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## A Pilot Study of Decision Factors Influencing Over-the-Counter Medication Selection and Use by Older Adults

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### Abstract

**Background and Objectives:** Despite their availability without prescription, OTC medications pose a risk for significant harm for older adults due to higher likelihood of polypharmacy, drug interactions, and age-related physiological changes. The purpose of this study is to identify the individual decision factors that influence how older adults select and use over-the-counter medications.

**Methods:** A pilot study was conducted with 20 community-dwelling older adults. Older adults met the interviewer at a regional mass merchandise store where they were given both pain and insomnia standardized scenarios. Participants described how they would select and then hypothetically use a given medication to treat the problem described in the scenario.

**Results:** OTC medication selection and reported use were influenced by several person-level decision-making factors including: personal beliefs/knowledge about OTCs, assessment of the ailment, and medical constraints.

**Conclusion:** The findings from this investigation provide direction for interventions to address unsafe OTC medication selection by older adults.

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Conflict of Interest  
None.

## Keywords

safety; pharmacy; older adults

## Introduction

There are over 300,000 individual over-the-counter (OTC) products available in the United States (US) today.<sup>1</sup> Adults aged 65 years and older account for 30% of OTC medication use despite making up only 13% of the US population.<sup>2</sup> Almost half of all older adults use an OTC medication daily or weekly.<sup>3</sup> Despite being available without prescription, these medications pose a risk for significant harm due to potential interactions with other medications, age, and medical conditions.<sup>2,4</sup> Older adults are particularly vulnerable to these harms, with one national survey finding that of the older adults who were at risk for a major drug-drug interaction, half were due to use of an over-the-counter medication.<sup>3</sup>

Older adults may not know the risks of using OTC medications at the time of purchase or use. They may perceive that OTC medications are safe, too weak to cause problems, or unlikely to cause adverse effects.<sup>5–11</sup> Consequently, prior studies report high rates of older adult selection of OTC medications that are potentially inappropriate for them.<sup>12–17</sup>

Understanding older adults' OTC decision making behavior is critical to the design of consumer-oriented interventions to improve the safe and effective use of OTC medications by older adults.<sup>13,18</sup> Existing research on OTC medication decision making has focused on individual-level characteristics that influence older adults' perceptions of OTC safety and contribute to the selection and use of OTCs (e.g., literacy, demographics, attitudes and beliefs, confidence, knowledge, and age). A limitation of this work is it was primarily conducted through laboratory experiments,<sup>13,19,20</sup> survey questionnaires,<sup>21,22</sup> or interviews.<sup>5,13</sup> Missing from the literature is an understanding of decision making as it occurs "in the moment" in the place where OTC decisions are often made: the OTC aisles. Because OTC purchases are made in the "real world," it is critical to explore how decision making takes place in this naturalistic environment. A pilot study was conducted in order to explore older adults' decision making about the selection and use of OTCs in a setting in which OTCs are often purchased, a community pharmacy located inside a regional mass market chain store.

## Methods

A convenience sample of 20 community-dwelling older adults was recruited. Eligible participants were adults, aged 65 years or more, who had used an OTC in the past and were able to travel to the study site, a local pharmacy. Participants were recruited through presentations, newsletters, and a health fair at two south-central Wisconsin senior centers and an older adult social club.

Data were collected at a regional mass merchandise chain store in south-central Wisconsin. The pharmacy department was sectioned off from the rest of the departments and contained several short OTC medication aisles and a patient waiting area. Longer OTC aisles were located outside the pharmacy department. Pain and sleep medications, along with cough/

cold and allergy medications, were located in an aisle outside the pharmacy. Signage for some categories of OTC medications was located on the endcap of each aisle.

## Interviews

Participants were greeted at the store entrance by the researchers and provided with two standardized scenarios—one using pain as the focal problem and the other using sleeplessness. Participants were then asked to show and tell how they would hypothetically address the health issue in each scenario (Table 1). This portion of the interview was conducted with an interviewer and a note-taking observer. As participants navigated the store displays and made their choices, the interviewer occasionally asked questions such as: “What were you thinking about when you decided to pick this medication instead of the other ones?” Interview questions were guided by the Systems Engineering for Patient Safety (SEIPS) 2.0 work system model.<sup>23</sup> Questions and probes explored each component of the work system (person, tasks, tools/technology, organization, and environment) and how they influenced OTC selection and use. Probes were designed to elucidate what factors were important to the participant when making OTC decisions from the moment they walk into the store until they confirm their OTC selection. The observer recorded where the participant walked, the direction of their general gaze (e.g. looking up and down the shelf), and when they pointed to, picked up, or put down a medication.

During the second portion of the interview, questions focused on how (e.g. dose and duration) and why they would take the medication they chose, knowledge of OTC medication risk, and confidence selecting OTCs. Interviews were audio recorded and photographs of the selected medications were taken.

Interviews lasted approximately 45 minutes and took place between October 2014 and January 2015. Participants were compensated \$25 for their time. The study was approved by the Institutional Review Board at the University of Wisconsin–Madison.

## Analysis

Audio recordings were transcribed and observational notes were added in brackets to the transcripts (e.g. [participant picks up Tylenol PM]). Data were analyzed in NVivo 10 using an inductive approach with descriptive coding by one researcher, JS.<sup>24</sup> Detailed and descriptive codes were then grouped into higher level themes. Individual codes and emerging themes were then brought to members of the research team for review and discussion of structure and minor adjustments were made for clarification. While the overall approach of the research was to explore the entire work system of the patient, the research team was struck by the robustness of codes related to person-level decision factors that influenced the selection of OTCs.

## Results

### Participant Characteristics

Twenty older adults ranging in age from 66 to 89 participated in the study. The sample was 75% female, 95% White (non-Hispanic) and 5% Black or African American. Sixty-five

percent had completed college or technical school. Participants self-rated their health as poor (0%), fair (15%), good (35%), very good (35%), and excellent (15%).

### **Decision-making Factors Associated with Selection and Use of OTC Medications**

During the simulated OTC decision task, participants' OTC medication selection was influenced by multiple factors including beliefs/knowledge about OTC safety, assessment of ailment, medical constraints, cost, and accessibility. This manuscript will explore in depth three factors that are unique to OTC selection and use: beliefs/knowledge, assessment of ailment, and medical constraints. OTC beliefs/knowledge fell on a continuum from viewing OTCs as relatively "safe" (i.e. they have no or limited side effects) to viewing them as "unsafe" (i.e. they should be used with caution). OTC selection and use were also influenced by how participants perceived the urgency of their ailment. "Low urgency" ailments were perceived as less urgent, short term, and less severe compared to "high urgency" ailments that were described as chronic or severe. Lastly, medical constraints also appeared to be a factor in OTC selection and use. At one end of the continuum were participants with few or no comorbidities who use few or no medications. At the opposite end of the spectrum were participants who reported multiple comorbidities or medications that could potentially interact with OTCs. Table 2 shows the range of each factor, demonstrates how each relates to the selection and use of OTC medications and provides examples.

### **Interaction of Decision-Making Factors**

These decision-making factors may interact with each other to influence choices surrounding the selection and use of OTC medications. For instance, a person's belief that all OTCs are safe may lead them to place little emphasis on their health constraints. In one instance, when asked if a selected OTC would be safe to take with his other medications one participant responded, "I generally consider that off-the-shelf medications are compatible with everything else that I take."

In another case, a person might know that their medical condition could interact with OTC medications but, based on their past experience of not having previous noticeable side effects, assumed their current OTC regimen is safe.

Greater awareness of potential OTC safety concerns may have been brought about by a participant having a high level of medical constraints. For instance, the participant who had the most knowledge about the potential for OTCs to be unsafe had several comorbidities and was taking many prescription drugs. She was aware that while taking prescription pain medications it would be unsafe to take any additional OTC pain medications without talking to her doctor. In her case, ailment urgency was irrelevant as other factors took precedence.

### **Discussion**

This study is one of the first to explore decision making surrounding the selection and use of OTC in a naturalistic setting in which OTCs are often purchased, a community pharmacy within a mass merchandise chain store.

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Leventhal's Common Sense Model (CSM) may provide us with insights into why knowledge/beliefs, urgency of the ailment, and medical constraints influence the selection and use of OTCs.<sup>25</sup> In this model, Leventhal describes how each person has unique, common sense, mental representations of their health which can influence how people make health care decisions. The representations guide coping behaviors, acting as motivators to engage in self-care or seek professional treatment e.g., use OTC medications, check container labels, or seek a pharmacist's expertise. They help a person determine if a decision may be safe or unsafe e.g., presume OTCs are safe, and to interpret the consequences of a treatment decision e.g., whether to worry about side effects.

The CSM demonstrates the importance of understanding patient mental representations of OTC safety and the influence these representations may have on selection and use. In one study, Holden et al. empirically derived two personas of consumers with differing mental representations of OTC safety: 1) "the habit follower" who frequently purchased OTC medications and considered them generally safe and 2) "the deliberator" who was more likely to weigh their options and consider alternatives to OTC medications.<sup>13</sup> Given that patients have unique representations and these representations are based upon a wide variety of influencing factors, some not medically sound, it is challenging to identify solutions that address safe OTC selection and use for a diverse population.

Donovan et al. suggested that representations are more likely to change when there is tension between current representations and new information or experiences.<sup>26</sup> For example, if a person who has taken NSAIDS without incident learns of a friend with a bleeding ulcer attributed to NSAID use, they may be more receptive to new "replacement" information.

Supporting decision making has also been explored through interventions such as improved OTC medication labeling<sup>27</sup> and behavior change interventions to enhance OTC consultations between pharmacy personnel and consumers.<sup>28</sup> One research project, in collaboration with a mass-merchandise chain pharmacy, that is currently underway by authors is the redesign of the OTC aisles to improve medication safety. This intervention is designed to challenge incorrect representations about OTC safety and provide access to a pharmacist who can help answer questions in a supportive environment.<sup>29,30</sup> By speaking with patients directly, pharmacists can understand the patient's assessment of their ailment, medical constraints, and knowledge/beliefs in order to tailor a recommendation specific to that person and advise them appropriately.

### Limitations

Limitations of this study include the small sample size of 20 older adults. About 85% of older adults completed some education beyond high school. While a limitation, the lack of knowledge surrounding the safe use of OTC makes the results even more startling.<sup>12</sup> Second, the scenarios during interviews were hypothetical. All the participants could relate to the pain scenario, but not all had experienced issues with insomnia or considered it an issue that would require treatment. In lieu of a hypothetical scenario, subsequent studies using this method should consider having a participant select a medication that is relevant to an issue that they have personally experienced to ensure a more realistic assessment. Third, this study focused on three predominant decision factors that related specifically to OTC

selection and use, but given the pilot nature of the method as well as small sample size, it is possible this method did not elucidate all person-level factors that could have impacted OTC selection and use.

## Conclusion

OTC medications pose a risk for significant harm for older adults. OTC selection and use may be influenced by a person's perceptions of whether medications are safe or unsafe, their assessment of their ailment, and their medical complexities. Interventions addressing OTC medication misuse in older adults should take into account the unique and variable mental representations of OTC safety that exist.

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## References

1. National Council on Patient Information and Education. Use your over-the-counter medicines safely. <http://www.bemedwise.org/medication-safety/otc-medicine-safe-use>. Published 2017. Accessed November 28, 2017.
2. National Council on Patient Information and Education. Medicaton management for older adults. <http://www.bemedwise.org/medication-safety/medication-therapy-management-for-seniors>. Published 2017. Accessed November 28, 2017.
3. Qato DM, Alexander GC, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *JAMA*. 2008;300(24):2867–2878. [PubMed: 19109115]
4. U.S. Food & Drug Administration. <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143566.htm>. Published 2017. Accessed November 28, 2017.
5. Hanna LA, Hughes CM. Public's views on making decisions about over-the-counter medication and their attitudes towards evidence of effectiveness: a cross-sectional questionnaire study. *Patient Educ Couns*. 2011;83(3):345–351. [PubMed: 21440405]
6. Roumie CL, Griffin MR. Over-the-counter analgesics in older adults: a call for improved labelling and consumer education. *Drugs & aging*. 2004;21(8):485–498. [PubMed: 15182214]
7. National Council on Patient Information and Education. Attitudes and beliefs about the use of over-the-counter medicines: a dose of reality. [http://www.bemedwise.org/documents/final\\_survey.pdf](http://www.bemedwise.org/documents/final_survey.pdf). Published 2002. Accessed November 30, 2017.
8. Indermitte J, Reber D, Beutler M, Bruppacher R, Hersberger KE. Prevalence and patient awareness of selected potential drug interactions with self-medication. *Journal of clinical pharmacy and therapeutics*. 2007;32(2):149–159. [PubMed: 17381665]

9. Wilcox CM, Cryer B, Triadafilopoulos G. Patterns of use and public perception of over-the-counter pain relievers: focus on nonsteroidal antiinflammatory drugs. *J Rheumatol.* 2005;32(11):2218–2224. [PubMed: 16265706]
10. Ngo SN, Stupans I, Leong WS, Osman M. Appropriate use of non-prescription ibuprofen: a survey of patients' perceptions and understanding. *The International journal of pharmacy practice.* 2010;18(1):63–65. [PubMed: 20405598]
11. Wawruch M, Kuzelova M, Foltanova T, et al. Characteristics of elderly patients who consider over-the-counter medications as safe. *International journal of clinical pharmacy.* 2013;35(1):121–128. [PubMed: 23104621]
12. Stone JA, Lester CA, Aboneh EA, Phelan CH, Welch LL, Chui MA. A preliminary examination of over-the-counter medication misuse rates in older adults. *Research in social & administrative pharmacy : RSAP.* 2017;13(1):187–192. [PubMed: 26853833]
13. Holden RJ, Srinivas P, Campbell NL, et al. Understanding older adults' medication decision making and behavior: A study on over-the-counter (OTC) anticholinergic medications. *Research in Social and Administrative Pharmacy.* 2018.
14. Kaufman DW, Kelly JP, Rosenberg L, Anderson TE, Mitchell AA. Recent patterns of medication use in the ambulatory adult population of the United States: the Sloane survey. *JAMA.* 2002;287(3):337–344. [PubMed: 11790213]
15. Larson AM, Polson J, Fontana RJ, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. *Hepatology.* 2005;42(6):1364–1372. [PubMed: 16317692]
16. Nourjah P, Ahmad SR, Karwoski C, Willy M. Estimates of acetaminophen (Paracetomol)-associated overdoses in the United States. *Pharmacoepidemiol Drug Saf.* 2006;15(6):398–405. [PubMed: 16294364]
17. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *Jama.* 2003;289(9):1107–1116. [PubMed: 12622580]
18. Albert SM, Bix L, Bridgeman MM, et al. Promoting safe and effective use of OTC medications: CHPA-GSA National Summit. *The Gerontologist.* 2014;54(6):909–918. [PubMed: 24846884]
19. Johnson MM, Drungle SC. Purchasing over-the-counter medications: the influence of age and familiarity. *Exp Aging Res.* 2000;26(3):245–261. [PubMed: 10919069]
20. Stephens EC, Johnson MMS. Dr. Mom and Other Influences on Younger and Older Adults' OTC Medication Purchases. *Journal of Applied Gerontology.* 2000;19(4):441–459.
21. McDonald DD, Amendola MG, Interlandi E, et al. Effect of reading additional safety information on planned use of over-the-counter analgesics. *Public Health Nurs.* 2007;24(3):230–238. [PubMed: 17456124]
22. National Council on Patient Information and Education. Uses and attitudes about taking over-the-counter medicines: Findings of a 2003 national opinion survey. [http://www.bemedwise.org/survey\\_summary\\_survey\\_findings.pdf](http://www.bemedwise.org/survey_summary_survey_findings.pdf). Published 2003. Accessed November 30, 2017.
23. Holden RJ, Carayon P, Gurses AP, et al. SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics.* 2013;56(11):1669–1686. [PubMed: 24088063]
24. Miles MB, Huberman AM. Qualitative data analysis : an expanded sourcebook. Thousand Oaks: Sage Publications; 1994.
25. Leventhal H, Phillips LA, Burns E. The Common-Sense Model of Self-Regulation (CSM): a dynamic framework for understanding illness self-management. *Journal of behavioral medicine.* 2016;39(6):935–946. [PubMed: 27515801]
26. Donovan HS, Ward SE, Song MK, Heidrich SM, Gunnarsdottir S, Phillips CM. An update on the representational approach to patient education. *Journal of nursing scholarship : an official publication of Sigma Theta Tau International Honor Society of Nursing.* 2007;39(3):259–265.
27. Bix L, Bello NM, Auras R, Ranger J, Lapinski MK. Examining the conspicuousness and prominence of two required warnings on OTC pain relievers. *Proceedings of the National Academy of Sciences of the United States of America.* 2009;106(16):6550–6555. [PubMed: 19332798]

28. Seubert LJ, Whitelaw K, Hattingh L, Watson MC, Clifford RM. Development of a Theory-Based Intervention to Enhance Information Exchange during Over-The-Counter Consultations in Community Pharmacy. *Pharmacy* (Basel, Switzerland). 2018;6(4).
29. Chui MA, Stone JA, Holden RJ. Improving over-the-counter medication safety for older adults: A study protocol for a demonstration and dissemination study. *Research in social & administrative pharmacy : RSAP*. 2017;13(5):930–937. [PubMed: 28130022]
30. Reddy A, Lester CA, Stone JA, Holden RJ, Phelan CH, Chui MA. Applying participatory design to a pharmacy system intervention. *Research in social & administrative pharmacy : RSAP*. 2018.

**Table 1**

## Sleep and Pain Scenarios

<b>Sleep and Pain Scenarios</b>	
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.
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.

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**Table 2**

Decision making factors and section and use outcomes.

Decision Making Factor	Continuum	Selection Outcomes and Representative Example	Use Outcomes and Representative Example
	<b>Safe</b>	<ul style="list-style-type: none"> <li>Selection based on personal preference (e.g. taken historically, caplets vs. tablets), not safety, since all OTCs are generally safe</li> </ul>	<ul style="list-style-type: none"> <li>May exceed dosing and duration guidelines unless a negative reaction occurs</li> <li>May read guidelines but may not adhere to them</li> </ul>
OTC Medication Safety Knowledge/Belief	OTCs are all generally safe	<i>Well, I know that medications can have side effects, but I wouldn't think these [OTCs] would.</i>	<i>Again, it says two morning and evening, and on one of those I might take three.</i>
	<b>Unsafe</b>	<ul style="list-style-type: none"> <li>Selection guided by preference not to take any OTC or exhibits caution (e.g. seeks information) if OTC is deemed necessary</li> </ul>	<ul style="list-style-type: none"> <li>May not use OTC as first choice. If used, stays within or below dosing/duration guidelines.</li> <li>May consult a health care professional if the issue continued.</li> </ul>
	Not all OTCs are safe	<i>It says, 'warning, do not use with any other product containing diphenhydramine even when used on the skin.'</i>	<i>I think even though it says take two, again, because of my stature, I would probably take one. And see how, see what effect that has.</i>
Assessment of Ailments	<b>Low Urgency</b>	<ul style="list-style-type: none"> <li>Selection may prioritize non-medication alternative before OTC medication.</li> </ul>	<ul style="list-style-type: none"> <li>May start with low dose or space doses further apart.</li> </ul>
	Ailment is short term and/or less severe	Ex: Alternative treatments include resting, using ice, or going for a walk	<i>I'd probably take half the dose and see if that helped, and then, if the pain persisted, I would take the other one</i>
	<b>High Urgency</b>	<ul style="list-style-type: none"> <li>Selection prioritizes relief, potentially at the expense of short- and long-term risk</li> </ul>	<ul style="list-style-type: none"> <li>May be willing to exceed dosing/duration guidelines to get relief.</li> </ul>
	Ailment is severe and/or chronic in nature	<i>I [made that decision] on my own... one having possible side effects of liver damage and one having possible side effects of bleeding, so that was my own desperate solution. When you're in pain, and it's gone on, you do not think rationally.</i>	<i>I can tell when I get up. Before the back surgery, I could tell the moment I stood, tried to stand up, how bad it was that day...Just use three and give us all a rest</i>
Medical Constraints	<b>Absent</b>	<ul style="list-style-type: none"> <li>Selection not restricted when few/no comorbidities and medications exist.</li> </ul>	<ul style="list-style-type: none"> <li>May exceed dosing/duration guidelines if OTC will not make health conditions worse or interact with other medications</li> </ul>
	Few/no comorbidities and use few/no medications.	Ex: If particular health condition or medication was not specifically listed on the box, medication considered safe to take.	Ex: Participant does not need to review box information regarding safe allowances of drugs that can be in both prescription and OTC medications
	<b>Present</b>	<ul style="list-style-type: none"> <li>Selection limited by potential disease and drug interactions.</li> </ul>	<ul style="list-style-type: none"> <li>May be cautious of concurrent overuse with other medications</li> </ul>
	Multiple comorbidities and/or use many medications	<i>I'd have to think about the interaction with medications I'm currently taking... I don't want to take anything anymore than I have to.</i>	<i>[After the heart attack]... I do look at the milligrams. You know, I'm a little bit conscious of it...I didn't use to pay attention.</i>