Safeguarding Older Adults From Inappropriate Over-the-Counter Medications: The Role of Community Pharmacists

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Purpose of the Study: To elicit the thought process or mental model that community pharmacists use when making recommendations on over-the-counter (OTC) medications to older adults and to elicit the current practices of community pharmacists in providing information, advice, and counseling to older adults about potentially inappropriate OTC medications. Design and Methods: Three separate focus groups with pharmacists were conducted with 5 to 8 pharmacists per group. A vignette about an elderly woman seeking an OTC sleep aid was used to elicit information that pharmacists seek to establish when making a recommendation. Focus groups were recorded, transcribed verbatim, and analyzed for themes using the initial and focused coding methods of grounded theory. Results: Community pharmacists’ mental models were characterized by 2 similarities: a similarity in what community pharmacists seek to establish about patients and a similarity in when community pharmacists seek to establish it—the sequence in which they try to learn key details about patients. It was identified that pharmacists gather specific information about the patient’s medication profile, health conditions, characteristics of the problem, and past treatments in order to make a recommendation. Community pharmacists recommended behavioral modifications and seeing their physician prior to recommending an OTC sleep aid, primarily due to medication safety concerns. Implications: Pharmacists can play a key role in assisting older adults to select and use OTC medications.

Key Words: Over the counter medication, Community pharmacy, Older adult, Medication counseling, Medication safety

Background

Older adults are the largest consumers of over-the-counter (OTC) medications (Qato et al., 2008), and the number of medications available over the counter without a prescription is rapidly increasing (Francis, Barnett, & Denham, 2005), with over 300,000 OTC drug products available today (U.S. Food and Drug Administration, 2012). The typical older adult takes an average of nearly four OTC medications along with nearly four prescribed medications. Taken together, 25% of older adults are on a combination of 10 or more OTC and prescription medications. This is concerning given the documented widespread polypharmacy and potentially inappropriate medication (PIM) use in this population (American Geriatrics Society,
A growing body of research suggests that inappropriate medication use has been linked with increased likelihood of hospital admission (Klarin, Wimo, & Fastbom, 2005; Lau, Kasper, Potter, Lyles, & Bennett, 2005), ambulatory or emergency care visits (Schmader et al., 1997), increased health care costs (Fu et al., 2007), inadequate blood pressure control (Schmader et al., 1997), and reduced health status (Fu, Liu, & Christensen, 2004). The health and economic consequences of unsafe medication use in older adults has made medication safety a “priority area for national action” (Agency for Healthcare Research and Quality, 2003), and a focus of Healthy People 2020 (U.S. Department of Health and Human Services, 2013). Given the documented prevalence and health consequences of PIM use from prescribed medications and the availability and significance of use of OTC medications, it is likely that OTC medications may also result in unsafe and poor outcomes for patients.

Although use of OTC medications is considered safe in the general population, many commonly purchased OTC medications contain ingredients deemed to be potentially inappropriate in older adult populations. Diphenhydramine, for example, is included in numerous OTC products marketed for a range of symptoms (allergies, cough and cold, sleep aids). This is particularly concerning because diphenhydramine has been shown to impair cognition, cause dizziness, and may increase risk of falling (The American Geriatrics Society 2012 Criteria Update Expert Panel, 2012). OTC analgesics such as ibuprofen may increase blood pressure, may reduce the effectiveness of antihypertensive medications (Sudano et al., 2012), and may cause kidney damage in patients with congestive heart failure and renal disease (Andersen et al., 2002).

Health care providers are often unaware of OTC medication use in their patients (Sleath, Rubin, Campbell, Gwyther, & Clark, 2001), and patients are often unaware of symptoms of potential medication side effects (Wilcox, Cryer, & Triadafilopoulos, 2005). Furthermore, lack of awareness about the use of OTC medications in patients may lead to duplication of therapies and potentially dangerous overdosing. In fact, the Centers for Medicare and Medicaid Services singles out several medications for drug utilization review specifically because of their availability over the counter and potential for therapeutic duplication (e.g., antihistamines, nonsteroidal anti-inflammatory drugs, H2 blockers, proton-pump inhibitors; Andersen et al., 2002; Gandhi et al., 2003). In the current system where potentially unsafe OTC medications can be purchased without a physician’s knowledge, and where electronic medication information does not include OTC medications, the availability of pharmacists at the point of sale of OTC medication has great potential for guarding seniors from these potentially harmful drug exposures.

Community retail pharmacists are considered to be among the most accessible and trustworthy health care professionals. As widely recognized medication experts, pharmacists can play a major role in ensuring appropriate OTC medication use in older adults. Eighty percent of Americans report they would buy a particular OTC medicine based on their pharmacist’s recommendation, or not purchase a specific OTC medication if their pharmacist advised against it (82%) (NCPIE, 2003).

Due to the prevalence of unsafe OTC medication use by older adults, and the medication expertise of pharmacists, an important question emerges: How do pharmacists assist patients in making safe OTC medication choices? Therefore, the overall objective of our study is to explore/understand how pharmacists can help older adults make OTC decisions. The specific objectives were as follows:

- To elicit the thought process or mental model that community pharmacists use when counseling older adults on OTC medications
- To elicit the current practices of community pharmacists in providing information, advice, and counseling to older adults about potentially inappropriate OTC medications

Design and Methods

Sample

Pharmacists were recruited to participate in one of three 90-min focus group discussions. The purposive sample consisted of community pharmacists who were recruited by phone at the pharmacies where they worked. Pharmacies were chosen nonrandomly from a directory of registered pharmacies in three medium to large cities in Wisconsin. Currently employed, full-time community pharmacists who interacted directly with customers in their normal day-to-day pharmacy work were eligible. Prospective participants were offered $150 in cash as an incentive to participate. This recruitment strategy, as well as a consent form that all participants read and signed before each focus group commenced, were approved by the Social
and Behavioral Sciences institutional review board of the University of Wisconsin–Madison.

A total of 21 community pharmacists were recruited and participated in one of three focus groups. Ten of the pharmacists were women; 11 were men. Pharmacists at all stages of their careers were represented. An attempt was made to ensure that each focus group consisted of pharmacists who practiced in different types of pharmacies. Therefore, pharmacists were recruited who worked in chain pharmacies, health system pharmacies, and independent pharmacies. Table 1 shows the recruitment results.

Study Design

Focus groups were chosen as the data collection method for this research in order to discover the broad range of factors that influence community pharmacists’ ability to counsel older patients on the use of OTC medications during a face-to-face interaction in the pharmacy. Focus groups were used to bring community pharmacists together to discuss these issues in depth and to use the interaction between group participants to generate insights on the barriers community pharmacists face in counseling older adults effectively. The focus groups were moderated by a researcher from the University of Wisconsin Survey Center (K. D. Croes) and attended by the principle investigator (M. A. Chui). Focus groups were held in each of three locations in southern Wisconsin. All focus groups took place during July of 2011.

A questioning route (Krueger & Casey, 2009) was developed and was administered at all three groups. Each group was first asked to describe the kind of pharmacy they work in with a focus on how they interact with customers regarding OTC medications. After this introduction, participants were presented with a vignette aimed at eliciting the thought processes of community pharmacists as they counsel older patients on OTC medication issues. Other questions included asking participants to list high-risk OTC medications for older adults, discussing the pharmacists’ knowledge of the Beers Criteria as well as barriers and solutions to using the Beers Criteria. This paper focuses on the first of five main questions in the questioning route—the vignette.

Vignettes are used in focus groups and other social research methodologies to explore attitudes, knowledge, and behaviors by way of research participants’ reactions to a hypothetical scenario (Schoenberg & Ravdal, 2000). Use of a vignette was intended to make it possible for pharmacists to speak in concrete ways about the questions they would ask of the customers in the vignette, actions they would take, and assumptions they might make. A vignette would also be an indirect way to discover how knowledgeable participants were about potentially unsafe medications for older adults.

Two versions of the vignette were used, the first at Location A and a revised version at Locations B and C. In the first version, a man seeks an OTC sleep aid for his wife who is not present at the pharmacy. The intention of this version was to see whether pharmacists would ask about the wife’s age and whether this would lead participants to talk specifically about inappropriate medications and the potential risks of OTC sleep aids for older adults. In a review of Location A’s responses; however, it was found that participants did not dwell on the issue of the wife’s age, and instead focused on whether they might violate patient confidentiality by speaking with the man about his wife. The study team therefore revised the scenario for use in the latter two groups, specifying that the couple was older and arriving at the pharmacy together, with the idea that this would allow focus group participants to reveal what they knew about inappropriate medications more quickly.

The question was as follows:

I’m going to give you a scenario that might occur in your pharmacy. After I give you the scenario, I’ll ask you to talk through how you would handle the situation.

<table>
<thead>
<tr>
<th>Focus group location</th>
<th>Pharmacy type</th>
<th>Group totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chain</td>
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<tr>
<td>Location A</td>
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<td>1</td>
</tr>
<tr>
<td>Location B</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Location C</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Pharmacy type totals</td>
<td>11</td>
<td>4</td>
</tr>
</tbody>
</table>
[ASKED AT LOCATION A] In this scenario, a man comes into your pharmacy. He's looking for a medication for his wife, who has been having trouble sleeping. The man asks you for a recommendation for an OTC drug.

[ASKED AT LOCATIONS B AND C] In this scenario, an older couple comes into your pharmacy. The wife is having trouble sleeping. She asks you for a recommendation for an OTC drug.

Please describe what your thought process would be in this scenario as well as what you would do and say in this situation.

All three focus groups were audio recorded with the permission of the participants. Verbatim transcripts of the audio recordings were prepared.

Analysis

Transcripts were coded using the initial and focused coding methods of grounded theory (Charmaz, 2006). Initial coding was chosen because of the open-ended nature of the question following the vignette (“Please describe what your thought process would be in this scenario as well as what you would do and say in this situation.”). Each response of the focus group participants was given a label such as “pharmacist would first ask patient in the vignette what medications she is taking” or “pharmacist would ask patient in the vignette about possible behavioral causes of her sleeplessness.” The second-cycle coding method focused coding was then used to refine the initial codes and to develop categories and subcategories. The resulting coding framework was then reapplied systematically to all focus group transcripts. Twenty-nine different codes were identified using this method (K. D. Croes). All codes were reviewed by a second researcher (J. A. Stone) to check for fit between the coded section and code. Minor adjustments were made to the codes (e.g., wording of code and moving a code that was in a more general code to a more specific subcategory), but no considerable adjustments to content coded or the codes themselves were made. Codes were discussed until agreement was reached.

One objective of the present research was to discern whether community pharmacists share a common thought process or mental model in how they conceptualize the work of counseling older patients about OTC medications, specifically what type of information they gather and in what sequence. A mental model refers to a set of concepts and the associations among them (Smith-Jentsch, Campbell, Milanovich, & Reynolds, 2001). Thus, mental models are defined in terms of both content knowledge, and structure or sequence of that content knowledge. Mental models “help people to describe, explain, and predict events in their environments” (Mathieu, Heffner, Goodwin, Salas, & Cannon-Bowers, 2000, p. 274). In a pharmacy, a mental model allows a pharmacist to draw upon past experiences to anticipate events and formulate plans (Coderre, Mandin, Harasym, & Fick, 2003).

To explore this objective, the responses in which pharmacists identified information they would gather were coded for the sequence in which they were raised during the focus groups. The first response at each group was coded “1,” the second response was coded “2,” and so on. Items that were mentioned by two or more of the focus groups were retained. Next, the average of each sequence rank across the three groups was calculated: The lower a code’s average sequence rank, the earlier the response occurred on average. Items were then ordered from lowest sequence rank to highest sequence rank. Coded responses were collapsed into themes to discern a larger pattern. This method was used to explore if the topics that arose during the focus groups were suggestive of a particular sequence in which pharmacists gather different types of information to make an OTC recommendation. Therefore, we analyzed at the group level, but then combined the groups together to come up with the mental model. Themes surrounding the information pharmacists sought to establish as well as recommendations were explored using quotes from the transcripts.

Results

Descriptive Codes

The 29 identified codes were grouped into two overarching categories: The information pharmacists would seek to establish and the recommendations the pharmacist would make about the patient in the vignette.

“Would Seek to Establish”

Table 2 identifies codes in the “would seek to establish” category that occurred in more than one focus group and orders them by the sequence rank average. The display of qualitative data in tabular form is consistent with Miles and Huberman’s (1994).
Although not identical, the sequence in which the ideas in Table 2 were raised across the groups is similar and suggestive of a commonly held mental model. Community pharmacists’ mental models were characterized by two similarities:

- a similarity in what community pharmacists seek to establish about patients, and
- a similarity in when community pharmacists seek to establish it—the sequence in which they try to learn certain key details about patients.

Figure 1 represents the mental model the pharmacists described during the focus groups in terms of their goals and the information that pharmacists sought to obtain that goal. These goals will be explored in more detail below using specific examples from the focus groups.

### Goal 1: Assess Medication Profile

The first goal was to understand the medication profile to avoid recommending a drug that the patient had already taken that was ineffective. To gather this information, the pharmacists determined if the patient was one of theirs so that they would know if the pharmacy computer system could serve as a source of information for the patient’s medication profile or if they would need to rely solely on information from the patient.

“A Patient of Mine?”—Participants at all three groups stated that the first thing they wanted to know about the woman experiencing sleeplessness in the vignette is whether she is a patient of theirs. Knowing a patient, the participants elaborated, means ready access to the patient’s medication profile via the pharmacy computer system:

P11: I guess usually my first question to a patient is whether they’re a patient of mine or not because then I am likely to have access to patient’s medication profile.

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Avoiding a Medication That Has Already Been Tried.—Knowing a patient’s medication profile is necessary to avoid recommending a product that a patient has already tried without success:

P15: One of my questions I like to ask is what have you tried because, inevitably, you go out there, and you say, well, this is what I recommend [, and the patient will respond:] “Oh, I tried that. That don’t work.” . . . so that’s a very good question to start out with.

A participant who raised the issue of knowing the patient’s medication profile added that many OTCs are the same so it might be necessary to

<table>
<thead>
<tr>
<th>Theme</th>
<th>Lower level code</th>
<th>Sequence rank average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s medication profile</td>
<td>Is the patient in the vignette a patient of mine? (Because then I am likely to have access to patient’s medication profile.)</td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>I would like to see the patient’s medication profile (general mention)</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>To avoid recommending a drug the patient in the vignette has already taken that was ineffective</td>
<td>3.0</td>
</tr>
<tr>
<td>Physician care for condition</td>
<td>Has the patient seen a medical doctor for her sleeplessness?</td>
<td>4.0</td>
</tr>
<tr>
<td>Causes and characteristics of symptoms</td>
<td>As much as possible about the characteristics of the patient’s sleeplessness (history of the symptom, frequency, conditions of onset, etc.)</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>Poor “sleep hygiene” (because things like watching TV or reading in bed, napping, noisy sleeping environment, caffeine, etc. can contribute to sleeplessness)</td>
<td>8.3</td>
</tr>
<tr>
<td>Patient-specific causes of sleeplessness</td>
<td>Current drug regimen might be causing or contributing to the patient’s sleeplessness</td>
<td>10.0</td>
</tr>
</tbody>
</table>
avoid all the medications with a common active ingredient:

P34: My first question to her is going to ask if she’s been on anything, if she’s had anything yet so far, if she’s tried anything. There are so many over-the-counter medications that are really the same thing that, you know, just giving her one or the other that she hasn’t tried is probably the same thing.

**Goal 2: Establish if Patient Has Seen a Physician for the Condition**

Secondly, the pharmacists sought to gather information about whether or not they are under the treatment of a physician. This information was important because it helped them to further understand what, if any treatment that patient has received to date, and the pharmacists did not want to recommend something that would be contraindicated due to an existing condition. The examples below illustrate what this additional information might reveal.

**Continuing Care.**—In all three groups, after participants said they would try to establish the patient’s medication profile, someone volunteered that they would ask the patient whether she is
under the care of a medical professional such as
a medical doctor for the sleeplessness or other
health conditions. Whether the patient is under
the care of a physician reveals several issues. First,
it can help the pharmacist establish the medica-
tion profile:

P25: I guess I would ask them if they’ve talked with
their practitioner about it. And what their practi-
tioner recommended if they did talk to them?

Second, knowing about a patient’s medication
profile and whether a patient is under the care of a
physician can reveal more about health conditions
that might need to be considered:

P21: [I would ask about] health conditions, because
antihistamines are the most commonly prescribed
over-the-counter sleep aid – and, with the elderly,
we have a lot of potential health conditions that
could interact with the antihistamine.

And finally, knowing whether a patient has
seen a medical professional for the condition can
provide pertinent information not only about the
patient’s medication profile but also about the
patient’s own strategy to resolve the problem:

P34: First, I want to know if she’s tried anything,
if the doctor has given her anything. Sometimes
they’ve been on prescription medicine. You know,
the doctor stopped giving it to them. Now they
want an over-the-counter.

P26: What have they tried, and have they talked
with their doctor about the problem yet, or are they
just trying to get some help before going to the doc-
tor? A lot of times it’s an elderly patient who says,
“Well, if I have to go to the doctor, then it’s going
to cost me because I have to pay, you know, for a
doctor’s visit.”

Goal 3: Identify Characteristics and Causes of
the Symptoms

After gathering information about the patient
as a whole by understanding the medication profile
and the patient’s medical conditions, the pharma-
cist shifted into gathering more specific information
about the issue the patient sought treatment for.

Learning About the Condition.—After the idea
of contact with a medical professional about the
condition was raised, participants at all three focus
groups then spoke of the need to learn as much
as they could about the nature of the condition of
sleeplessness: first onset, duration, frequency, char-
acteristics, and so forth.

P16: In that situation, a couple – I would ask the
patient for permission to – if I could ask them some
questions about what they’re suffering from. I’d
ask them how long it’s been a problem for them, if
this is something that’s been a chronic problem or
something that just developed, and if they have a
discernible cause for it.

P24: I also like to get them to characterize their
problem a little better. Is it difficulty falling asleep,
staying asleep? Is it every night? Did it just start?
Did you just have a death in the family or some-
thing? Is it the circumstances? I need to know more
about the problem.

Sleep Hygiene and Other Behavioral Factors
Affecting Sleep.—All three groups also explored
the range of behavioral and “sleep hygiene” factors
that can affect sleep. Finding out whether there
could be a behavioral cause to a patient’s sleepless-
ness is a way to identify the appropriate OTC sleep
aid or possibly avoid an OTC sleep aid altogether:

P31: I question on their eating habits also, what
time they eat at night, what they eat at night, cer-
tain type of foods. Also of what their exercise, do
they do any exercise? Have they tried taking a
walk maybe after supper? Do they nap a lot, [they
might say:] “I got up, and I had my coffee. I read
the paper. I took a nap. I got up, watched TV, had
lunch, took a nap.” You know, and, okay, [I might
say in response] “That’s why you’re not sleeping at
night because you slept the whole day away.”

Working With the Caregiver.—At Location B,
participants commented on how they would try to
learn more about the sleeplessness of the woman
in the vignette by corroborating information with
her husband:

P24: I think if they’re coming in as a couple, and
they’re both willing to discuss it, I might ask . . .
some questions of each of them to see if they both
actually see the same problem or if some patient’s
perception isn’t really what the other people sees.
You know, [the husband might say:] “You don’t
really have trouble falling asleep, honey. You’re just
waking up, you know, an hour and a half later.”

MODERATOR: And why you would be asking
them?

P24: I’m still gathering information. You never
have too much information, and maybe from talk-
ing to the first patient, and I’m not confident that
that they’re actually giving me a clear picture. I’d
like a little corroboration.

P22: And it might be like something like rest-
less legs, and so the spouse might notice that their
legs are going all night long, and the patient themselves might not realize that's what's keeping them awake. So you could pull some information from the other person.

_Corroboration Might Also Be Helpful When the Patient Has a Cognitive Deficit_

P28: I think it’s good that both of them are there together . . . in case there is a deficit in one of the partners . . . one usually assumes the caretaker role, whether it’s the spouse, the husband or the wife. And I guess I would really rely more on that person. But as we age, cognitive impairment is just something that’s much more likely to be a factor. So even remembering to take the medication could be an issue, so it’s important to have family involvement in general.

**Goal 4: Understand the Relationship Between Medication Profile and Causes of Condition**

Lastly, the pharmacists came full circle and once they had gathered information about the condition went back to the medication profile to examine if the physician may have recommended a medication for the issues in the past and if other drugs the patient is taking may be contributing to her sleeplessness.

_Are Other Medications Causing the Sleeplessness?—_Another reason to know a patient’s medication profile is to determine whether medications are causing the sleeplessness:

P24: Is it something that they’re taking that’s causing the difficulty? Is it the drug itself? Is it the time of administration – the drug kicking in, the drug wearing off?

P31: If you narrow down the medications that they’re on, certain ones you can maybe talk to them about taking earlier in the day because they might cause the insomnia. You know, you find out if they’re on prednisone, when they’re taking the prednisone.

**Recommendations Made by Pharmacists**

After pharmacists had discussed the information that they would need to gather from the patient and/or caregiver, they talked about how they would use that information to make a recommendation. In the case of this vignette, none of the recommendations at any of the groups included advice to take a sleep aid on the Beers Criteria.

Specific Recommendations Regarding the Vignette

Participants at all groups brought up the anticholinergic side effects of OTC sleep aids for older adults.

P12: [With the] older patient population too, I suppose there’s situations that I avoid recommending over-the-counters, which generally consist of antihistamine type medications, would be people with certain types of incontinence or certain types of glaucoma shouldn’t be using those medications either

P21: I basically try and stay away from all anticholinergic type antihistamines with anyone who is elderly.

MODERATOR: Why is that?

P21: Well, because they end up with a hangover. It can make them what I call squirrelly. So I normally try and go with something gentler . . . Everyone seems to want to grab for the Tylenol PM because that’s the one that’s on the TV, and sometimes I just don’t think that’s the best bet for someone who is elderly who has other medical conditions and is on other medications.

P32: Anything you would take for sleep would cause a cognitive impairment, so you have to be pretty careful.

Several participants said they sometimes counsel patients suffering from sleeplessness to make changes in behavior before treating it with a drug:

P12: Some of the other sleep hygiene things I’ve heard before is, it’s surprising how many people have TVs in their bedrooms . . . Designating the bed just for sleeping and not reading your book in bed, not watching TV in bed are a lot of cues that you try to remove from your mind so that when you go to bed, you’re automatically moving into sleep mode. And a lot of people, I think, get some benefit from kind of just making simple changes like that.

P14: I’d probably recommend things what I’d call lifestyle changes before I’d recommend a product. Usually there are some things in there that are a problem. They’re not relaxing. They exercise too late in the day, took a nap in the afternoon. And I look into those things first, and probably suggest some changes. And if that didn’t give them relief in a couple of days, to have her come and talk to me, and then we’ll go from there.

Other alternatives to risky OTC sleep aids would involve changing patients’ expectations about how much sleep they think they should get and counseling homeopathic sleep aids.
P35: We get the eight-hour thing ingrained into our head, but that's not necessarily true. I mean, the average does decline with age . . . but a lot of people still insist that they need that much, and I'm just going to say, “Well, it's okay to go a little less as long as you feel okay.”

P31: You've got not really that many choices, either Benadryl and a couple other antihistamine type products, or you can go to the homeopathic ones. And there you show them that, and there's a whole list, and they want you to explain every one of the different homeopathic remedies that are in there, and good luck with that.

Circumstances in Which Pharmacists Would Not Recommend an OTC Product Even When Customers Ask for One

Pharmacists also noted the circumstances in which they would not give a recommendation for an OTC medication, even when a customer asks for one. In these cases, pharmacists often recommended the patient go see their physician first:

P18: If there's an underlying condition that needs to be treated, we would not recommend an over-the-counter. We would recommend that they see their doctor to have that evaluated if there's some depression, anxiety, or something going on.

P26: You need to get a kind of a medical history and know what their drug regimen is . . . [because] possibly [it] could be one of the medications that's causing the problem. And if one drug triggers something, you might say, “Well . . . I don't think I would recommend something for you. I think it would be best for you to talk to your physician and have them recommend something.”

P34: I've had people that have tried them all [all the OTC medications], and it's obvious they're not working. [In such cases, I tell them,] “You're not going to go with something like that. Don't even bother. See your doctor.”

After gathering all the information, the pharmacist could gather it was often still the case that they did not have enough information for them to feel they could safely make an OTC recommendation in this situation and therefore they referred the patient back to their physician so the physician could gather more information.

Barriers to Providing OTC Recommendations

Pharmacists also cited a number of barriers to providing safe OTC medication recommendations. First, pharmacists rarely have all of the information necessary to make a sound recommendation. This is due to the fact that pharmacists do not have access to electronic medical records that contain information about comorbidities, laboratory values, and other diagnostics. Although pharmacists do have access to the medication profile from the prescriptions that had previously been filled at that pharmacy, these profiles are housed in the prescription filling department, which is sometimes not proximal to where patients are speaking with pharmacists in the OTC aisles. Older patients may provide incomplete and sometimes inaccurate information regarding the medications they are taking.

P15: We all know that patients a lot of times don't know what they're taking. “What are you taking?” [we ask, and the patient responds,] “I don't know. I'm taking a bunch of prescription medicines, and a couple of over-the-counter”

Second, a lack of privacy exists for the types of questions pharmacists reported asking patients when triaging their concerns in the OTC aisles. Pharmacists are sensitive to the personal nature of some of the questions they ask and are cognizant that there may be other patients present in the aisles. Because the OTC area is not close to the prescription department (where there may be private space), it is awkward to ask the patient, who may have trouble ambulating, to walk to a more private area to converse. As a result, pharmacists were concerned that they would not get accurate information from the patient. Pharmacists must sometimes decide if the information that is necessary to make an appropriate recommendation is worth sacrificing potential patient confidentiality.

Discussion

This study set out to explore the thought processes used by pharmacists to make a recommendation for older patients considering an OTC
medication. The type of information gathered and the sequence pharmacists use to ascertain information was explored. This study also describes the recommendations that pharmacists made, and their decision-making process in coming to their recommendations. Interestingly, a medication was not the first thing that pharmacists recommended. Instead, pharmacists appeared to take a holistic approach to addressing a patient’s self-care needs, actually trying to rule out other causes for sleeplessness before turning to medication as an option. Pharmacists also appeared to play an important role in referring patients to physicians to address more complex issues.

This finding is not surprising given pharmacists’ training and expertise in screening patient health information and applying their knowledge to make recommendations about self-care. Pharmacists’ training includes how to specifically assess high risk and special patient populations, such as older adults. This training is guided by expertise in physiologic and pharmacokinetic differences, as well as drug interactions, duplications in therapy, and nonadherence issues associated with the aging population. Because of this expertise, pharmacists can play a key role in assuring the appropriate use of OTC medications in older adults.

Accessibility of the pharmacist is particularly relevant for older adults given the fact that the overwhelming number of OTC medications has grown exponentially to over 300,000 marketed products (U.S. Food and Drug Administration, 2012), including medications for immediate symptomatic relief as well as for chronic medications. It should be no surprise that older adults have a difficult time selecting OTC medications in light of the numerous products for pain, gastrointestinal symptoms, cough and cold, and other ailments available, many of which are labeled similarly. Although label warnings are required on OTC products, labeling may be inadequate, and patients’ ability to discern critical information about the condition and treatment options is highly variable. Older adults, who tend to have more comorbidities and cognitive impairment, are faced with aisles of confusing OTC medication choices.

Our findings also suggest that pharmacists did appear to use a mental model when seeking to establish the information necessary to make an OTC recommendation. This mental model is generally consistent with a published model that has been adopted in Schools of Pharmacy which teaches students to (1) gather information about symptoms and patient history; (2) identify the problem; (3) identify exclusions for self-treatment; (4) identify alternative solutions; (5) select an optimal solution; (6) prepare and implement a plan; and (7) educate patient (Krinsky, Berardi, & Ferreri, 2012).

Although pharmacists reported the medications that they would NOT recommend and why they would not recommend them, they did not cite published guidelines such as the Beers list as part of their rationale. There may be several reasons for this. First, there are many different sets of overlapping yet distinct criteria for potentially inappropriate medications including the Beers and the START/STOPP criteria (Lam & Cheung, 2012). Chang and colleagues (2011) found that simpler criteria (i.e., in which providers would not have to calculate doses or determine drug–drug interaction with another medication) were easier to apply. Second, the Beers Criteria is focused on prescribed medication. Even though OTC medications are listed on the Beers Criteria, pharmacists may not link inappropriate OTC medications together with Beers Criteria medications.

These findings have implications for pharmacists, older adults, and their caregivers. For pharmacists, the study highlights the need for pharmacists to maximize the personal service they offer by actively promoting the value of their guidance in selecting and monitoring treatment with an OTC medication. For older adults and caregivers, this study sheds light on the value of inquiring with pharmacists when selecting OTC medications. A pharmacist can determine whether self-care is in the best interest of the patient or if the condition requires a primary care provider’s intervention. When considering the purchase of OTC medications for self-care needs, older adults and caregivers should consider shopping in a retail establishment where there is an available pharmacist rather than shopping at a similar department in a nonpharmacy outlet (e.g., a convenience store).

Although the mental model identified through this study appears to be similar to the model currently taught in Schools of Pharmacy, this was the first time an assessment was conducted to describe practicing community pharmacists’ mental model when triaging an older adult’s request for an OTC medication. Future research should continue to elicit specific strategies pharmacists can use to most effectively provide safe OTC medications to older adults. Additionally, it is important to take a patient-centered approach to identifying barriers that older adults and their caregivers face.
when attempting to select an OTC medication. Understanding barriers to safe OTC medication use from both the pharmacists’ and patients’ perspective is the first step to developing and testing strategies to support older adult self-care.

**Limitations**

This study had several limitations that should be acknowledged. Sample size was small with only 21 subjects in three focus groups within one state. Subjects were selected for convenience and focus groups were not continued until saturation was achieved. Differences between focus groups, including geography, pharmacy type, or the fact that the vignette changed slightly after the first group, were not addressed. As a result, caution should be used in generalizing the findings to a wider population of community pharmacists. The OTC counseling scenario that was used in the vignette was specific to a pharmacist/patient face-to-face interaction in which the patient was seeking a recommendation for an OTC product. Over the phone recommendations of OTC products and scenarios in which a patient may receive advice from a pharmacist over the internet were outside the scope of this project and warrant further investigation.

**Conclusion**

The health and economic consequences of unsafe medication use in older adults has made medication safety a “priority area for national action” (Agency for Healthcare Research and Quality, 2003), and a focus of Healthy People 2020 (Byers, 1983). Although prior research has documented the prevalence and health consequences of inappropriate medication use from prescribed medications, many potentially harmful medications can be purchased over the counter without a prescription. This study provides the first practice-based evidence for the pharmacists’ utilization of a problem-solving model that supports the critical role pharmacists can play in safeguarding older adults from the potentially harmful adverse effects of OTC medications.

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