadiness/Balance difficulties		
No	98 (68.1%)	91 (63.2%)
Yes	43 (29.9%)	46 (31.9%)
Effects of stroke		
No	132 (91.7%)	129 (89.6%)
Yes	9 (6.3%)	8 (5.6%)
Parkinson's disease		
No	140 (97.2%)	136 (94.4%)
Yes	1 (0.7%)	1 (0.7%)
High blood pressure		
No	61 (42.4%)	55 (38.2%)
Yes	80 (55.6%)	82 (56.9%)
Heart trouble or disease		
No	95 (66.0%)	90 (62.5%)
Yes	46 (31.9%)	47 (32.6%)
History of falls (described as 2 or more falls in 1 y)		
No	114 (79.2%)	125 (86.8%)
Yes	27 (18.8%)	12 (8.3%)
Circulation trouble in arms or legs		
No	116 (80.6%)	115 (79.9%)
Yes	25 (17.4%)	22 (15.3%)

(Continued next page)

TABLE 3. *(Continued)*

	Control Sites (n = 144)	Treatment Sites (n = 144)
Arthritis or rheumatism		
No	52 (36.1%)	63 (43.8%)
Yes	89 (61.8%)	74 (51.4%)
Other joint or muscle problems		
No	94 (65.3%)	83 (57.6%)
Yes	47 (32.6%)	54 (37.5%)
Stomach or duodenal ulcers		
No	132 (91.7%)	125 (86.8%)
Yes	9 (6.3%)	12 (8.3%)
Liver problems or disease		
No	137 (95.1%)	137 (95.1%)
Yes	4 (2.8%)	0 (0%)
Glaucoma or cataracts		
No	113 (78.5%)	93 (64.6%)
Yes	28 (19.4)	44 (30.6%)
History of Insomnia (Described as lasting 1 mo or longer)		
No	110 (76.4%)	112 (77.8%)
Yes	31 (21.5%)	24 (16.7%)
Missing	3 (2.1%)	8 (5.6%)

* The occurrence of missing data for all nondemographic variables was 3 cases (2.1%) for control sites and 7 cases (4.9%) for treatment sites, except where otherwise noted.

misuse frequencies for participants in treatment and control sites, it is evident that those experiencing the system redesign were less likely to demonstrate all misuse types related to high-risk products and even all products, although statistical confirmation was not possible for many misuse types due to small treatment group size. That is, all misuse comparisons were in the direction of anticipated effects, with lower frequencies occurring in the treatment group.

Additional findings from multivariate GLMM models involving high-risk OTC medications revealed effects for other variables that tended to be consistent across at least some misuse types. OTC pain medications were the least likely to be involved in Drug-Age and Drug-Drug misuse, compared to cough/cold/allergy products. Such findings could be due, at least partly, to enhanced awareness of pain medication safety risks from national

outreach efforts, such as from the Gerontological Society of America[32] and the American Association of Retired Persons.[33] Most significantly, however, all misuse types generally occurred for adults who were 85 years or older and, therefore, most vulnerable to medication risks. Further efforts are needed to target the oldest of this age group to better protect against these age-related vulnerabilities.

For GLMM modeling involving misuse of all OTC products, fixed-effects results varied based on the participant's selected scenario. For example, pain medications were less likely involved in Drug-Age misuse, whereas sleep medications characterized Inappropriate Duration of Use misuse, due perhaps to the general chronicity of sleep-disruption problems.[34,35] The only time that a significant effect emerged for the OTC Use Scenario variable was with Over Daily Dosage and Exceeds Recommended Single Dosage misuse, with extreme scenarios more involved in both cases. Such results suggest that older adults are prone to simply increasing the dose beyond product label instructions when attempting to self-treat their persisting symptoms. Finally, participant age showed a significant effect for Drug-Disease misuse, but only when comparing participants aged 65–74 years to those 85 years or older. These findings revealed that, when evaluating misuse of all OTC products, effects were more sporadic and inconsistent across misuse types compared to misuse involving high-risk OTC products.

Given the overall fewer instances of misuse in treatment sites compared to control sites, the signage designating high-risk OTC products seemed effective in heightening the caution around specific products. Particularly for BTC signage, which was placed where the product was typically located, the objective was to prompt people to seek medication information from pharmacy staff. In fact, the research team conceived the BTC signage as creating a "forcing function,"[21] introducing a physical barrier for those considering a product purchase for which they would then have to go to the pharmacy counter to request the product. That is, BTC signage was designed to force interactions between older adults and pharmacy staff about potential risks involved in using such products. In a less direct fashion, Stop Signs were meant to serve as a "soft barrier"[20] by communicating warnings and directing patients' attention to alternative products designated with the Green Senior Safe Banner. All Senior Safe medication-related signage was designed to promote beneficial patient/pharmacy staff encounters to increase understanding of potential risks with selected products and greater consideration of alternate medications with higher safety profiles. Causing an older adult to reconsider potentially unsafe OTC selections was the goal of this

TABLE 4. Total Misuse Frequencies by Types of OTC Products

	High-Risk OTC Products (%)	All OTC Products (%)
Drug-Age misuse	40/591 (6.8)	52/602 (8.6)
Drug-Drug misuse	67/323 (20.7)	416/717 (58.0)
Drug-Disease misuse	14/390 (3.6)	63/441 (14.3)
Drug-Label misuse		
Exceeds recommended single dose	0/409 (0.0)	41/450 (9.1)
Use for inappropriate indications	3/442 (0.7)	11/450 (2.4)
Over daily dosage	6/393 (1.5)	63/450 (14.0)
Inappropriate timing or frequency	7/401 (1.7)	56/450 (12.4)
Inappropriate duration of use	6/339 (1.8)	118/450 (26.2)

Numerator values represent the number of cases for which misuse was identified. Denominator values represent the number of cases for which a study-relevant medication was selected for use.

TABLE 5. Frequencies of Misuse of High-Risk OTC Products in Control and Treatment Sites

	Drug-Age Misuse (n = 40)		Drug-Drug Misuse (n = 67)		Drug-Disease Misuse (n = 14)	
	C	Tx	C	Tx	C	Tx
Site type						
Pharmacy	28	4	44	7	12	0
Remote dispensing sites	6	2	13	3	2	0
Symptom scenario						
Pain	2	0	5	0	2	0
Sleep	11	1	21	0	6	0
Cough/Cold/Allergy	21	5	31	10	6	0
OTC use scenario						
Typical	30	6	50	10	12	0
Extreme	4	0	7	0	2	0
Participant age, y						
65–74	24	4	36	5	9	0
75–84	5	1	13	5	1	0
85+	5	1	8	0	4	0

Drug-Label misuse	Over Daily Dosage (n = 6)		Inappropriate Timing/Frequency (n = 7)		Exceeds Recommended Single Dose (n = 0)		Inappropriate Duration (n = 6)		Inappropriate Indication (n = 3)	
	C	Tx	C	Tx	C	Tx	C	Tx	C	Tx
Site type										
Pharmacy	3	0	4	0	0	0	5	0	0	1
Remote dispensing sites	3	0	3	0	0	0	0	1	2	0
Symptom scenario										
Pain	2	0	2	0	0	0	0	0	2	0
Sleep	0	0	1	0	0	0	4	0	0	1
Cough/Cold/Allergy	4	0	4	0	0	0	1	1	0	0
OTC use scenario										
Typical	4	0	5	0	0	0	5	1	2	1
Extreme	2	0	2	0	0	0	0	0	0	0
Participant age, y										
65–74	4	0	5	0	0	0	4	0	0	1
75–84	0	0	0	0	0	0	1	0	0	0
85+	2	0	2	0	0	0	0	1	2	0

C indicates control sites; Tx, treatment sites.

intervention, and these study outcomes substantiate this effect. Future research activities should document and validate intervention mechanisms contributing to safer older adult OTC medication selection and, when high-risk products are chosen, the factors influencing those potentially unsafe decisions.

Senior Safe is a pharmacy-based intervention requiring a permanent structural redesign (e.g., reorganizing shelving for OTC products, displaying medication signage, and allocating space for BTC-related products) and pharmacy staff commitment to older adult engagement around medication safety issues. Cumulatively, these features can improve access to valuable and consistent information when older adults are choosing an OTC medication for symptom relief. Information imparted through Senior Safe resources will enhance older adults' risk awareness, which may contribute to their self-determination of risk levels and opting for safer OTC products, and to be more confident in their safer selection. Outcomes confirm that Senior Safe is a beneficial resource for engaging pharmacists and technicians in efforts to strengthen patients' ability to make informed OTC medication decisions for improving their safe OTC medication use.

Strengths and Limitations

Beyond Senior Safe's innovation, a principal strength of this research was using an RCT design and a multivariate modeling approach to empirically evaluate differences in occurrence of various OTC misuse types, while comparing sites that implemented the pharmacy redesign to matched control sites. Table 3 reveals that the collected patient-related characteristics, such as demographics, health literacy items, and numerous health conditions, were largely homogeneous between the 2 experimental groups. Importantly, the achieved participant sample size conformed to the study power and sample size calculations, which strengthens the validity of the estimated variable coefficients.

Despite the study strengths, certain limitations also need to be considered. First, there is likely nongeneralizability to other health system community pharmacies or other locations where OTC products are sold. For example, because the participating community pharmacies are within a large health system, there are no times in which the pharmacy remains open while the pharmacy counter is closed. However, in sites where the pharmacy counter

TABLE 6. Logistic Regression Comparing Relevant Fixed-Effects Factors in Drug-Age Misuse Status for High-Risk OTC Medications (n = 40)

	Odds Ratio	*P*	95% Confidence Interval	
			Lower Bound	Upper Bound
Experimental group				
Control	2.752	0.004	1.396	5.424
Treatment	1			
Site type				
Pharmacy	1.103	0.799	0.519	2.342
Remote dispensing site	1			
Symptom scenario				
Pain	0.303	0.002	0.140	0.654
Sleep	1.564	0.248	0.732	3.346
Cough/Cold/Allergy	1			
OTC use scenario				
Typical	1.506	0.387	0.594	3.815
Extreme	1			
Participant age, y				
65–74	0.351	0.041	0.129	0.958
75–84	0.217	0.009	0.069	0.680
85+	1			

Values of 1 for each variable represent the statistical comparator group.

can be closed during store hours, the presence of BTC Signage could be a barrier to patient access to needed medications. All study sites also have the same organizational structure of the health care organization to which they belong, including a systems-level commitment for patient safety. This organizational philosophy can limit generalization to other pharmacy settings. Second, a possibility of selection bias may exist between older adults who were recruited and those who could not participate. It is important to note, though, that differences between control and treatment groups seemed largely mitigated by the study design (the same recruitment strategy for control and treatment sites) and by the demographic similarities between groups as presented in Table 3. Still, these results may not be extrapolated to other populations. Third, participants' information about OTC medication selection and use was in reaction to hypothetical health symptom scenarios and may not completely mirror their "real-world" medication-taking behaviors. Fourth, in cases involving dose/frequency ranges, the methodological decision to use the higher dose or lower frequency may have increased misuse frequencies. Finally, participant medication and health information was determined through self-report, rather than from health systems databases.

CONCLUSIONS

Project findings showcase the first multipharmacy intervention to demonstrate effectiveness at reducing various types of older adult OTC misuse, using a rigorous methodological design. Senior Safe implementation substantively reduced OTC product misuse, particularly for high-risk products and for older adults aged 65 to 84 years, while also illustrating that older adults can engage in multiple types of misuse even at symptom onset. Such evidence is consistent enough to warrant future evaluation of sustained post-implementation improvements when expanded more widely to pharmacy sites throughout the health system. Even at this stage, however, this project supports the need for and benefit of an effective intervention to reduce patient safety harms through OTC medication misuse. These findings, therefore, provide insights into practice recommendations that could be supported by broad

regulatory or professional guidance. Through various communication mechanisms (e.g., newsletters, e-notifications, policy statements), state boards of pharmacy and even national- or state-level pharmacy associations could use this information to periodically inform pharmacists of critical considerations around older adults' use of OTC products, especially high-risk products. Enhanced professional awareness about these issues, coupled with

TABLE 7. Logistic Regression Comparing Relevant Fixed-Effects Factors in Drug-Age Misuse Status for All OTC Medications (n = 52)

	Odds Ratio	*P*	95% Confidence Interval	
			Lower Bound	Upper Bound
Experimental group				
Control	5.120	0.001	1.916	13.682
Treatment	1			
Site type				
Pharmacy	0.976	0.964	0.343	2.777
Remote dispensing site	1			
Symptom scenario				
Pain	0.359	0.015	0.158	0.816
Sleep	2.044	0.130	0.810	5.161
Cough/Cold/Allergy	1			
OTC use scenario				
Typical	0.986	0.975	0.410	2.370
Extreme	1			
Participant age. y				
65–74	0.176	0.002	0.059	0.522
75–84	0.068	<0.001	0.018	0.253
85+	1			

Values of 1 for each variable represent the statistical comparator group.

the availability of an intervention specifically designed to address those issues, would improve older adult safety around OTC medication misuse.

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