



# The High Prevalence and Complexity of Over-the-Counter Medication Misuse in Older Adults

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## Abstract

**Background and Objectives:** Older adults (≥65 years) are the largest consumers of over-the-counter (OTC) medications and exceptionally vulnerable to the risks of these medications, including adverse drug events (ADEs). However, little is known about how older adults select and use OTCs. This is the first multisite study designed to prospectively quantify the type and intended use of OTCs selected by older adults in community pharmacies where products are purchased.

**Research Design and Methods:** Older adults ( $n = 144$ ) were recruited from 10 community pharmacies from a Midwestern health system. Participants were given hypothetical symptoms and asked to select one or more OTCs for self-treatment. They were asked to report how they would use the products at symptom onset and when symptoms persisted or worsened. They also reported their current medication list and health conditions. Participants' OTC selections were evaluated for 4 types of misuse: drug-age, drug-drug, drug-disease, and drug-label.

**Results:** Of the 144 participants, 114 (79%) demonstrated at least one type of misuse when describing how they would use their OTC selections at symptom onset. Drug-drug and drug-label misuse had the highest prevalence. Overall, 26 (18%) and 28 (19%) participants showed only drug-drug or drug-label misuse, respectively. Notably, 55 (38%) of participants demonstrated misuse in 2 or more misuse categories. Misuse potential was exacerbated when participants described treating persistent or worsening symptoms.

**Discussion and Implications:** The results highlight the high prevalence and complexity of OTC misuse in older adults and the need for additional work to improve OTC safety.

**Keywords:** Community pharmacy, Inappropriate medication use, Medication safety, Self-care, Self-treatment

**Translational Significance:** This is the first study to demonstrate and characterize significant potential misuse of over-the-counter (OTC) medications in older adults. Importantly, it provides a clear direction for future research, including assessing the clinical impact of OTC misuse and developing and implementing interventions that promote safe OTC selection and use without limiting patient autonomy.

## Background and Objectives

Over-the-counter (OTC) medications are drug products sold directly to the public without a prescription, including medications that previously required a prescription (U.S. Food and Drug Administration, 2021, 2023). Today, there are over 300,000 OTCs available in the United States

(U.S. Food and Drug Administration, 2022). Older adults (≥65 years) are the largest consumers of OTCs, accounting for 30% of OTC use despite comprising 17% of the population (National Council on Patient Information and Education, 2017; U.S. Census Bureau, 2023). Almost 50% of older adults use an OTC daily to weekly (Qato et al.,

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2008). Because OTCs do not require a prescription, there is little knowledge of or even consideration for how these medications are used, including the extent of their misuse (Chui et al., 2017).

Over-the-counter misuse poses a patient safety risk and can lead to adverse drug events (ADEs; [Center for Disease Control and Prevention, 2024](#), April 17). ADEs associated with OTCs contribute to 178,000 hospitalizations annually ([United Health Foundation, 2005](#)). Older adults are exceptionally vulnerable to ADEs due to various age-related factors, including changes in pharmacokinetics and pharmacodynamics, multimorbidity, polypharmacy, health condition complexity, declining cognition, and general frailty ([Woo et al., 2020](#)). For older adults, high-risk OTC medications include sleep and pain medications, such as aspirin, ibuprofen, acetaminophen, and diphenhydramine. These OTCs are the most frequently used by older adults and implicated in ADEs leading to emergency department visits ([Kaufman et al., 2002](#)).

In the face of OTC-related ADEs, nearly a decade ago the Gerontological Society of America (GSA) and Consumer Healthcare Products Association (CHPA) convened a National Summit. The purpose of the Summit was to set an agenda for research in OTC behaviors among older adults, which was published in a white paper. The agenda included understanding the ways older adults select OTC medications and how they decide to start, use, and stop them ([Albert et al., 2014](#)). However, since this paper's publication, minimal work has been done to answer these central questions.

This is the first multisite study designed to understand how older adults select and use OTCs in community pharmacies, where products are typically sold. By asking older adults to make hypothetical decisions, this study sought to understand how older adults would use OTCs at symptom onset and when symptoms persisted or worsened, quantify the OTC misuse prevalence, and characterize different misuse types.

## Research Design and Methods

### Recruitment

Older adults were recruited from 10 community pharmacies located within clinics of a large Midwestern health system between June 2022 and October 2022. The clinics were geographically dispersed to ensure engagement with diverse populations. Posters and fliers were available within the clinics to create awareness. Patients in the facilities approached researchers, who were stationed outside of the pharmacies, to inquire about the study and were recruited in real time. Eligible participants were  $\geq 65$  years old, would consider using an OTC product for self-care, and passed a six-item screener used to identify individuals with cognitive impairment ([Callahan et al., 2002](#)). The Institutional Review Board at the University of Wisconsin-Madison approved this study.

### Data Collection

After giving informed consent, participants were asked to select whether they had the most experience with treating cough/cold/allergy, pain, or sleep symptoms, which are common health issues for older adults and associated with high-risk OTCs. Experience was defined as having a history of these symptoms. Participants were then given one of the following hypothetical scenarios:

- 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 medications for your symptoms yet, and it's not bad enough to call your doctor."
- 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."
- Sleep: "Over the last couple of days, you have been having difficulty falling asleep or staying asleep. You have not taken any medication to help with this sleep problem, and it's not bad enough to call your doctor."

Participants were asked to go into the pharmacy and choose one or more OTCs to treat their hypothetical symptoms. To better replicate a real-world experience, they were given a pretend credit card to "buy" their selected products, and they could interact with the staff if desired. Participants were not given a time limit for this process. Prior to data collection, pharmacy staff were instructed to interact with the participants as they normally would.

Participants were told to bring their selected OTC products to the researcher to complete a short, follow-up interview. During the interview, participants could refer to the package when answering questions. Participants were asked to describe how they would use their OTC selection(s), including dose, frequency, and duration, at symptom onset. In instances where participants selected more than one OTC, they were also asked to describe if and how they would use the products in combination. Participants were then told to imagine they were experiencing persistent or worsening symptoms and asked what they would do. If the participant indicated that they would call the doctor or use a non-pharmacological treatment option (such as icing or seeing a chiropractor), the interview was concluded. If the participant indicated that they would continue using their initial selections, use a different dose of the same products, or use different OTCs, they were once again asked how they would use the selected OTC(s), as described above. The full symptom scenarios and interview questions are included in [Supplementary Material Section 1](#). All interviews were audio recorded, and OTC product photographs were taken for clinical interpretation purposes.

After the in-person interview, a 20-min phone interview was scheduled with the participant. Participants were asked to report home medications they used in the last 30 days, including prescriptions, OTCs, vitamins, and herbal and alternative medications. For each medication, the interviewer collected the name, dose/strength, frequency, and where they purchased their medications. Participants completed the three-question Brief Health Literacy Screen (BHLS), with low health literacy defined as a summative score  $\leq 9$ , and adequate health literacy defined as a score  $> 9$  (max score of 15; [Chew et al., 2004](#)). Participants responded yes or no to a list of health conditions modified from Older Americans Resources and Services (OARS; [Duke Aging Center, 2005](#)). Lastly, participants reported demographic information. The phone interview guide is included in [Supplementary Material Section 2](#). All phone interviews were recorded. After both interviews were completed, participants were mailed \$40 for participating. The participants' selected OTC products and

all interview responses were entered and verified in REDCap, a web-based software platform for data management (Harris et al., 2009, 2019).

### Misuse Classifications

Analysis aimed to identify 4OTC misuse types: (1) drug-age, (2) drug-drug, (3) drug-disease, and (4) drug label. Drug-age and drug-drug misuse could be determined without clinical judgment and were independently evaluated by three PharmD students and verified by a pharmacist researcher. Drug-disease and drug-label misuse were independently evaluated by three clinical pharmacists with experience treating older adult patients.

Drug-age misuse was based on the 2019 Beers Criteria (American Geriatrics Society, 2019). The Beers Criteria included two main OTC classes. The first was oral nonsteroidal anti-inflammatory drugs (NSAIDs) used chronically (>90 days). Oral NSAIDs included aspirin (>325 mg), ibuprofen, naproxen, and magnesium salicylate tetrahydrate. Although magnesium salicylate tetrahydrate is not listed on the Beers Criteria, it was included as an NSAID. The second class was anticholinergics, including chlorpheniramine, triprolidine, doxylamine, diphenhydramine, and brompheniramine. For each OTC, the active ingredients were compared to the Beers Criteria. For OTCs with multiple active ingredients, each ingredient was evaluated separately. Additionally, OTCs categorized as NSAIDs were assessed for chronic use by reviewing the patient-reported duration of use from the in-person interview.

Drug-drug misuse was defined as using two or more medications that have a drug–drug interaction. Interactions were determined by comparing each selected OTC to the participant's home medications using Lexicomp (Lexicomp, 2023b). Lexicomp does not include entries for generic combination medications. For these OTCs, a brand equivalent was selected. If a brand equivalent was not available, selections were made for each individual ingredient. If there was not an entry in Lexicomp that matched (e.g., a homeopathic product), the OTC selection or home medication was labeled, “no match in Lexicomp,” and excluded from evaluation. The Lexicomp Drug Interactions Module (Lexicomp, 2023a) was used to identify drug–drug interactions. Interactions with the following domains carried enough risk to be considered misuse: C (monitor therapy), D (consider therapy modification), and X (avoid combination). Any interactions with an A (no known interaction) or B (no action needed) risk rating were considered safe use (Lexicomp, 2023a).

The inclusion of interactions with “C” risk ratings was decided through discussions with a panel of clinical pharmacists. All interactions fall into one of three severity ratings: minor (effects would be considered tolerable in most cases—no need for medical intervention), moderate (medical intervention needed to treat effects), or major (effects may result in death, hospitalization, permanent injury, or therapeutic failure). Only “C” interactions with “moderate” or “major” severity were determined to constitute misuse. Although a “C” risk rating typically indicates that concomitant use of two medications outweighs the risks, those with “moderate” or “major” severity may lead to the need for medical intervention or serious health consequences (Lexicomp, 2023a).

Only interactions between an OTC selection and home medication were reported. Interactions between two OTC

selections or two home medications were excluded. In some cases, an OTC selection interacted with multiple home medications, or had multiple interactions with the same home medication. In these cases, each interaction was reported separately.

Drug-disease misuse was defined as medication use that is contraindicated with a participant's health conditions. Potential contraindications included those between the selected OTCs and disease states designated as high risk per the 2019 Beers Criteria, a health condition listed on the product labeling, or a condition determined to be clinically significant by the evaluators (American Geriatrics Society, 2019). Certain melatonin products included a warning to, “not use [the] product, unless advised by a physician, if you are pregnant, attempting to become pregnant, nursing, taking any medications, or have any chronic medical conditions.” For these cases, drug-disease misuse was not automatically assumed if the participant affirmed any health conditions, and clinical judgment determined misuse. Discrepancies were identified and sent back to the pharmacists to reexamine the data and add comments or update their response if needed. Final misuse determination was based on any health condition identified by at least two pharmacists. If multiple health conditions were identified, each condition was considered a separate drug-disease misuse instance.

Drug-label misuse was defined as medication use not conforming to label instructions. This definition was compartmentalized into five categories: (1) exceeds daily dosage (exceeds threshold consumption amount for a 24-h window), (2) exceeds single dose (maximum amount recommended for a single dose), (3) dose timing/frequency (second dose taken earlier than the recommended time span between doses), (4) use duration (taken longer than the maximum number of days), and (5) inappropriate indication (used to treat symptoms that the product is not intended to treat). For drug-label misuse, the participants' reported use of each OTC product was evaluated. If a participant indicated a dose and frequency range, the higher dose and higher frequency were assumed for evaluation. The clinical pharmacists reported a decision for each drug-label misuse category, and final decisions were determined by agreement between at least two pharmacists. If a participant's reported use met multiple categories, each category was considered a separate drug-label misuse instance.

### Data Analysis

For each type of misuse, prevalence was analyzed. Prevalence was first calculated at the participant level, using individual participants as the unit of measurement. Next, misuse prevalence was calculated with OTC selections as the unit of measurement. Because participants could select more than one OTC to treat their hypothetical symptoms, the sample size for OTC selections was larger than the participant sample. Not all OTC selections could be evaluated for each misuse category due to insufficient product information or missing phone interviews. Additionally, if a participant discussed using a prescription medication or was unable to provide the exact medication name, it was excluded from analysis. The total number of misuse instances was also calculated. This included an OTC selection that demonstrated drug-age misuse, a drug–drug interaction, a drug–disease interaction, or an instance of drug-label misuse in any category. Misuse prevalence at the participant and selection levels and total instances were also calculated for participants who stated they would

change their medication use or use/add a different OTC when symptoms persisted or worsened. For the purposes of this manuscript, OTC selections used to treat symptoms at onset are referred to as “typical OTC selections.” OTC selections that were changed or added to treat persistent and worsening symptoms are referred to as “persistent/worsening OTC selections.”

## Results

In total, 144 older adults participated in the in-person interview, with all but three completing the follow-up phone interview. On average, participants who completed the phone interview were 72 years old (range of 65–91 years old), used 11 home medications, and had 5 health conditions. The prevalence of each health condition is further outlined in [Table 1](#). Overall, 136 (96%) participants identified as White, 5 (4%) as Black or African American, 5 (4%) as American Indian or Alaska Native, and 1 (1%) chose not to identify. None of the 141 participants reported Hispanic or Latino origin or descent. A total of 83 (59%) participants identified as female, and 57 (41%) identified as male. Lastly, 132 (94%) received a score >9 on the BHLS.

Of the 144 participants, 114 (79%) demonstrated misuse in at least one category when describing how they would use their OTC selections at symptom onset. Overall, 365 misuse instances were identified among these 114 participants ( $\bar{x}$  = 3.20 instances per participants). When the 144 participants

**Table 1.** Prevalence of Participant ( $n$  = 144) Health Conditions From Adapted Older Americans Resources and Services List

Health conditions	$n$ (%)
Arthritis or rheumatism	89 (62%)
Allergies or sinus problems	83 (58%)
High blood pressure	80 (56%)
Other joint or muscle problems	47 (33%)
Heart trouble or disease	46 (32%)
Unsteadiness/balance difficulties	43 (30%)
Diabetes	35 (24%)
Thyroid or other gland disorders	35 (24%)
Other urinary tract disorders (including prostate trouble)	33 (23%)
Asthma or wheezing	32 (22%)
History of insomnia (described as lasting one month or longer)	31 (22%)
Bronchitis/emphysema/chronic obstructive pulmonary disease	28 (19%)
Glaucoma or cataracts	28 (19%)
History of falls (described as two or more falls in one year)	27 (19%)
Circulation trouble in arms or legs	25 (17%)
Kidney disease	18 (13%)
Cancer or leukemia	12 (8%)
Effects of stroke	9 (6%)
Stomach or duodenal ulcers	9 (6%)
Liver problems or disease	4 (3%)
Alzheimer's disease or dementia	1 (1%)
Parkinson's disease	1 (1%)
Seizures or epilepsy	1 (1%)

described how they would use their selections when symptoms persisted or worsened, 113 (78%) indicated that they would discontinue their OTC selection and call the doctor, use a non-pharmacological treatment option, or continue using their selection in the same way. However, 31 (22%) indicated that they would use their initial selection differently (increase dose, frequency, or duration) or add a new product. Of these 31 participants, 23 indicated a change that would contribute to further misuse. In these 23 individuals, 110 misuse instances were identified ( $\bar{x}$  = 4.78 instances per participant). These results are further outlined in [Figure 1](#).

## Participant Level

As shown in [Table 2](#), 114 participants (79%) demonstrated at least one misuse type when describing how they would treat symptoms at onset, with most exhibiting drug-drug and drug-label misuse. Additionally, 55 (38%) of these participants demonstrated misuse in more than one category, and 6 (4%) in all four categories. When discussing how they would treat persistent or worsening symptoms, 31 (22%) participants said that they would change their OTC use. This included changing the dose, frequency, or duration of use of their initial OTC selections, or changing to or adding a new OTC product. Of these 31 participants, 23 (74%) demonstrated misuse in at least one category, with 15 (48%) having misuse in more than one category, and 3 (10%) exhibiting misuse in all four. Again, most of these participants demonstrated drug-drug and drug-label misuse.

In participants with typical OTC selections demonstrating drug-drug misuse, an average of 2.5 drug–drug interactions was seen. This average increased to 2.6 drug–drug interactions in participants with persistent/worsening selections demonstrating drug-drug misuse. In those with typical selections demonstrating drug-disease misuse, selections interacted with an average of 1.3 health conditions per participant. This average decreased to 1.0 for those with persistent/worsening selections exhibiting drug-disease misuse.

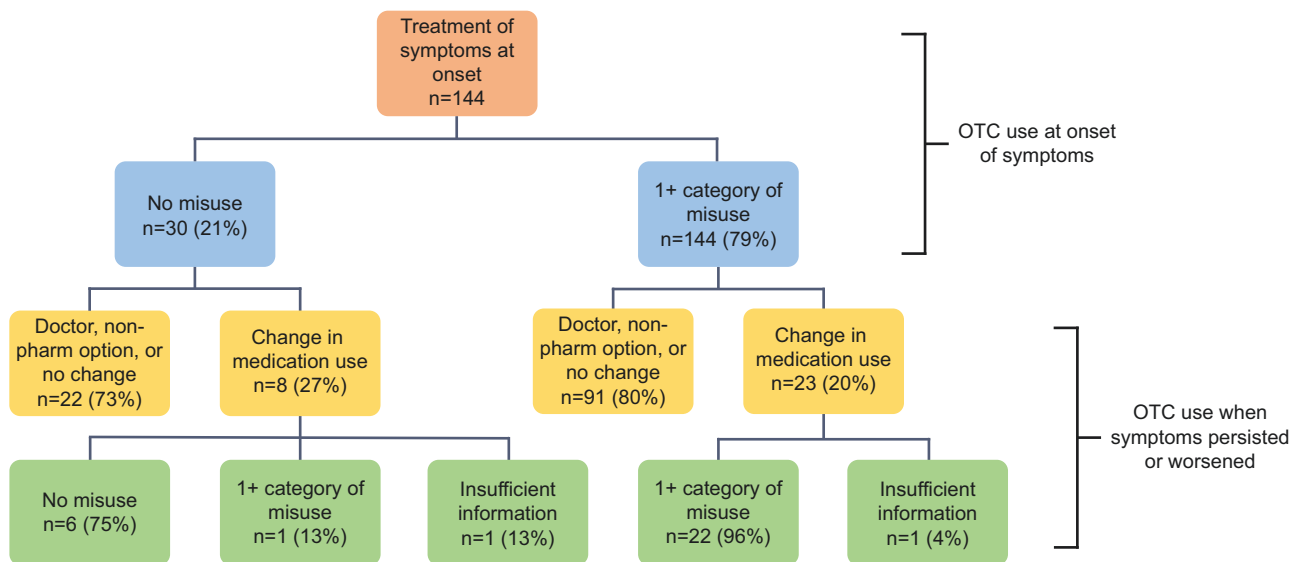
## Selection Level

The following results focus on each individual OTC product as the unit of analysis. Due to the limitations described in the “Data Analysis” section above, some OTC products could not be evaluated for every misuse category. As a result, each category had the following sample size:

- Drug-age: 197 typical, 34 persistent/worsening OTCs
- Drug-drug: 191 typical, 30 persistent/worsening OTCs
- Drug-disease: 192 typical, 32 persistent/worsening OTCs
- Drug-label: 194 typical, 34 persistent/worsening OTCs

[Table 3](#) shows misuse prevalence (categorized by misuse type and symptom scenario) for typical OTC selections. [Table 3](#) also shows misuse for persistent/worsening OTC selections. Across all typical and persistent/worsening misuse categories and symptom scenarios, the following OTCs contributed to the most misuse: ibuprofen, acetaminophen, diphenhydramine, naproxen, doxylamine, and combination products containing at least one of these five active ingredients.

Overall, typical selections demonstrated the highest drug-drug misuse prevalence, as 82 (43%) had a drug–drug interaction. These 82 selections created 189 total drug–drug interactions, which were classified into the following risk ratings: 141 (75%) C (moderate severity), 4 (2%) C (major



**Figure 1.** Participant self-described over-the-counter (OTC) use outcomes.

severity), 28 (15%) D, and 16 (8%) X. Additionally, these drug–drug interactions were most common with home medications from the following drug classes: cardiovascular (44%), supplements (12%), neurological (12%), and psychiatric (12%). Drug-label misuse showed the next highest prevalence, with 77 (40%) typical OTC products demonstrating misuse. Table 4 shows drug-label misuse for each category. When broken down by symptom scenario, the highest prevalence was seen with drug-label misuse of pain products. For drug-disease misuse, misuse was most commonly due to contraindications with hypertension, unsteadiness/balance difficulties, kidney disease, and history of falls (two or more falls in one year).

As seen with the typical selections, drug-label and drug-drug misuse showed the highest prevalence for persistent/worsening selections, with 21 (62%) and 17 (57%) demonstrating misuse, respectively. Table 4 also shows the prevalence for each drug-label misuse category for the persistent/worsening selections. For drug-drug misuse, 45 total drug-drug interactions were identified and classified into the following risk ratings: 33 (73%) C (moderate severity), 1 (2%) C (major severity), 8 (18%) D, and 3 (7%) X. Persistent/worsening OTC selections most commonly interacted with home medications from the cardiovascular drug class (53%). When classified by symptom scenario, the highest overall prevalence was for drug-drug misuse of cough/cold/allergy products. Finally, for participants making a persistent/worsening selection, drug-disease misuse was most commonly seen in those with hypertension.

### Discussion and Implications

To date, this is the first and largest study to evaluate older adult OTC selection and use in a naturalistic environment where older adults typically select these medications. This is in comparison to the numerous lab-based simulations and self-reported surveys that have been done. Results highlight the high prevalence and complexity of OTC misuse in older adults, as nearly 4 out of 5 participants demonstrated at least one type of misuse when treating symptoms at onset, with half exhibiting misuse in multiple categories. This is consistent

with literature indicating that OTC misuse is widespread among older adults (Chui et al., 2017). Misuse potential was exacerbated when participants made a change in OTC use to treat worsening symptoms. Misuse was also present, to varying extents, across all three symptom scenarios. Overall, this issue can contribute to serious health consequences and hospitalizations (Donneyong et al., 2023; Karlowicz-Bodalska et al., 2023).

Most drug–drug interactions were classified as a “C” risk rating with “moderate” or “major” severity. This means that the benefits of concomitant medication use typically outweigh the risks, assuming that both physicians and pharmacists are monitoring and documenting that potential risk. Providers should consider a monitoring plan to prevent negative patient outcomes and adjust medication doses accordingly—even for OTCs, which are typically not considered in clinical decision-making.

The drug-label misuse analysis demonstrates that older adults are often using OTCs for an inappropriate amount of time. Long-term OTC use further stresses the importance of monitoring and potential intervention. Unfortunately, pharmacists and other healthcare providers are often not aware of the OTCs being used by their patients, especially if they are excluded from electronic health records, making it difficult to monitor therapies (Kebodeaux, 2019; Serper et al., 2013). Overall, this stresses the importance of considering interactions with a “C” risk rating as misuse, especially those with “moderate” or “major” severity that could deteriorate a patient’s conditions or cause permanent harm if not acknowledged.

These findings have several implications. First, next steps should include increasing awareness of risks associated with OTC selections, including educational programming to share these results with older adult advocacy groups or organizations working directly with this patient population. Future research should also examine the clinical impact of OTC misuse, including its contribution to ADEs and subsequent outcomes for older adults, and focus on reducing its prevalence in older adults by developing and implementing interventions that guide OTC-selection decisions without limiting patient autonomy. These interventions could also help

**Table 2.** Prevalence of Misuse by Category for Participants With Typical and Persistent/Worsening OTC Selections

Misuse categories	n (%)
<i>Participants with typical OTC selections (n = 144)</i>	
No misuse	30 (21%)
1 misuse category	59 (41%)
Drug	26 (18%)
Age	5 (3%)
Label	28 (19%)
Disease	0 (0%)
2 misuse categories	35 (24%)
Drug and age	8
Drug and label	16
Drug and disease	5
Age and label	3
Age and disease	2
Disease and label	1
3 misuse categories	14 (10%)
Drug, age, and label	5
Drug, age, and disease	4
Drug, label, and disease	5
Age, label, and disease	0
4 misuse categories	6 (4%)
Insufficient information	0 (0%)
<i>Participants with persistent/worsening OTC selections (n = 31)</i>	
No misuse	6 (19%)
1 misuse category	8 (26%)
Drug	3 (10%)
Age	0 (0%)
Label	5 (16%)
Disease	0 (0%)
2 misuse categories	6 (19%)
Drug and age	1
Drug and label	4
Drug and disease	0
Age and label	1
Age and disease	0
Disease and label	0
3 misuse categories	6 (19%)
Drug, age, and label	3
Drug, age, and disease	0
Drug, label, and disease	3
Age, label, and disease	0
4 misuse categories	3 (10%)
Insufficient information	2 (6%)

Note: OTC = over-the-counter.

providers improve older adult communication and monitor OTC selections.

At the policy level, this study has implications for prescription-to-nonprescription medication switches. Applications for these switches require safety data demonstrating that the drug product is safe to use in the nonprescription setting. It also requires data demonstrating that

**Table 3.** Misuse for Typical and Persistent/Worsening OTC Selections by Symptom Scenario

Misuse categories	Typical OTC selections n (%)	Persistent or worsening OTC selections n (%)
<i>Drug-age evaluation (typical n = 197; persistent/worsening n = 34)</i>		
Cough/cold/allergy	17 (24%)	
Drug-age misuse	8 (8%)	4 (57%)
Pain		
Drug-age misuse	10 (37%)	4 (20%)
Sleep		
Drug-age misuse		0 (0%)
<i>Drug-drug evaluation (typical n = 191; persistent/worsening n = 30)</i>		
Cough/cold/allergy		
Drug-drug misuse	43 (44%)	4 (80%)
Pain		
Drug-drug misuse	11 (42%)	12 (60%)
Sleep		
Drug-drug misuse		1 (20%)
<i>Drug-disease evaluation (typical n = 192; persistent/worsening n = 32)</i>		
Cough/cold/allergy		
Drug-disease misuse	13 (13%)	2 (40%)
Pain		
Drug-disease misuse	5 (19%)	4 (20%)
Sleep		
Drug-disease misuse		0 (0%)
<i>Drug-label evaluation (typical n = 194; persistent/worsening n = 34)</i>		
Cough/cold/allergy		
Drug-label misuse	47 (47%)	4 (57%)
Pain		
Drug-label misuse	10 (40%)	14 (70%)
Sleep		
Drug-label misuse		3 (43%)

Note: OTC = over-the-counter.

consumers can understand how to use the drug safely without provider supervision (U.S. Food and Drug Administration, 2022). Our results, especially the high prevalence of drug-label misuse, suggest that these data should ensure that prescription-to-nonprescription switches are safe for all populations, including older adults. This study also has potential implications for OTC labeling. The Food and Drug Administration's OTC Drug Facts Label regulation aimed to redesign OTC labels in an easy-to-read format that can help patients navigate medication selections (U.S. Food and Drug Administration, 2015). The high prevalence of drug-label misuse demonstrates that OTC labels may still be insufficient for older adults' safe use. This is especially concerning considering that many patients are not told *how* to use OTC products, even when providers tell them *what* OTCs to purchase. Additionally, in the United States, select medications,

**Table 4.** Prevalence of Each Drug-Label Misuse Category for Typical and Persistent/Worsening OTC Selections

Drug-label misuse categories	n (%)
<i>Typical OTC selections with drug-label misuse (n = 77)</i>	
Over daily dosage	2 (3%)
Inappropriate timing/frequency	9 (12%)
Exceeds recommended single dose	5 (6%)
Inappropriate duration of use	33 (43%)
Inappropriate indication	0 (0%)
Multiple drug-label categories	28 (36%)
<i>Persistent/worsening OTC selections with drug-label misuse (n = 21)</i>	
Over daily dosage	1 (5%)
Inappropriate timing/frequency	0 (0%)
Exceeds recommended single dose	2 (10%)
Inappropriate duration of use	5 (24%)
Inappropriate indication	0 (0%)
Multiple drug-label categories	13 (62%)

Note: OTC = over-the-counter.

including pseudoephedrine, are placed behind the counter as a public safety measure (U.S. Food and Drug Administration, 2017). Future work could explore the expansion of this policy to other high-risk products. Lastly, other countries' OTC policies, especially those requiring certain OTCs to be stored behind the counter, could be examined to evaluate how these decisions affect OTC product selection and use, which could inform U.S. policy (López et al., 2023).

### Limitations

OTC misuse prevalence may be underreported for several reasons. First, if participants selected more than one OTC product to treat their hypothetical symptoms, potential interactions between these selections were considered out of scope and not included in the analysis. It is possible that concomitant use of multiple OTCs may have resulted in additional misuse. Second, participants self-reported medications and health conditions. It is possible that these lists were incomplete and additional misuse was not identified. Third, our study was conducted in community pharmacies, but OTCs can be purchased at non-pharmacy locations, including convenience stores and gas stations. These locations do not provide direct access to healthcare providers in real time, requiring older adults to make decisions independently and potentially leading to greater misuse. Fourth, we evaluated OTC selections to treat hypothetical symptoms, rather than evaluating OTCs selected by older adults to treat existing symptoms in real time. However, we assumed the higher dose and higher frequency for participants who provided a range for their OTC selections, so some misuse may be overreported. Lastly, our patient population was homogenous and had adequate health literacy.

### Conclusions

Overall, results indicate that nearly 80% of older adults using OTC products demonstrated probable misuse. There are currently over 55.8 million older adults in the United States (United States Census Bureau, 2023), and research shows that

around 50% use an OTC daily to weekly (Qato et al., 2008). If we extrapolate our findings to the U.S. population, over 22.3 million older adults are potentially misusing these medications, representing a population health problem that has gone undetected. Beyond that, the number of Americans aged 65 and older will continue to grow at an increasing rate (U.S. Census Bureau, 2019). Over the last decade, millions of dollars have been allocated for research to address older adult prescription medication safety, but little has been done to address OTC use. This first study focusing on this gap has highlighted that older adults' ability to safely self-treat with OTC products is overestimated. Shedding light on this problem is crucial, as we cannot afford to wait another decade to understand and improve the safe use of OTCs among older adults.

### Supplementary Material

Supplementary data are available at *Innovation in Aging* online.

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### Conflict of Interest

None.

### Data Availability

This study is not preregistered, and the data are not available because the authors have not completed their original work with the data set.

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