



Published in final edited form as:

Res Social Adm Pharm. 2021 March ; 17(3): 578–587. doi:10.1016/j.sapharm.2020.05.008.

A Pharmacy-Based Intervention to Improve Safe Over-the-Counter (OTC) Medication Use in Older Adults

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Abstract

Background: For older adults, health risks from inappropriate use of over-the-counter (OTC) medications represent a prevalent clinical and public health challenge. Focus groups with pharmacists led to the identification of a number of pharmacy systems barriers supporting older adults' safe selection and use of OTC medications. Such feedback informed the development of the Senior Section™, a physical redesign that located a curated inventory of lower-risk OTC medications proximal to the prescription department.

Objectives: To determine whether implementation of the Senior Section resulted in improvements to the ability of pharmacy staff to engage with older adult patients to support OTC medication safety issues.

Methods: A qualitative approach, in which pharmacy staff from 4 pharmacies within a single chain in Wisconsin, USA, participated in a semi-structured interview, was used to evaluate the implementation of the Senior Section in their pharmacies. Interview transcripts underwent a deductive and iterative content analysis.

Results: Eight pharmacists and 5 technicians were interviewed. They viewed the Senior Section as contributing to notable improvements in proximity, medication safety, convenience, and patient selection behaviors. The Senior Section's safer OTC inventory and its sectional layout, its relationship to the prescription department, and its signage served to enhance its usefulness as an OTC safety improvement intervention. Moreover, it functioned beneficially while streamlining the coordination of services between pharmacists and technicians, and did not interfere with existing pharmacy workflows.

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Declarations of Interest: none

Conclusions: Pharmacy staff believed that the Senior Section facilitated their ability to engage with older adults to support safe OTC selection and use and thus to reduce OTC-related harms.

Keywords

Medication Safety; System Redesign; Pharmacist-Patient Communication

Introduction

Pharmacists have long served as an important resource for patient medication safety, including for over-the-counter (OTC) medications.¹ Safety issues in which pharmacists are often involved include professional, patient, and healthcare system influences on medication-related errors. Such issues could include the need to educate patients about interactions between medications and potential side effects, referral of patient to their healthcare professional when it is considered necessary, and medication management and delivery.¹ This situation is specific to the U.S., in which medications are classified as either prescription or OTC. This designation contrasts with many countries, such as Australia, New Zealand and Ireland, there is a unique schedule of “pharmacy only medicines” that are stored “behind the counter.” These medications are stored in an area of the pharmacy in which the public does not have access and have been identified as “substantially safe in use but require professional advice or counseling by a pharmacist.”²⁻³

For older adults, health risks from inappropriate use of OTC medications represent a prevalent clinical and public health challenge.⁴⁻¹¹ In fact, recent estimates suggest that almost a third of older adults report regular use of OTC products, with about half of people aged 75 to 85 reporting such use;¹² the same data demonstrate that over one million older adults are in physical jeopardy from harms related to the use of 2 or more OTC medications.¹² As a result, older adults’ involvement in emergency hospitalizations for adverse drug events continues to increase, including for OTC medications.¹³ Efforts to strengthen pharmacists’ abilities around assisting patients with assessing and selecting safe medication have traditionally been limited to education initiatives. However, pharmacists’ training and professional experience generally ensure that there is little need for additional awareness-enhancing about medication properties and their safety.¹⁴ There is, therefore, a clear need to find opportunities to effectively utilize pharmacists’ involvement in OTC medication behaviors among older adults, and for pharmacists to consistently serve as a conduit to enhanced OTC safety messaging. This approach corresponds to recent U.S. national research recommendations.¹⁵

Prior Work to Develop the Intervention

To begin understanding feasible methods to improve pharmacists’ ability to promote patient safety around patient OTC use in the U.S., a series of 3 90-minute focus groups were conducted in 2012 across Wisconsin.¹⁶ The goal of the focus groups was to prompt pharmacists to identify professional barriers that impede providing OTC-related recommendations to older adults. Focus group questions were guided by the Input-Transformation-Output (ITO) conceptual model, which attempts to identify the system factors involved in improving health professionals’ practice to enhance safe and effective

patient care.¹⁷ Twenty-two participating pharmacists represented chain, health system, and independent retail pharmacies. The diversity of practice settings better ensured elicitation of a broad range of professional barriers related to safe OTC medication use. Each focus group session was audio-recorded and transcribed, and those transcriptions were reviewed and coded to identify prominent themes related to the ITO framework.

The OTC recommendation barriers that pharmacists identified during the focus groups were categorized into 4 overarching ITO domains – (1) Provider (Pharmacist) Factors, including a lack of information, (2) Patient Factors, (3) Work System/Unit Factors, and (4) Organization Factors – with a number of thematic sub-groups within each.¹⁶

This focus group method provided a detailed explanation about interpersonal and systems impediments to pharmacist/patient interactions around OTC safety, and was sufficient to produce recommendations about the need for system designs aimed at reducing OTC harms. Specifically, pharmacists identified certain OTC medications (e.g., pain relievers and cough/cold) as having higher risk profiles for older adults, but these products usually are located some distance outside the prescription department. Less accessible product placement hinders the pharmacist's ability to notice patients who are attempting to select an OTC medication, and then to approach those who may require assistance to identify and address safety issues. Even when pharmacists are motivated to promote safe medication selection and use, the inaccessibility of OTC medications can create barriers. That is, the distance between OTC product location and the prescription department requires a greater time commitment when the pharmacist must leave the area to assist patients. As a result, the pharmacy's traditional physical layout has 2 practice ramifications. First, taking time to traverse the distance to OTC medications for patient discussions interferes with the pharmacy staffs' work. Second, this distance and time commitment can deter the pharmacist from leaving the prescription department. It was clear, then, that a pharmacy layout redesign seemed warranted to address this prevalent pharmacy barrier.

Development of the Senior Section

A novel physical layout, called the Senior Section™, was designed to support more efficient and effective communications between pharmacists and older adults while maintaining patient autonomy regarding their self-care. Two primary features characterize the Senior Section: (1) the location and layout of selected high-risk OTC medication categories (i.e., pain, sleep, allergy, cough/cold) and (2) use of signage and aisle redesign to highlight medication safety warnings.¹⁸

(1) Senior Section Location and Layout.—Medications that were deemed safer for older adults were curated by pharmacist focus group members, and confirmed by pharmacotherapy experts. These included non-sedating antihistamine cough and cold products, and acetaminophen and topical analgesics for pain. Non-drug alternatives, such as saline drops, nasal irrigation, and heating pads, were also included. High-risk medications for older adults, such as diphenhydramine products, aspirin (when used for pain), and certain cough/cold combination products,¹¹ were excluded from the OTC inventory for this section. Also, selected OTC medications were moved proximally to the prescription department and

within the line of sight of pharmacy staff, so that pharmacy staff are better able to view older adults who are in the process of selecting a medication and have fewer reasons to leave the prescription area to provide assistance.

(2) Signage and Aisle Redesign.—Pilot-tested signage throughout the Senior Section designated safety warnings for older adults, all in noticeable positions, with understandable language, and with design attributes (e.g., font size and colors) determined to be appropriate for older adults. The OTC medications also were placed at heights more appropriate for older adults' mobility and vision. Two additional tools (i.e., a counter and a lighted magnifying glass) were supplied and intended to support patients who wanted to spend time to read medication ingredients lists and warning labels, as a means to compare medications. All features can enhance older adults' awareness of potentially-unsafe medications and, having gained insight into their lack of knowledge about medication risks, motivates them to approach pharmacy staff to help inform their medication decision-making. This objective was facilitated by having the older adults begin their OTC medication selection process at the Senior Section, which also allowed for the potential to determine whether the patient stayed in the area and used the associated resources or left the area for the store OTC aisle.

The hypothesis underlying the Senior Section was that facilitating more frequent collaboration, whether initiated by pharmacy staff who are closer to the OTC medication aisles and who witness patients deliberating about medication selection or by older adults who have become aware of medication safety concerns, increases the likelihood of older adults making safer OTC medication decisions.

The Senior Section was conceptualized using participatory design and a human factors engineering model, called Systems Engineering Initiative for Patient Safety (SEIPS) 2.0.^{18,19} The SEIPS 2.0 model has been employed to study a variety of patient safety issues in many healthcare settings,^{20–24} and allows for a broad conceptualization of the healthcare system – including person (i.e., practitioners and patients), tasks, tools and technology, organization, internal environment, and external environment.¹⁹ In the context of the Senior Section, the pharmacist/patient engagement to determine potential for harm when considering whether to take an OTC represents the work activities within the healthcare system. Specifically, pharmacists' work could include medication management, discussion of potential side effects and medication interactions, and referrals to healthcare professionals when necessary. Alternatively, the older adult patients' work could involve consideration of the medications' potential impact on existing health conditions and their decision-making process used to select OTC medications. Overall, SEIPS 2.0 allows for the determination of the healthcare system features that either facilitate or hinder such work and, ultimately, informs improvement in pharmacist/patient engagement. By addressing the internal environment (i.e., physical layout), as well as supporting the work required by pharmacy staff and older adults to safely select an OTC (i.e., through training and providing cautionary signage), the Senior Section represents an unprecedented interventional approach to achieve beneficial patient outcomes.

Objective

The objective of the work reported here was to determine the extent that the Senior Section addressed personal and programmatic barriers identified previously through the focus groups. A qualitative assessment/evaluation was conducted as part of a pilot study that sought to assess both feasibility and preliminary effectiveness of the intervention. The *a priori* hypothesis is that, when compared to prominent themes emerging through the focus groups, interviews with pharmacists and technicians involved in implementation of the Senior Section would reveal improvements in areas previously identified as barriers to pharmacists engaging with patients about OTC medication safety.

Methods

A formal qualitative approach²⁵ was used to explore the extent that the Senior Section was perceived by pharmacy staff as successfully addressing issues related to OTC safety. Standards for Reporting Qualitative Research²⁶ were used during the execution of this project and in the preparation of this manuscript.

Pharmacy staff were interviewed to elicit descriptions of each respondent's role and how the intervention was implemented in their store, in an effort to evaluate both process and outcomes factors. This study is a component of a larger research project that was approved by the University of Wisconsin-Madison Institutional Review Board.

Setting

For this pilot study, 4 Midwest pharmacies were selected from within a single pharmacy chain, and the Senior Section was implemented in these pharmacies beginning in 2016. The pharmacies were located in Wisconsin communities with a populations ranging from about 37,000 to over 200,000 people, representing a diverse age, gender, and race demographics (<https://suburbanstats.org/population/>).

Recruitment

A more comprehensive description of the pharmacy staff recruitment process has been published elsewhere.²⁷ Recruitment meetings were held and consent for study participation was obtained from pharmacists and technicians (the professionals most likely to engage with patients about medication issues). This recruitment strategy resulted in 8 pharmacists from 4 sites, and 5 technicians from 3 sites being consented and enrolled for this study. All pharmacists, and pharmacy technicians working more than half-time, were recruited because they were expected to have a better understanding of the pharmacy workflow and have more time to interact with customers and engage within the Senior Section. As a result, this recruitment of pharmacy staff was structured to better ensure data saturation, especially for pharmacists.²⁸

Training

After recruitment, training sessions were conducted for all recruited pharmacists and technicians in anticipation of its full implementation. An hour-long training session was held to describe the project's activities and goals and to introduce the pharmacy staff to the

Senior Section features, as well as the reasons for those features. Participants received a total of \$60 for completing both trainings. The same training was provided to all pharmacists and technicians, and they were trained together. Pharmacists then participated in an additional 30-minute training, for which they received a \$30 remuneration, to reinforce information about the most serious adverse health events that are common when older adults use OTC medications. An academic pharmacist conducted the training, and the subject matter was based on OTC expert guidance and on current pharmacy course curricula.

Senior Section Implementation

Subsequent to the pharmacy staff recruitment and training, the Senior Section was implemented in all participating pharmacies.

Interview Guide Development

An interview guide was developed by the research team for both pharmacists and pharmacy technicians. It was informed by components of the SEIPS 2.0 model and was designed to assess implementation facilitators and barriers, as well as effectiveness of the intervention. Related to the purpose of this pilot study, a series of questions were designed to elicit information about work system factors according to the SEIPS 2.0 model domains: *person, environment, tasks, technology and tools*, and *organization*. Such factors allowed for detailed descriptions of each respondent's role in both the pharmacy and the Senior Section, as well as activities related to Senior Section implementation in their store. Resulting interview content represents what has come to be known as "rich data."²⁹

The interview guides were pilot-tested at an initial, single, pharmacy site and then refined, which involved non-substantive improvements in readability and understandability to more directly prompt responses from participants, resulting in a document that would guide interviews up to 60 minutes long.

Pharmacy Staff Interviews

All pharmacists and pharmacy technicians agreed to participate in a semi-structured interview at the conclusion of the study at the end of 2018, for which they received \$50. Times and locations for interviews (conducted by JS or MC) were chosen that were convenient for each participant. Interviews were audio-recorded and transcribed into a de-identified format.

Analysis of Interview Data

Transcripts were verified by a researcher and imported into NVivo v.12. The Proctor et al. taxonomy³⁰ was used to conduct a deductive and iterative content analysis approach, which informed the identification and examination of thematic categories in the interview data. The process of developing the final coding scheme was described in detail elsewhere,²⁷ which was equally applicable to both pharmacists and pharmacy technicians. The final coding dictionary consisted of 21 main themes and 25 sub-nodes across many of those themes, for a total of 46 nodes.

Using this finalized coding scheme, 2 researchers (AMG and KZX) independently coded all pharmacy staff interview transcripts in batches by intervention site. After each batch coding, researchers met to compare their coding results. Any differences were discussed until consensus was reached. Upon completion of coding, the same 2 researchers validated the coding by analyzing identified and extracted content within each node for consistency.

Once coding was completed, the researchers identified categories that addressed personal and programmatic barriers earlier identified during the pharmacist focus groups. Both researchers selected, with 100% conformity, a combined total of 22 codes as relevant for this analysis. These nodes were extracted and examined for themes related to provider, patient, work system, and organization factors. Table 1 compares the ITO domains with the codes used for this study, and defines each of the 19 codes.

Results

A total of 8 pharmacists and 5 pharmacy technicians were interviewed following implementation of the Senior Section; 1 technician did not respond to the interview request. Aggregate demographic data about the pharmacy staff participants are provided in Table 2. Although age and length of experience and employment at the pharmacy varied considerably, pharmacy staff were female and predominantly white.

Themes below are presented in 4 sections, according to the relevant ITO factors (provider, patient, work system/unit, and organization), the various ITO variable domains within each section, and the SEIPS variables related to the ITO variable domains. Exemplar quotations obtained through pharmacy staff interviews are provided to offer qualitative support for each of the domains. When necessary, pharmacy staff quotations were edited to remove non-substantive interjections or partial phrases that were eventually stated in their entirety.

Provider Factors

ITO Variable Domain: Provider skills/knowledge/training/education

Competence: Every pharmacist expressed confidence in their knowledge, training, or experience to offer OTC medication-related recommendations, which often was strengthened by the training given prior to Senior Section implementation.

Yes, I do [have sufficient knowledge and training]... For regular over-the-counter medications, yes [I'm comfortable].... (Pharmacist 5)

Pharmacists also indicated that, when further information was needed, electronic databases (e.g., Facts and Comparisons, Micromedex, or Natural Medicine Database) were the go-to resource. Access to these databases was made easier due to the proximity of the Senior Section to the prescription department.

For the single pharmacy technician who provided information about this theme, competence seemed to be gauged by the understanding that questions about specific medications would be handed off to the pharmacist.

Anything that's more...medication-related, just so that they're not taking too many...we ask them what they would take and so forth, but kind of see if it falls within their range, just because I've been there 30 years, and I could kind of gauge whether or not I could handle the question or...grab a pharmacist. (Pharmacy technician 4)

Safety: The Focus Group identified that some pharmacists may not have the knowledge to make OTC recommendations. However, pharmacists consistently recognized the Senior Section, through its training, proximity, and selected OTC inventory, as prompting and preparing for more frequent discussions with patients about safety issues (as a principal effectiveness outcome), and ultimately contributing to people choosing safer medications. Cumulatively, the various Senior Section features were seen as facilitating conversations about medication safety.

But it did open the dialog a little bit more too if somebody knew that they wanted a certain thing and it wasn't there. And they're asking why it wasn't there. Then we could explain, this is on [the Beers Criteria] list where it's not necessarily safe for somebody that's over whatever age. (Pharmacist 3)

The primary safety issue with which pharmacy technicians were involved related to discussions with patients about potential interactions with other medications, including bringing these issues to the pharmacist when considered necessary.

Some things work better [than] others...and then also referring to their medication, what they take. I always ask that because we never know if it's going to interfere with their medication...And if there's any other questions concerning interference, then I would get the pharmacist involved with that. (Pharmacy technician 1)

Overall, the inventory of OTC medications contained in the Senior Section, coupled with the absence of popular and expected products that patients were seeking, prompted more frequent conversations about medication safety and alternative recommendations.

Training: No pharmacist or technician reported anything negative about the training that they received to implement the Senior Section. The educational content was deemed sufficient in length, and led to pharmacy staff gaining increased comfort about what they were supposed to do and what was going to happen once the Senior Section was implemented.

Yeah, it was good. I feel like it was a good refresher and focus us on what we needed to specifically speak to older adults about [when it comes to OTC medication consultations]. (Pharmacist 8)

Training-wise, I think I was prepared for everything that was [to come]. (Pharmacy technician 4)

ITO Variable Domain: Provider needs/biases/beliefs/moods

Provider Convenience: Universally, pharmacy staff considered the Senior Section's convenience as a principal benefit to their work, facilitating both patient encounters and better medication selection.

I just think it made it easier for us to interact with them. It made it easier for them, you know, to want to interact with us as well... I thought it was a good selection. You know, I think the categories worked well... I think [the Senior Section contained] the primary...things that people ask about most often. (Pharmacist 1)

It made it easier, because I didn't have to get up and go out to help them find something. I could keep working on what I was working, that multitasking thing. Or if I was on hold a lot because I did the billing, I was able to help people when I was on hold, which was really nice. (Pharmacy technician 2)

However, one pharmacist offered the following caution about an unintended consequence of this convenience:

The thing I was worried about is that they would not ask questions because they found it right away, whereas some of the people [when] we had to help them find it, we were right there in front of them, and we had their total attention. And they would be able to ask us without feeling like they were interrupting us working.

That's kind of a bonus for the people who did ask us, where is that, whereas, if they found it right away, they had it, and they were on their way. (Pharmacist 4)

Although this concern generally did not seem to be borne out during the experience of Senior Section implementation, it should be kept in mind and addressed, when anticipated, whenever possible in future applications of the Senior Section.

Technician Role: In many cases, pharmacy technicians were reported to be the first to initiate patient encounters and then, depending on the details of the conversation, refer the patient to the pharmacist when more complex medication issues were raised. In this way, there were clear and consistent delineation of responsibilities when making medication recommendations, and the Senior Section seemed to streamline this relationship.

I do think it made the technicians more comfortable with approaching them and then saying, let me get you the pharmacist here, because then...it made the patient feel like that they weren't interrupting what we were doing ...[the patient] could talk to somebody in the pharmacy, and they would get the answer...(Pharmacist 6)

I have answered [patients] in the past, depending on the pharmacist, if they're busy or not, asking them if they've tried anything once...the techs would mainly interact...But if the questions got too detail, well, I'm taking this medication. Is this going to interfere? Then we would involve the pharmacist. But otherwise, the technicians were the first ones, basically, to see them and greet them. (Pharmacy technician 1)

Patient Factors

ITO Variable Domain: Patient age/gender/ethnicity/language

Demographics: Age was the only demographic variable relevant to this intervention, since the Senior Section was designed specifically to improve medication safety in the older adult patient population. However, pharmacy staff reported that the Senior Section appealed to people of all ages, especially when the safety of the OTC inventory was more generally known.

I think it helped, because the medicine was right there. So when you're coming in and you have a sick kid with a cough and you're picking up an antibiotic, the Delsym was right there. That's the number-one thing that we would have recommended for a kid for a cough... Instead of having to run 4 or 5 aisles down and then come back, all while dragging a sick kid, they could just grab it right off the shelf there. (Pharmacist 3)

And when [the OTC medications] got put into the Senior Section, it was all kind of in one section, obviously, benefiting the seniors. But I saw that it ended up benefiting a lot of other people too, just by being consolidated into one section, and they're not walking around the store going, well, I don't know where, you know, the sleep aids are... (Pharmacy technician 5)

ITO Variable Domain: Patient skills/knowledge/training/education

Purpose of Senior Section: It was the overall perception that the Senior Section increased patients' awareness that not all medications are safe to take at their ages. Although it was believed that most patients came to understand the Senior Section's purpose due to the signage and other features, it was also evident that some other patients needed explanation from pharmacy staff. Fortunately, closer proximity of pharmacy staff to patients allowed easier discussion of this issue.

So we told them that it was the section of [OTC] medications that were safe for their age group, based on their disease states and their medications typically, based on not causing drowsiness, not being on the Beers list, basically, making them have increased falls... That's kind of how we started the conversation. (Pharmacist 2)

I don't think a lot of older adults knew that some medicines were bad for them. So I think when we explained it to them and showed them the actual medicine that would be safe, they were really mind baffled that there [were] medications that weren't safe for them. (Pharmacy technician 3)

Selection Behaviors: Given the pharmacy staff feedback, it was apparent that the Senior Section increased patients' understanding about the importance of seeking information from pharmacists about a medication that they were considering. In this way, the availability of the Senior Section offered a means to relay more information to help guide patients' medication selection decisions.

I think it gave them a little bit of a pause to think about what might be safe for them, and then maybe encourage them to talk to the pharmacist if they really did have a question or concern. I think sometimes when they're out in the aisles, it's just hard to see them, and hard for them to overcome that barrier of wanting to talk to the pharmacist. (Pharmacist 8)

...you could see [the patients] right there, even just the patients waiting that were... looking at the Senior Section, going, oh, look at this. And you could notice them looking at things, and then they would actually pursue the pharmacist a little bit more when they would pick up their prescription, ask about [an OTC medication]...But especially if they have a product that...they picked from the main section that is not such a great idea... or it may interact, we'll have them take, they'll take several products, and then they'll come in with the pharmacist. (Pharmacy technician 4)

ITO Variable Domain: Patient needs/biases/beliefs/moods

Purpose of the Senior Section: In relation to the theme of patients' needs, the Senior Section's objective of safe medication use often was successful at causing patients to reconsider their selection choices based on their symptom needs, even when the patient entered the pharmacy already intending to choose a particular product.

But I think that's good because I think sometimes, depending on the person, it's really easy to be like, oh, well, here is the Nyquil...[rather than] maybe you should talk to the pharmacist. Nyquil might not be the best choice for you. And so, and of course sometimes people don't care, and they're going to get their Nyquil anyways...but you can encourage them and educate them...that med's not there because that is not a good idea for the patient. (Pharmacist 7)

[The melatonin is] something they don't know about that. They may only know about...the products like that that were marketed back in the day. (Pharmacy technician 4)

However, one technician reported that consistent interactions about safety issues may not have always been possible. This was especially the case when patients entered the pharmacy looking for a predetermined product, selected that product when it was located outside the Senior Section, but then did not then approach the Senior Section to discuss concerns about the medication.

...they had it in their head that they wanted, you know, Tylenol PM, or whatever [which was not located in the Senior Section]. So, yeah, I do feel like that was a failing on our part, maybe or on the store's part. We weren't able to really communicate the safer alternatives to them. (Pharmacy technician 2)

Patient Convenience: A feature of convenience was that patients often appreciated the improved feeling of privacy when choosing a medication. The Senior Section was a more contained environment in the pharmacy area, and thus was considered to have more opportunities for discretion than having OTC medications only in the main aisle (i.e., not out in the store where other people could hear the patients discuss the medications). A secondary advantage of the Senior Section was that, as patients became more familiar with this intervention and its characteristics, they would use the Senior Section with greater frequency for their medication selection needs.

But I do know that people expected things to be there ...And they would go right to where...the [medication] was and grab it and come back. They knew they had

gotten it there before, and they could just grab it right there again. Again, without having to go to the aisle, search through the hundreds of products, and then come back [to the prescription department]. (Pharmacist 7)

I think it was because it was a quicker route than walking to the other section. (Pharmacy technician 3)

Selection Behaviors: The presence and features of the Senior Section seemed to frequently satisfy patients' needs to either have their medication concerns addressed through signage warnings or by discussing safety issues through direct contact with pharmacy staff.

I felt like they just came right up and said, I need help...Can you please help me? I'm looking for this type of product, that sort of thing. So most of them were pretty comfortable, I felt like, with asking first before they even tried to look themselves. (Pharmacist 1)

...I think [the Senior Section] gave them like that momentary like does this category go with what I want to do? And then now I don't have to interrupt and ask versus you know, I'm not really sure. Or maybe I do want to ask a question or 2, you know, just to verify, should I be taking this? So it kind of worked both ways. (Pharmacy technician 5)

Work System/Unit Factors

ITO Variable Domain: Physical layout and geography

Layout: The sectional layout of the OTC inventory, categorized into allergy, cough/cold, pain, and sleep, as well as the distinct shelving construction to benefit the older adult patient population, better enabled pharmacy staff/patient engagement and stimulated discussions of medication-related issues.

So to me, I feel like you listen to the people talking, and the stuff wasn't located too high, and it wasn't located too low, and that they could read the boxes, and it was carefully labeled. And there were just so many things that were taken care of, so, certainly, the where-is-this piece was taken care of for those products. (Pharmacist 4)

And then also, it was the way it was laid out because those things were so common, we didn't have to search through...You didn't have to search through everything. It was just going to be there. (Pharmacy technician 2)

Proximity: A principal concept inherent in the Senior Section was its proximity to the prescription department. The closeness of pharmacy staff to OTC medications allowed for better patient observation and greater opportunities to address patients' medication concerns in an expedited manner.

Having it close to the pharmacy, close to the register, just made it easier for them to navigate to the area and help choose products and then ring out without having to walk all the way out to the other area, which is hard for them...Because we could see them, and they were more likely to ask questions because they could see us too.

We were right there versus when they're out in the main store, they don't want to walk all the way back in and then come, go all the way back out... Since the Senior Section was closer to the tech window where they drop off prescriptions, a lot of time, they would start the encounter by just asking them if they needed help finding something... I think that having it closer to the pharmacy makes them more willing to ask questions... I think it just made it a little faster to do OTC consults and then get back to the consultation area, just because they were closer to each other.
(Pharmacist 2)

The location was great because all the medications usually are out in the main store, and bringing those in... forced interaction with the technicians and the pharmacist... It prompted people to ask more questions. But I like the fact that they did, that they had that experience that they could get the answers that they wanted... if it was out in the main store, I don't think they would have asked us.
(Pharmacy technician 1)

Prescription Department: A consequence of having the Senior Section located closer to the prescription department, and something that was predicted to be a direct function of this intervention, was that pharmacy staff would be better able to engage with patients while remaining in or near the prescription department. As a result, the research team anticipated the possibility that pharmacy staff/patient interactions would increase, but that the investment of time in those interactions could diminish because of the shorter distance, limited OTC inventory, and fewer opportunities for distractions from other store customers. Interviewee feedback supported this effect.

But this made it a lot easier to go out and do the OTC consult in probably 2 minutes or less versus going out into the main store and getting sucked out there. And then on your way back, you just want to cover your nametag because you can't back without getting asked, you know, where are the shoes? Where's the make-up, where's whatever? (Pharmacist 2)

I don't think [the Senior Section contributed to more interruptions requiring leaving the prescription department]. Like I said, there was a lot of, is this all you have? And then we would often have to go help them find what we did have. But that would have been, they probably would have interrupted us anyway. (Pharmacy technician 2)

OTC Inventory: In addition to the benefits of the smaller product selection contained in the Senior Section, the chosen products facilitated conversations about the reasons that certain medication were excluded from this section. Not only was this seen as shortening engagement times, because patients seemed less burdened by medication choices, but it also invariably led to the topic of safety becoming a foundational consideration for medication recommendations.

...I think it makes it easier for them just because it's a more limited section, so they're not overwhelmed by aisles and aisles of medication... we had it narrowed down for them. So I think that helps them make a decision better because a lot of

them don't really know where to start. So it's giving them a starting point, by having...here's [something] for pain. Here's something for cough. Here's something for cold. So I think that really helped... And then they weren't really worried about like what was in it and what other things could be wrong...

(Pharmacist 1)

So [patients] wanted to know if these were the main products that seniors should be taking and these were recommendations based on the elder generation or the medications that people are usually on...they liked that idea that we had them out in front there, that they were more recommended for their [symptoms]....

(Pharmacy technician 1)

ITO Variable Domain: Functions/features and availability of usable tools/technology

Tools from Senior Section: Pharmacy staff tended to endorse the theoretical potential for the tools provided in the Senior Section (i.e., the counter and lighted magnifying glass) to assist patients' reading of medication ingredients lists and warning labels. However, they also reported that these resources were used only sporadically, if at all.

I never saw anybody turn the light on. There were times I turned the light on just to see what would happen, if somebody would use it. There were times I put a box down there just to make it look like, oh, this is what it's for. I think they got an idea what it was for, but they did not use it...it could be just so different that they weren't expecting [those tools]. (Pharmacist 4)

...people can't read those fine prints on those warning, like if a warning is in the back. So I think that would be beneficial to have [the magnifying glass] there. But then people don't look at pills themselves either...so I guess it would be beneficial if you did move [the magnifying glass to a more prominent location], because some people can't read those warning signs on the back. (Pharmacy technician 3)

Tools in the Pharmacy: A secondary advantage of the Senior Section, with its proximity to the prescription department, was easier pharmacist access to electronic databases when questions arose about specific medications that required deeper investigation. Some of the most prevalent databases on which pharmacists relied included Vax comparisons, Facts & Comparisons, Natural Medicines, Epocrates, RxShortages, WebMD, Medscape, Micromedex, Google, and those containing patient medication profiles. Another prominent resource that was consistently identified was guidelines for safe OTC use, such as the Beer's Criteria list. Importantly, using these resources as a function of the Senior Section often led to pharmacy staff recommending that patients communicate further with the prescribing practitioner to determine safer treatment substitutions.

But if they had a doctor...note that...they were supposed to get something, and it was on the Beers list, I would show them where it was. And I would explain, are you sure you want to do this, and then explain that there are some issues associated with this medication and that there might be some safer alternatives. And I know the doctor suggested this one, and we would open the dialogue to see what we could come through as far as what things have you tried... (Pharmacist 4)

I think a lot of times, if I had issues or concerns, then I would strongly recommend they speak to their doctor about, you know, some of their concerns, or what I was worried about them. (Pharmacist 8)

Signage: As with the Senior Section-related tools, pharmacy staff feedback varied notably in their perceptions about the patients' use of and reaction to the cautionary signage placed throughout the section. About half of the respondents either (1) believed that people generally did not notice or read the signs, whether it was due to their size or wordiness, or (2) were completely unaware of whether the patients observed the signs. Those pharmacy staff who recalled when patients made use of the signage, considered this feature of the Senior Section to be a valuable method to relay warnings and prompt patient interactions.

The stop sign was kind of like, wait, don't take these. If you don't see it here, you might not want to take it. Ask somebody. Like the whole point really is to encourage that communication and that interaction. The bullet points, while [they] are important because some of those meds still aren't recommended if you are on X, Y, or Z, I think may be too much information. (Pharmacist 7)

I think that was really helpful for the older people, because I think it really made them kind of stop and think about, why am I getting this? So, it definitely made it easier for them to have a conversation. Because some of it almost seemed like it reminded them why was I going to pick this up? Oh, maybe I really should go talk to the pharmacist about why I want to pick this up. And so it made a bigger impact for them, and it made it easier...So I thought the signage itself was really, really good and informational to both us and them, because sometimes it would remind us like maybe why are they coming to get this. (Pharmacy technician 5)

ITO Variable Domain: Time and sequence demands

Workflow Integration: Another accomplishment of the Senior Section was its seamless integration into the existing pharmacy workflow. The combination of features, including its proximity to the prescription department, its selected inventory, and the increased opportunities for pharmacy staff engagement with patients, served to complement the already-strong collaborations between pharmacists and technicians without creating significant time or effort burdens.

Really, those interactions didn't take much time when you look at it here. We will always have some of those things where you go to answer one question for a patient and then they have one more and then they have one more. And all of a sudden, you've spent 5, 6 minutes talking to this person. But that's not what the majority of these things were at all. Most of these things were, maybe 2, 3 minutes at the most that you were spending with them...It made it easier because we had a certain amount of stuff right here in the pharmacy to be able to help them with here, not having to run out there. I liked it. I wish that [other pharmacies] would do something like that, actually. (Pharmacist 6)

Well, you have to multitask, you know...I mean, people already asked recommendations or questions as it is during the day, but it did help that it was

closer. That helped a lot...And, just having those safer products in that area where they like to come, and they don't necessarily have to go out too far...I think that was nice having it there. (Pharmacy technician 4)

Organization Factors

ITO Variable Domain: Staffing levels

Staffing: While continuing to recognize the typical problems of staffing levels within community pharmacies (e.g., persistent turn-over because of leaving for a higher wage), and of the challenges inherent in working in the prescription department, pharmacy staff indicated that the responsibilities of the Senior Section did not add appreciably to the demands of the general pharmacy staff workflow.

I mean, we always had a pretty good staff. We had a good amount of techs in there at one time, so we felt like we were pretty okay on that...normally, we had enough coverage, so there wasn't ever an issue where we felt like we were overwhelmed or couldn't handle something because we didn't have enough help. (Pharmacist 1)

I think it was doable. It was just a little bit more strenuous to balance the 2 a little bit, because if you're the only tech, and you have the pharmacist running, and the phones are ringing, and you're trying to get people through lines, you don't want to ignore them. But you have to try to prioritize which way you're going. (Pharmacy technician 5)

ITO Variable Domain: Organizational policy/priorities

Stocking: As there was no corporately-sponsored policy priority to maintain product inventory in the Senior Section, which could impose a potential barrier to its implementation, pharmacists worked to assume responsibility to keep the section stocked with the appropriate medications. Even when store managers were supportive of the Senior Section, this did not necessarily translate into more consistent or sufficient stocking activity. Unlike every other variable relevant to this project, the pharmacy technicians did not discuss stocking issues.

They were just ignoring [stocking]. It was holiday season, and they didn't take any time at all...then we took personal responsibility too for that. [Pharmacists and other staff] were all watching that section to make sure there was all this product there...bring it over and fill it up, make sure that section looks good. (Pharmacist 4)

ITO Variable Domain: Social norms and pressures

Corporate Support: Pharmacy store managers and upper management are perceived as being primarily interested in product turn-over, which is a bottom-line business issue. In the U.S., this corporate motivation has traditionally prompted placement of the OTC aisles in more prominent locations for customers, which are outside of the prescription department, often requiring pharmacy staff to leave the prescription area (sometimes for extended periods of time to answer patients' questions). Regardless of historical OTC aisles placement, however, patient care was considered a priority within the corporation's mission.

Once the Senior Section was set up in the pharmacy, this new intervention was seen to substantiate the corporate-wide expectation to engage with patients about their care.

Well, they do encourage us to escort patients to product. Yeah, so that's definitely a corporate thing...And they do support us consulting patients' prescriptions every time, so [the pharmacy organization] has always been very pro-patient care, so I would say, yes, they're very supportive of it. (Pharmacist 2)

They supported [our interacting with older adult patients]...They let us go out and answer questions and if there was any further, you know, instruction with, like I said, interactions with medication. [That's the] general culture, yeah...They encouraged that, yep. (Pharmacy technician 1)

Discussion

Interviews of all pharmacy staff involved in the Senior Section implementation provided support for its primary objectives, to promote patient engagement around OTC medication safety issues. People 65 and older was the population chosen as the intervention's focus because of the high prevalence for harms due to a variety of biopsychosocial factors.⁹ An unanticipated success, however, was its noticeable use by a considerably wider age demographic. In fact, although designed specifically and solely for older adults, the Senior Section was perceived as advantageous for all patients due to its being near both to pharmacy staff and to a safer OTC medication inventory, creating opportunities for broader patient interactions about a variety of medication-related issues. As a result, the Senior Section's presence was viewed as useful beyond the safety objectives underlying the intervention's design for older adults. These results beg the question about whether it might be appropriate to develop OTC sections specific for other patient populations, such as pediatric patients, given the high prevalence of dosing mistakes with pain and fever medication for different pediatric age groups.³¹ Or, perhaps, one might investigate the possibility of highlighting higher risk products generally, either in one specific OTC section, or throughout the entire OTC section of a retail establishment.

Given that a central characteristic of the Senior Section was its proximity to the prescription department, it is not surprising that this feature was universally considered a benefit to patient engagement about OTC medication choice. Being able to conduct OTC encounters with patients, while not having to accompany them to other sections of the store, was a considerable time-saving method. Also noteworthy was the reported positive effect of Senior Section proximity on other practitioner, patient, work system, and organizational factors. Proximity seemed to benefit safety, convenience, technician role, workflow integration, age, Senior Section purpose, selection behaviors, prescription department, signage, pharmacy tools (i.e., information databases), and corporate support (i.e., expectation for patient care engagement). Taken together, these and other factors establish the Senior Section as an important resource for overcoming general pharmacy barriers to pharmacists' and technicians' abilities to assist older adults in making safe medication decisions by ensuring the benefits and lessening the risks of OTC use.

Both pharmacists and pharmacy technicians reported that the Senior Section served to expedite technicians' hand-off of patients to pharmacists to make recommendations based on specific medication needs. Feedback from pharmacy staff confirmed that patient engagement brought about through the Senior Section could be accommodated within the existing workflow without creating additional burdens. This outcome was anticipated when designing the Senior Section, and is a feature with the greatest potential to promote the intervention's utility within a busy pharmacy practice setting.

Training related to the Senior Section reinforced pharmacy staff competence in providing safety recommendations for OTC use. An associated benefit of the Senior Section's placement near the prescription department was that pharmacists had ready access to information databases (e.g., Facts & Comparisons) and safety resources (e.g., the Beers Criteria list), which further prepared them to have meaningful patient engagements. These 2 factors better ensured that OTC encounters became more robust once the Senior Section was put in place, and seemed to contribute to referrals to the patient's practitioner when there was an identified need to address complex clinical or treatment issues.

Some countries have a pharmacy-only section that stocks non-prescription medications "behind the counter."²⁻³ These medications can only be purchased in a pharmacy (i.e., not a convenience store). The premise of this section is to require a consultation with a pharmacist prior to purchase to encourage safe use. No such section currently exists in the United States. In 2009, the U.S. General Accounting Office published a report regarding a "behind the counter" (BTC) drug category.³² It concluded that a BTC model was feasible, but that effective operation would require a demonstration that benefits outweighed the risks and/or costs, sufficient resources and compensation were available, and that encounters could be documented in the electronic record. This project is the first to examine those benefits, costs, and resources needed to prioritize the acceptance of this model.³³

Despite the generally positive feedback associated with the Senior Section, 2 aspects of the intervention received more moderated reactions: (1) Tools and (2) Signage. Patients did not always notice (or did not read if noticed) the cautionary signage that was placed in the section, while patients' use of the provided counter and lighted magnifying glass to aid consideration of product use instructions and warnings was even more infrequent. It was not apparent, however, that limited patient involvement with these tools appreciably affected pharmacy staff acknowledgement about the overall benefit of the intervention or even the potential usefulness of these 2 features. Further research is necessary to determine how to maximize the utility of these Senior Section-related tools, including the extent of and motivations for patients who stayed within the Senior Section and used those tools (rather than leaving the area to select OTC in another section of the store), so that they can better contribute to increased patient safety.

Limitations

Although the qualitative approach for this study seemed to reveal obvious support about the benefits of the Senior Section, the results should still be viewed through an understanding of the limitations that characterize this project. First, the qualitative findings represent information obtained through interviews conducted with 8 pharmacists and 7 pharmacy

technicians. Given that these 13 participants represent all pharmacy staff who took part in the Senior Section training, the feedback can be considered a valid indication of the thoughts from those involved in intervention implementation. Second, only 4 pharmacies from the same organization with similar layouts participated in Senior Section implementation, but a future research project is aimed at expanding this intervention to examine its effects in a different, and larger, healthcare organization. Third, the results from this pilot study are likely not generalizable, but provide the basis to justify a future and larger research project. Fourth, the pharmacy staff interviewed for this study represent a racially and ethnically non-diverse sample. Fifth, as already mentioned, the Senior Section was designed to improve safe OTC medication selection in the elderly, but many pharmacy staff noticed prevalent use by other age groups, including parents of young children. Although it will be valuable to learn how a Senior Section-type intervention can benefit other age demographics, use by younger people shifted Senior Section resources to issues not necessarily related to OTC medication safety. Finally, intervention costs were not estimated for the purpose of this study, but itemized intervention costs and scalability will be determined through future research.

Implications

Findings from the systematic qualitative analysis of pharmacy staff interviews demonstrated consistent conclusions about the Senior Section's ability to address systemic behaviors (previously identified through focus groups with pharmacists), while suggesting that successful implementation allows for intervention at the level of pharmacy staff/patient communication that could be reasonably expected to affect safe selection and use of OTC medications. That is, a physical system redesign, which located a specially-selected inventory of OTC medications (with lower risk profiles for older adults) proximal to the prescription department and contained cautionary signage to communicate warning information, seemed to successfully introduce processes that could reasonably be expected to ultimately result in OTC medication safety within this population. In addition, this intervention did not seem to disrupt current pharmacy practice workflow. Future research is necessary (and indeed planned) to determine generalizability and sustainability potential. However, this initial evaluation of interview content from pharmacists and pharmacy technicians working in multiple pharmacies is promising, and supports the Senior Section as a valuable method to promote opportunities to engage about OTC safety issues, not only with older adult patients but also those representing a broader age demographic.

For this study, a sample of pharmacists and pharmacy technicians provided insights into the overall effectiveness of the Senior Section, when implemented in selected pharmacies, at addressing and overcoming a number of systemic barriers impeding engagement with patients about OTC medication safety. The Senior Section was consistently seen as a valuable method to successfully promote patient discussions to minimize OTC-related harms, at least within an initial selection of similar pharmacies. To begin understanding the generalizability of the Senior Section, and its influence on outcomes, the research team now is working to introduce the intervention into a greater number of pharmacy settings with different sizes and configurations. Senior Section expansion decisions will involve technical input from architects, system engineers, and workflow management specialists.

Acknowledgements:

Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Wisconsin-Madison School of Medicine and Public Health (see Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, *J Biomed Inform.* 2009 Apr;42(2):377-81, for example). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Funding Sources: This work was supported by the Agency for Healthcare Research and Quality [grant number R18HS024490]; and the Clinical and Translational Science Award (CTSA) program, through the NIH National Center for Advancing Translational Sciences (NCATS) [grant UL1TR000427 (now UL1TR002373)]. The content is solely the responsibility of the authors and does not necessarily represent the official views of either the Agency for Healthcare Research and Quality or the NIH.

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Table 1:

Symmetry Between Coding Themes: Input-Transformation-Output model vs. SEIPS 2.0 model

Input-Transformation-Output Model Variable Domains	SEIPS 2.0 Model Variables	SEIPS 2.0 Model Variable Definitions
Provider Factors		
Provider skills, knowledge, training, education	Competence	Pharmacy staffs' perceived ability to make OTC recommendations
	Safety	Discussion of safety issues with patients
	Training	Training related to the Senior Section
Needs, biases, beliefs, moods	Convenience	Pharmacy staff or patient conveniences related to the Senior Section, but are not solely related to other variables (e.g., Proximity)
	Technician role	Description of interactions involving pharmacy technicians only
Patient Factors		
Patient age, gender, ethnicity, language	Demographics (Age)	Benefits of the Senior Section to other patient age groups
Patient skills, knowledge, training, education	Purpose	Related to patients acknowledging the purpose of the Senior Section
	Selection behaviors	Description of patient behaviors/needs while selecting medications
Patient needs, biases, beliefs, moods	Purpose	Related to patients acknowledging the purpose of the Senior Section
	Convenience	Pharmacy staff or patient conveniences related to the Senior Section, but are not solely related to other variables (e.g., Proximity)
	Selection behaviors	Description of patient behaviors/needs while selecting medications
Work System / Unit Factors		
Physical layout and geography	Layout	Sectional organization of the Senior Section (i.e., pain, cough/cold allergy, sleep)
	Proximity	Utility of closeness of Senior Section to prescription department
	Prescription Department	Need for pharmacy staff to leave the prescription department (including the Senior Section area) to go out to the main store
	OTC Inventory	Related to the types of OTC medications/products found in the Senior Section
Functions/features and availability of usable tools/technology	Tools from Senior Section	Tools included in the Senior Section
	Tools in the pharmacy	Tools to support OTC counseling and make recommendations, which are not part of the Senior Section
	Signage	Issues related to the Senior Section signage
Time and sequence demands	Workflow integration	Senior Section integration into the pharmacy workflow (may include time pressure issues)
Organization Factors		
Staffing levels	Staffing	Related to staffing of the pharmacy
Organizational policy/priorities	Stocking	Stocking issues related to the Senior Section
Social norms and pressures	Corporate support	How the pharmacy organization influences Senior Section implementation
External Environment		
Extra-organizational rules, standards, legislation, enforcement	<i>no specific node</i>	

Table 2:

Demographic Characteristics of Interviewed Pharmacy Staff (n=13)

Job Title	
Pharmacist	8 (62%)
Pharmacy technician	7 (38%)
Years of experience in your current job title	17 ± 13.520 (range: 1–40)
Years worked at this pharmacy	17 ± 12.492 (range: 1–35)
Age	43.46 ± 13.568 (range: 20–64)
Gender	
Female	13 (100%)
Male	0 (0%)
Highest school grade completed	
Some college or technical school	3 (23%)
College or technical school graduate	10 (77%)
Hispanic or Latino origin	
Yes	0 (0%)
No	13 (100%)
Race	
White	12 (92%)
Black or African American	0 (0%)
Asian	1 (8%)
Native Hawaiian or other Pacific Islander	0 (0%)
American Indian or Alaska Native	0 (0%)
Other	0 (0%)

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