A Preliminary Examination of Over the Counter Medication Misuse Rates in Older Adults

Jamie A Stone, MS[a], **Corey A Lester, PharmD, MS**[a], **Ephrem A Aboneh, BPharm, MS**[a], **Cynthia H Phelan, PhD, RN**[b], **Lauren L Welch, PharmD**[b], and **Michelle A Chui, PharmD, PhD**[a],[*]

[a] University of Wisconsin - School of Pharmacy, 777 Highland Ave, Madison, WI 53705, USA

[b] William S. Middleton Memorial Veterans Hospital, Department of Veterans Affairs, 2500 Overlook Terrace, Madison, WI 53705, USA

Abstract

Background—Older adults are the largest consumers of over the counter (OTC) medications. Of the older adults who are at risk of a major adverse drug event, more than 50% of these events involve an OTC medication.

Objective—To explore how older adults select and hypothetically use OTC medications and if the selected medications would be considered safe for use.

Methods—Walking interviews were conducted with 20 community-dwelling older adults in a community pharmacy. Each participant selected an OTC medication for a hypothetical pain and sleep scenario. Data were analyzed for four types of misuse: drug-drug interaction, drug-disease interaction, drug-age interaction, and excess usage.

Results—At least one instance of potential misuse was found in 95% of participants. For sleep medications, drug-drug interactions and drug-age interactions were more common, affecting 50% and 65% of participants respectively. The most common type of misuse noted in the pain products selected was that of drug-drug interaction, with a total of 39 occurrences, affecting 60% of the participants.

Conclusions—OTC misuse is common among older adults, and it is important for older adults to seek out resources, such as a pharmacist, to help them make safe OTC decisions.

Keywords

drugs; medication; health; sleep; community pharmacy

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[*]Corresponding Author michelle.chui@wisc.edu, 608-262-0452 (t).
jamie.stone@wisc.edu
calester@wisc.edu
ephrem.aboneh@wisc.edu
cynthia.phelan@va.gov
lauren.welch@va.gov

Introduction

Older adults, aged 65+, are the largest consumers of over the counter (OTC) medications. While older adults comprise 13% of the U.S. population, they account for 30% of OTC medication use.[1] One-fourth of all older adults are on a combination of 10 or more OTC and prescription medications.[2]

Of the estimated 2.2 million older adults who are at risk of a major adverse drug event (ADE), more than 50% of these events involve an OTC medication.[1] Four of the 10 most frequently used drugs are OTC ibuprofen, aspirin, acetaminophen, and diphenhydramine.[3] Older adult use of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and aspirin, results in 80,000 preventable ADEs annually. NSAIDs account for a larger burden of ADEs (15.4%) than anticoagulants (10.2%), one of the top priority drugs in the National Action Plan for ADE prevention.[4,5] Unintentional overdoses of acetaminophen result in 14,000 emergency department visits, and up to 50% of all acute liver failures per year.[6,7] Diphenhydramine has anticholinergic properties which can increase risk of falling.[8,9] Of older adults taking diphenhydramine for sleep, 40% were also taking one or more anticholinergic medications concurrently, compounding the risk of ADEs.[10]

Providers often do not know which OTC medications their patients are consuming.[11] Such lack of awareness and documentation about OTC medication use may lead to duplication of therapies and dangerous overdosing. In fact, the U.S. Centers for Medicare and Medicaid Services single out diphenhydramine and NSAIDs for review specifically because of their OTC availability and potential for therapeutic duplication.[12,13] One study found that 57% of elderly patients taking chronic prescription and OTC medications were not taking their OTC safely and required a pharmacist intervention.[14] The current study sought to explore how older adults select and would hypothetically use (dosing and duration) OTC pain and sleep medications and if the selected medications would be considered safe use.

Methods

Recruitment

Participants were recruited through 2 Wisconsin senior centers and a social club. Eligible participants were 65+ who had used an OTC medication in the past and were able to travel to the study site (a local community pharmacy). Interviews took place between October 2014 and January 2015 and lasted about 45 minutes. Participants were compensated $25. The study was approved by the Institutional Review Board at the University of Wisconsin.

Setting

Interviews took place in one regional mass-merchandise store in south-central Wisconsin (U.S. State). The pharmacy department was sectioned off away from the rest of the larger store and contained several OTC medication aisles and a patient waiting area. The longer OTC aisles were located "outside" the pharmacy department and separated by a main walking aisle that contained short shelves of non-pharmacy items. Pain and sleep

medications, along with cough/cold and allergy medications were located in one of the long OTC aisles.

Data Collection Materials

Questionnaires—Participants were asked to rate their overall health on a 5-point, Likert-type scale from poor to excellent (1=poor, 5 = excellent). They also were asked to indicate their health conditions using the Older American Resource Survey.[15] The OARS is a self-report checklist of 19 illnesses common in midlife and older adults (e.g., asthma or wheezing, high blood pressure, kidney disease).

Demographics collected included age, gender, education, race and ethnicity. Additional questions on the number of prescribers/doctors and the number of pharmacies the participant uses were also included.

Lastly, participants were asked to self-report any prescription medicines, OTC medications, dietary supplements, or herbal remedies that were used in the last 30 days. Information collected for each drug included drug name, dose/strength, how often the medication is taken and when, how long they have been taking the medication, why they are taking the medication, and if they have had any problems with the medication.

Interviews—Interviews were conducted by one primary interviewer. An observer recorded observational notes during the interview. The interview consisted of two parts. The first part, the "walking interview", occurred in the OTC aisles. During the walking interview, participants were provided with two cases (See Table 1 for cases and example probes). Participants were assured that this was a hypothetical situation to help the research team learn what was important to older adults when choosing OTC medications.

Following the walking interview, the interviewer and interviewee sat together in a semi-private section off the pharmacy. Questions during the seated interview focused on knowledge of OTC medication risk, how they would take the medication (e.g. dose and duration), and confidence in selecting safe OTC medications. All interviews were audio recorded and transcribed and photographs of the medications selected were taken.

Classification of Misuse

The OTC medication selected and reported use was compared to the reported disease states and medication list that each participant provided to identify cases of misuse. Four potential types of misuse were identified a priori: drug-drug interaction, drug-disease interaction, drug-age interaction, and usage that exceeds product labeling recommendations.

The drug-drug interaction was determined by comparing each selected OTC drug to the participant's medication list using LexiComp[16] risk ratings of drug interactions. Risk ratings of X (avoid combination), D (consider therapy modification), and C (monitor therapy), were considered potential instances of misuse. Ratings of B (no action needed) or A (no known interaction) were considered safe use.

The drug-disease interaction was determined using the 2012 American Geriatrics Society Beers Criteria for Potentially Inappropriate Medication Use in Older Adults due to Drug-Disease or Drug-Syndrome Interactions that May Exacerbate the Disease or Syndrome[17] and by reviewing the warnings/interactions listed on the selected OTC product. Drug-disease interaction was considered misuse if the condition that the participant reported on the questionnaire and the OTC selected were part of the Beers Disease/Syndrome Criteria or identified with a warning on the product label. Drug-disease interactions not listed on the Beers List or on the product label were considered safe use.

The Drug-age interaction was categorized as misuse if the OTC drug selected appeared on the list: 2012 American Geriatrics Society Beers Criteria for Potentially Inappropriate Medication Use in Older Adults.[17] Drug-age interactions not listed on the Beers List were considered safe use.

Lastly, reported usage was considered misuse if the way the participant described how they would take the OTC medications they selected during the scenarios exceeded daily product labeling dosage or duration of use. Medication use described within product guidelines was considered safe use.

Analysis

Descriptive statistics were used to examine the types of OTC medication misuse. Analysis was completed at the patient-level as well as medication-level to gain a deeper understanding of the data. All statistical analysis was performed using R.[18]

Results

Participants were generally Caucasian older adults (M=75.7, SD = 6.7), largely female (75%), educated, in good to excellent health, reporting daily medication use. See Table 2 for demographic and health characteristics.

OTC medication selection during the scenarios are presented in Table 3. Categorization of medication by misuse and frequency data are reported in Table 4. For sleep medication, drug-drug interactions and drug-age interactions were more common, affecting 50% and 65% of participants respectively. Sleep medication drug-disease interactions and usage misuse were lower, affecting 25% and 10% of participants respectively. Overall, the sleep medication selection of 12 out of 20 patients was considered misuse by falling into one (or more) of the types of misuse identified a priori.

The most common type of misuse noted in the pain products selected was that of drug-drug interaction with a total of 39 occurrences, affecting 60% of the participants. For pain medications, no selections were contraindicated (X rating). Also, none of the OTC pain products selected were considered misuse by the Drug-Age definition. 30% of participants selected a drug that may have resulted in a drug-disease interaction, with hypertension being the disease most likely to react with the selected drug. Similarly to the sleep medications, only a small percentage (15%) stated they would use the drug selected outside the

recommended guidelines. Overall, the pain medication selection of 13 out of 20 patients was considered misuse by falling into one (or more) of the types of misuse identified a priori.

Discussion

Surprising levels of misuse among older adult participants were identified: at least one instance of potential misuse in 95% of participants (19 out of 20). 80% of participants selected an OTC that if taken with their current medication regimen, could cause a potential drug-drug interaction. The average number and range of drug-drug interactions for these participants was 3.9 (1-8). 45% and 60% of participants were at risk of having drug-disease or drug-age interactions, respectively. In total, 87 potential instances of misuse in nineteen participants were documented.

Because the majority of sleep medications contain doxylamine or diphenhydramine, both of which are listed on the Beers List as unsafe medications for older adults, it was difficult for older adults to select a sleep medication that would be considered safe for them to take. Many older adults did note some concerns about taking a sleep medication and stated that taking something to help them sleep would likely not be their first choice - stating they would try reading or having a cup of tea as an alternative. A few also recognized the potential for side effects such as dizziness or feeling hungover in the morning.

The highest instances of misuse occurred in the drug-drug interaction category for pain medications. No pain medications for acute use are listed on the Beers List although NSAIDs are listed for chronic use. Given that the scenario described an acute pain problem, NSAIDs were not included in the drug-age misuse category. During the walking interview, participants were more familiar with pain medications than sleep medications suggesting they are used more commonly. Most of the older adults had a "go to" pain medication that they usually used, and thus selected, based on past experience. Interviews also suggested, especially for pain medications, that many older adults equated the wide spread use of pain OTCs as a safety concern. Some possible, more "acute" side effects were noted with pain medications such as upset stomach, but rarely were more severe outcomes noted as possibilities (e.g. liver damage due to overuse of acetaminophen). Results show that although on an acute basis and given the lack of comorbidities or other medications, OTC pain medications may be considered safe, the biggest potential for misuse with this drug category occurs when pain medications are used with other prescription or OTC drugs.

There are several limitations to the study, including small sample size and lack of diversity in the population. Participants understood the scenario was hypothetical in nature; thus, nearly every participant made a drug selection, but many noted they would not pick out a medication without consulting their physician or pharmacist first, which may have resulted in an overestimation for misuse; it is possible the physician or pharmacist would deter the older adult from taking an OTC medication. Results are more generalizable to a group of people that would select a medication independently. Misuse of drug-disease occurrences may have been underestimated as the OARS is not fully inclusive of all possible disease states although it does cover a wide range and the most common diseases for older adults.

Findings reveal that many older adults may use an OTC medication that may not be safe for their age, with their other medications, their disease states, or might not follow or read label directions. Two of these types of misuse, usage (outside labeling guidelines) and drug-age (Beers List) are more transparent in nature, with the medication selected and how the person decides to take it either within or outside of recommended guidelines, whereas interactions between a medication and disease states and medication regimens are complex and may be more difficult for an older adult to determine on their own.

Conclusion

It is critical to inform older adults that "OTC" is not synonymous with "safe" medication. It is also critical to make older adults aware of resources that may be able to help them determine the safety of an OTC medication, such as a pharmacist who is an available and cost-effective resource.

Acknowledgments

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Highlights

- Types of OTC misuse include drug, disease, and age interactions, and excess usage.

- Our findings suggest that OTC misuse is common among older adults.

- It is critical to inform older adults that "OTC" is not synonymous with "safe".

- Older adults should seek out resources to help them make safe OTC decisions.

Article Synopsis

This article describes a research study using interviews to identify four potential types of over the counter drug misuse amongst older adults: drug-drug interaction, drug-disease interaction, drug-age interaction, and excessive usage. At least one instance of potential misuse was found in 95% of participants. 80% of participants selected an OTC that, if taken with their current prescription medication regimen, could cause a potential drug-drug interaction. The average number of drug-drug interactions for these participants was 3.9. 45% and 60% of participants were at risk of having drug-disease or drug-age interactions, respectively. In total, 87 instances of potential misuse were documented.

Table 1

Sleep and Pain Scenarios

Sleep Scenario	*Recently, you have been having (more) difficulty falling asleep or staying asleep. You are here at [pharmacy] to look for a medication that can help you sleep. Talk to me about how you would go about choosing a medication to help you sleep. No detail is too small and there are no right or wrong answers. Show me how you would go about choosing a medication to 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 [pharmacy] to look for a medication that can help you feel better. Talk to me about how you would go about choosing a medication to help you feel better. No detail is too small and there are no right or wrong answers. Show me how you would go about choosing a medication to help you feel better.*
Example Probes	• What clues or signs helped you to get to this aisle? • Why did you pick this particular medication? • What are you thinking about when you decided to pick this medication instead of the other ones?

The researcher alternated which scenario was asked first.

Table 2

Participant Demographic Characteristics

Demographic/Variable	Statistic
Age (SD)	75.7 (6.7)
Gender	
Male	5 (25%)
Female	15 (75%)
Ethnicity	
White/Caucasian	19 (95%)
African-American	1 (5%)
Education	
High School / GED	3 (15%)
Some College or Technical School	4 (20%)
College or Technical School Graduate	13 (65%)
Mean Number of Prescribers (Range)	2.1 (0 - 5)
Mean Number of Pharmacies (Range)	1.2 (1 - 3)
Mean Number of Medications (Range)	12.3 (5 - 28)
Overall Health Rating	Participants (%)
Poor	0 (0%)
Fair	3 (15%)
Good	7 (35%)
Very Good	7 (35%)
Excellent	3 (15%)
Health Conditions	Mean (SD)
Number of Conditions (out of 19)	4.1 (3.2)

[+]There were 7 missing values for disease presence, recorded here as "no"

Table 3

OTC Sleep and Pain Medication Selections

Sleep Medication	Number of Times Selected	Pain Medication	Number of Times Selected
Diphenhydramine 25mg	9	Ibuprofen 200mg	7
APAP 325mg / Doxylamine 6.25mg / Dextromethorphan 15mg	3	Naproxen 220mg	5
APAP 650mg / Doxylamine 12.5mg / Dextromethorphan 30mg	1	APAP 325mg	1
Melatonin 1.5mg) / Bromelain 20mg	3	APAP 500mg	3
Naproxen 220mg	1	APAP ER 650mg	1
None	3	Aspirin 81mg	1
Total	**20**	Camphor 3.1% / Menthol 16% / Methyl Salicylate 10%	1
		Trolamine 10% / Menthol 3.7% / Menthol 16%	1
		None	2
		Total	**22**[*]

[*]
Two participants selected 2 products

Table 4

OTC Sleep and Pain Medication Misuse

	Sleep		Pain	
Drug-Drug Interaction	Occurrences	Participants	Occurrences	Participants
C: Monitor therapy	11	6	30	11
D: Consider change	10	6	9	8
X: Contraindicated	1	1	0	0
Total	22	10 (50%)[*]	39	12 (60%)[*]
Drug-Disease Interaction	Occurrences	Participants	Occurrences	Participants
Glaucoma	5	5	0	0
Asthma	1	1	1	1
Hypertension	0	0	5	5
Bronchitis / Emphysema	0	0	1	1
Stomach Bleed	0	0	1	1
Total	6	5 (25%)[*]	8	6 (30%)[*]
Drug-Age (Beer's List)	Occurrences	Participants	Occurrences	Participants
Doxylamine	4	4	N/A	N/A
Diphenhydramine	9	9	N/A	N/A
Total	13	13 (65%)	0	0
Usage	Occurrences	Participants	Occurrences	Participants
Might exceed recommended daily dose	1	1	2	2
Might take medication more frequently than recommended	2	2	1	1
Total	3	2 (10%)[*]	3	3 (15%)

[*] Some participants had more than one instance of unsafe use