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Exploring How Pharmacists Engage with Patients about Over-the-Counter Medications

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Abstract

Objectives: This study employed an innovative information-gathering approach to provide insight into the nature/structure of pharmacy staff encounters with patients seeking over-the-counter (OTC) medications, and revealed specific activities of pharmacy staff around these encounters.

Methods: A multi-step process was used to develop and standardize an 8-item OTC Encounter Form to document the characteristics of pharmacy staff/patient encounters. The OTC Form contained a number of domains, including topics discussed and problems/symptoms identified during the encounter, staff functions during the encounter, and approximate time spent with the patient. Nine pharmacists and 8 technicians used the OTC Form to document patient encounters over 7 consecutive days. Frequency distributions for each OTC Form item are reported.

Results: One-hundred-eleven OTC Forms were completed. Adults age 65 or older were involved in 46% of all encounters. Pharmacists provided the only assistance in 41% of encounters and worked in partnership with other pharmacy staff for another 25% of encounters. Many encounters required the pharmacy staff to leave the prescription department, involved discussions about a variety of problems/symptoms, and lasted less than 3 minutes. Although the most prevalent encounter topic was locations of a particular product, about one-third of encounters involved either recommendations about a product or providing information about a product, and 41% involved

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communications about two or more topics. Finally, 11% of encounters generated a non-drug recommendation and 8% resulted in a referral to a physician.

Conclusion: Pharmacists play a key role in ensuring that the benefits of OTC medications outweigh the risks, thereby providing an important resource for patient engagement about safe medication selection and use. Examining the features of OTC encounters creates an evidence base to promote best practices for OTC encounters, increasing pharmacists' ability to help people, especially older adults, navigate the intricacies of OTC medication use, without significantly increasing pharmacy staff workload.

Background

Over-the-counter (OTC) medications are non-prescription and are used by people to treat such common symptoms as acute pain, allergies, cough/cold/flu, and headaches, as well as health issues such as sleep disturbances, gastrointestinal discomfort, and heart health. Since OTC medications can be obtained without a prescription, their use often is undisclosed to the practitioner, obviating any opportunity for clinical supervision of that use.¹ A person's use of any medication without awareness, consent, or oversight from a healthcare professional contributes to increased risks associated with that use, especially for older adults (aged 65 and over).²

Potentially inappropriate OTC medication use in older adults is a largely overlooked medication safety issue, although it is prevalent with almost 40% of this population reporting OTC medication use.³ Evidence further suggests that more than half of older adults who take OTC medications are not using those medications safely.⁴ In fact, OTC-related adverse drug events (ADEs) involving older adults are estimated to result in almost 100,000 hospitalizations nationally each year.⁵ Additional ADEs, especially with older adults, can include increased rates of falls, insomnia, delirium, cognitive impairment, and severe gastro-hepatic problems.⁶⁻⁷ However, the health benefits of safe OTC use cannot be downplayed, with every dollar spent on OTCs estimated to save \$6.00 to \$7.00 in other healthcare system costs.⁸ As such, healthcare professionals should not be striving to completely deter OTC use by older adults, but rather to reduce their inappropriate use and associated harms. Recent regulatory activities also have targeted ensuring OTC availability and concomitant safe use, such as the Food and Drug Administration's (FDA's) establishment of the Nonprescription Safe Use Regulatory Expansion task force⁹ and state regulatory agency website information.^{10, 11} The FDA additionally requires that packaging for OTC products contains drug facts labeling, including easily-understandable information about the indications, contraindications, and precautions when using the medication.¹²

Harm reduction regarding OTC use has been a long-standing goal within healthcare, undertaken primarily through the adoption and implementation of evidence-based clinical practice standards. An important medication safety resource of this type has been the Beers Criteria, which was initially conceptualized in 1991¹³ and updated periodically thereafter,¹⁴⁻¹⁷ with the most recent update occurring in 2019.¹⁸ The Beers Criteria list has been used as a resource for pharmacists in U.S. healthcare systems¹⁹ and in Veterans Administration hospitals.²⁰ Throughout its history, the Beers Criteria have consistently contained cautions

about a number of OTC products, promoting the selection of OTC medications based on understanding of their pharmacologic properties and an individual's current vulnerabilities as part of individualized care.

Pharmacists are in a unique, prominent, and authoritative position to promote recommendations from current safety protocols to assist older adults with appropriate selection and use of OTC medications. These healthcare professionals interact with patients on a regular basis, have access to patients' prescription profiles to identify therapeutic duplications and potential drug-drug interactions, are trained to assess whether an OTC medication is safe to take based on a person's concurrent health conditions, and can offer safer pharmacological, or even non-pharmacologic, alternatives to OTC medications that are being sought.²¹⁻²³ Unfortunately, numerous work-related barriers exist that can hinder pharmacists from maximizing their positions to assist with safe and appropriate OTC selections.²⁴ For example, the distance between the pharmacy workstation and OTC placements throughout the store, the continual time pressure to fill prescriptions and maintain quality control, and a typically heavy workload all serve as obstacles to pharmacist-patient OTC consultations. Although pharmacists acknowledge many potential barriers to patient engagement about safe OTC use, insufficient knowledge or ineffective communication typically are not considered hindrances.²⁵⁻²⁷ Consequently, pharmacists' expertise and prominence related to this key medication safety area is currently underutilized, and has been under-examined in the U.S.

In an effort to begin more specifically characterizing OTC medication interactions with patients within pharmacies, as well as the pharmacist's role in these interactions, a novel OTC Encounter Form was used (see Methods section). The Form was designed as a brief data collection tool for patient encounters that could be integrated easily into the pharmacy workflow.

Objectives

The objective of this study was to use an innovative information-gathering approach to characterize the specific activities and time commitment of pharmacy staff to provide insight into OTC-related pharmacy encounters.

Methods

Participants and Setting

Nine pharmacists and eight pharmacy technicians collected data at four mass merchandise stores located in Wisconsin, all within the same community pharmacy organization. Each pharmacy staff member was instructed to document each OTC encounter occurring with a patient over seven consecutive days, and was compensated \$20.

Data Collection Tool

An OTC Encounter Form (referred to hereafter as the OTC Form) was developed to document the characteristics of an encounter between a patient and a pharmacy staff person. Form construction involved a number of steps. First, study staff drafted an initial version of

the OTC Form. Second, cognitive interviews were conducted with two pharmacists who were requested to review the form and provide feedback about its contents. Information obtained from the interviews related to such content topics as suggestions about wording/terminology and assuring the clear understanding of terms used, ideas for additional or modified items, and additional types of problems/symptoms and pharmacy staff tasks specifically included on the form. In addition, various process issues were discussed and decided, including how to measure the duration of each encounter, procedures for data collection and completion of the form, and the most useful format for the form (i.e., computer tablet vs. paper). Finally, the form was refined in response to the pharmacists' comments and suggestions, contributing to the final version used for this study.

The resulting OTC Form is a one-page document consisting of eight items with fixed-choice response options. The form items capture the following domains: (1) estimated patient/customer age, (2) topics discussed during the encounter, (3) the problem/symptom involved, (4) whether pharmacy staff left the prescription area, (5) who initiated the OTC encounter, (6) which staff assisted, (7) staff functions during the encounter (e.g., making medication or non-drug recommendations), and (8) the approximate time spent with the patient/customer.

Data Collection Procedure

Following completion of the OTC Form after each interaction, the collected information was entered into a secure web-based application designed to support data capture for research studies (RedCap²⁸) to expedite data aggregation, validation, and analysis.

This study is a component of a larger research project that was approved by the Institutional Review Board at the University of Wisconsin-Madison.

Statistical analysis

Frequency distributions were computed for each OTC Form item, including the extent of pharmacists' involvement in OTC-related interactions. All variables collected were categorical. Items for which a single response was required ranged from dichotomous to six categories, and were analyzed as a distinct variable. For multi-categorical items in which more than one response could be collected, the response categories were analyzed individually. IBM SPSS Statistics v25© was used to create new variables and to calculate the frequency distributions for all variables and response categories.

Results

During the week-long data collection period, 111 OTC Forms were completed across all four pharmacy sites. Older adults represented 46% of all OTC encounters, with the remaining interactions split between adults (ages 18-64) (51%) and, extremely infrequently, children/adolescents (4%). Patients initiated a significant majority (87%) of OTC encounters, while pharmacists, caregivers, technicians or pharmacy cashier, or main store employees comprised the remaining 13% of interactions. During these encounters, pharmacists, while acting alone, provided the most frequent assistance (at 41%); interestingly, pharmacists were involved in 66% of interactions either solely or in partnership with other staff (including technicians and pharmacy students or interns). Almost

two-thirds (66%) of encounters required the pharmacy staff to leave the prescription department to escort a patient to the OTC aisle when discussing and selecting a safe medication. Documenting the estimated length of an OTC-related patient interaction demonstrated that a notable majority (85%) lasted less than three minutes, while the remaining encounters consisted of 3 to 5 minutes (11%) and 5 to 10 minutes (5%).

When considering the topics discussed during the encounters, the single most prevalent request was about the location of a product (85%), followed by the pharmacy staff recommending a product (32%), providing information about a specific OTC product (31%), considering self-care appropriateness of using the OTC (6%), and other, unspecified, subjects (5%). Moreover, many interactions were not characterized by a discussion about a single issue – 41% of encounters involved communications about two or more of these topics. Table 1 contains frequencies for the many specific problems/symptoms that could be central to the encounter discussion and were considered important for the purpose of this study; no specifically-identified problem/symptom was addressed over 13% of the time, while 7% of encounters involved the discussion of two or more health issues. When determining the activities of pharmacy staff during the OTC interaction, 68% actually showed the patient the product location, while slightly fewer than a third (31%) provided an OTC medication recommendation, and another 23% were involved in an other, unspecified, activity. In addition, 11% of encounters generated a non-drug recommendation and 8% resulted in a referral to a physician for clinical or medication issues.

Discussion

Results from this study suggest that a significant majority of OTC encounters are patient-initiated, involve a pharmacist, are composed of non-clinical issues, and entail showing patients the location of particular products, and that a notable portion of those encounters involve older adults and lasted at least 3 minutes. It is apparent that systematic methods can help improve initiation and efficiency of such interactions. Interventions that place OTC stock proximally to the prescription department, while promoting targeted patient interactions specific to those medications, is an objective of ongoing research.⁶

Pharmacy staff successfully used a brief data collection form to capture important information about OTC-related patient encounters within a community pharmacy, and gained insights into the pharmacist's role during these interactions. Such data can be used to guide interventions designed to streamline the engagement process and make these encounters more functional for both pharmacy staff and patients. As a result, pharmacists' crucial patient interactions can better serve the purposes of medication selection and management issues, rather than being used for product location requests and other non-clinical topics. Pharmacists' time, therefore, would be more targeted on determining the appropriateness of specific OTC medications based on patients' current prescription profiles, use of other non-prescription medications, and health considerations.

Reducing the length and enhancing the quality of pharmacist-patient OTC encounters is a paramount need identified through these findings, especially since pharmacists were involved at some point with two-thirds of all interactions within the study timeframe. The

high degree of pharmacist involvement, coupled with the predominant occurrences of non-clinical topics discussed during the encounters, suggests the need for a more informed triaging of pharmacists' involvement to when their skills and expertise would be best employed. This objective is even more critical considering that most encounters required the pharmacists to leave the prescription department, diverting attention away from responsibilities that only they can fulfill – counseling patients about medication issues.

Although non-clinical topics were central to a majority of patient engagements around OTC issues, it is important to acknowledge that there were encounters that effectively utilized the pharmacists' expertise and elicited recommendations around medication decisions. For example, topics specifically identified on the OTC Form, such as pain and cough/cold (at 9% each) and eye/ear (at 8%), in addition to the 7% of encounters covering a combination of issues, offered opportunities for effective communication about safety. Also many encounters involved OTC-related advice, while others involved tasks such as providing OTC information, discussions about non-drug alternatives, or suggestions for patients to contact their physician before considering OTC medication use. Interactions that address such topics are more likely to broach strategies for safe use if OTC medications are chosen, to better protect individuals' health.

Another notable finding relates to the almost-exclusive role of patients in initiating the OTC encounters. Of course, this situation does not include the unknown frequency of patients who had a question for pharmacy staff but chose not to approach the staff. A probable reason for the lack of pharmacy staff involvement with beginning patient engagements about OTC issues is the distance between the products and the prescription department; pharmacists often are unable to observe patients in a distant OTC aisle who may need help when considering medications. It is difficult for pharmacy staff to initiate encounters with people who are not easily visible from their primary workstation. Having OTC products in closer proximity to the prescription department would better assure visual identification of patients who may require OTC-related consults, preventing the departure of those with unfulfilled healthcare information needs and enhancing the likelihood of facilitating beneficial encounters.

Overall, these research findings demonstrated that community pharmacists are valuable access points for healthcare information, including guidance related to OTC medication decision-making. During the OTC encounters documented in this study, pharmacists were asked questions about the correct medications to use, based on patients' presenting symptoms and any identified risks or benefits. Importantly, only around a third of encounters resulted in the pharmacist recommending a specific OTC medication, while a notable proportion led to a suggestion involving a non-drug alternative therapy or even a prompt for patients to communicate clinical/medication concerns with their primary care physician. These activities reinforce the breadth of pharmacists' currently-expected responsibilities,²⁹ expanding beyond being dispensers of prescription medications to serving as convenient community-based sources for effectively triaging pharmacy and healthcare services for patients, either by providing medication information or by directly encouraging physician referrals.³⁰ Many patients clearly rely on the pharmacists in their community for expert and reliable counsel relating to healthcare needs. Indeed, the explicit purpose of examining OTC

encounters was to facilitate and optimize this pharmacist-patient dynamic, as a means of reducing OTC medication-related harms.

Limitations

A number of limitations characterize this research. First, the exploratory nature of this study resulted in only 111 OTC encounters from which data were collected. It is possible that more encounters would have yielded different results. Second, these data were self-reported and are subject to the limitations inherent in such data, and may have been affected by the time of day in which the data were collected. Third, since data collection occurred using a brief form, there is no more specific information about the OTC encounters (e.g., the nature of recommendations) to more precisely inform potential interventions. Additional, more qualitative, feedback can provide further insights. Fourth, there were times when pharmacist-patient encounters occurred, but OTC Forms were not completed. Finally, pharmacies have unique characteristics that could influence the initiation/content of encounters.

Conclusion

Pharmacists play a key role in ensuring that the benefits of OTC medications outweigh any risks by dint of their professional practice standards – the expectation to engage with patients about safe medication selection and use. Further progress in this area is achievable by examining the features of OTC interactions, which was the purpose of this study and the first phase of ongoing research. Evidence-based efforts to promote effective OTC encounters can increase the ability of pharmacists to help people, especially older adults, navigate the intricacies of OTC medication use without significantly increasing pharmacy staff workload.

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The following contributions have been identified for each author of the manuscript, according to the CRediT taxonomy:

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Data curation: Jamie Stone

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Table 1.

Types of problems/symptoms involved in OTC encounters (n=111)

Problem/Symptom	Frequency (%)
Other	48 (43.2%)
First Aid	14 (12.6%)
Cough/Cold	10 (9.0%)
Gastrointestinal	10 (9.0%)
Pain	10 (9.0%)
Eye or Ear	9 (8.1%)
Vitamin/Supplement Question	9 (8.1%)
Sleep Trouble	5 (4.5%)
Allergy	4 (3.6%)
Heart Health	0 (0%)
Combinations of problems/symptoms	8 (7.2%)

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