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**Key Words**: Falls Prevention, Community Pharmacy, Medication Therapy Management, Community Engagement

**Abstract**

*The objectives of this article are to discuss the process of community engagement experienced to plan and implement a pilot study of a pharmacist-provided MTM intervention focused on reducing the use of medications associated with falling, and to present the research methods that emerged from the community engagement process to evaluate the feasibility, acceptance, and preliminary impact of the intervention. Key lessons learned from the community engagement process also are presented and discussed. The relationship building and planning process took twelve months. The RE-AIM framework broadly guided the planning process since an overarching goal for the community partners was developing a program that could be implemented and sustained in the future. The planning phase focused on identifying research questions that were of most interest to the community partners, the population to study, the capacity of partners to perform activities, and process evaluation. Much of the planning phase was accomplished with face-to-face meetings. After all study processes, study materials, and data collection tools were developed, a focus group of older adults who represented the likely targets of the MTM intervention provided feedback related to the concept and process of the intervention. Nine key lessons were identified from the community engagement process. One key to successful community engagement is partners taking the time to educate each other about experiences, processes, and successes and failures. Additionally, partners must actively listen to each other to better understand barriers and facilitators that likely will impact the planning and implementation processes. Successful community engagement will be important to develop both formative and summative evaluation processes that will help to produce valid evidence about the effectiveness of pharmacists in modifying drug therapy and preventing falls as well as to promote the adoption and implementation of the intervention in other communities.*

## Introduction

One-third of people 65 years and older (older adults) and one-half of people 80 years and older will fall in a given year.[1] Nationally, it is estimated that falls will cost $55 billion in 2020.[2] Effective fall prevention has the potential to reduce serious fall-related injuries, emergency department visits, hospitalizations, nursing home placements, and functional decline.[3] Because falling is not a normal part of aging and can be prevented, developing strategies to prevent falling is an important public health goal that involves several community stakeholders.[4]

In Wisconsin, an Aging and Disability Resource Center (ADRC) is a community-based, public health organization that is a key stakeholder in falls prevention. A network of ADRCs was created by statute in Wisconsin to complement and support the statewide expansion of managed long term care beginning in 2006.[5] An ADRC can be a county or tribal entity, a multi-county consortium, a private non-profit organization,

or a combination of entities. ADRCs are required to provide a broad spectrum of services including providing information and assistance, prevention programing, benefit specialist services, long term care options counseling, and access to a wide array of public and private programs and services. Services provided by ADRCs must be available to the elderly, adults with developmental and/or physical disabilities, and adults with mental illness and/or substance use disorders. ADRC funding is tied to providing evidence-based programming, so they have an interest in research demonstrating the effects of programming.

Since falls are caused by many different factors, effective falls prevention strategies are multifactorial.[4] Reviewing medication is important since several therapeutic categories of drugs are classified as fall risk-increasing drugs (FRIDs)[6] because their use is associated with falling.[7-10] On average, older fallers use 2.34 of these medications regularly.[6] Current falls prevention guidelines suggest all fallers have their medications reviewed by a health care provider to identify medications that could be removed.[11] Removing FRIDs has been shown to be effective at reducing the number of falls among older adults.[6,12]

Pharmacist- provided medication therapy management (MTM) for older adults using FRIDs likely is feasible and effective. Pharmacist-provided MTM is effective in reducing medication related problems among older adults mainly by pharmacists discussing and evaluating medications with patients and making recommendations to prescribers for medication modifications (stop, switch, or reduce the dose of a drug).[13-20] One known study demonstrated that community pharmacists were effective, relative to controls, in reducing the proportion of older fallers who discontinued use of a FRID following a face-to-face MTM session.[21]

*Community-Academic Partnership*

The project described in this article is a partnership between community stakeholders and academic partners, both of whom wanted to develop and test the feasibility and other outcomes of a pharmacist-provided MTM program as a component of preventing falls in older adults. A key stakeholder involved in the project was the ADRC of Brown County (ADRCBC). Brown County is located in the northeast quadrant of Wisconsin, and contains the city of Green Bay. In 2005, ADRCBC initiated and led the Safe, Active, Independent Living (SAIL) coalition, largely focused on falls among older adults. Several other community stakeholders were involved in the SAIL coalition including health care providers from inpatient and outpatient rehabilitation departments from local health systems, a community pharmacist, representatives from local higher education facilities training health care providers, and the Green Bay Fire Department. Currently, ADRCBC offers evidence-based programming on falls prevention including Stepping On, Keep Stepping, in-home falls risk screens, and other classes on falls prevention topics.

Considering the community health organizations, health care providers, and academics involved in this project, we initiated a community engagement process. Community engagement is defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people".[22] Stakeholders in the "community" include those individuals impacted by the health issue being addressed as well as academics, public health professionals, and policy makers. In general, the goals of community engagement are to build trust, enlist new resources and allies, create better communication, and improve overall health outcomes as successful projects evolve into lasting collaborations.[22-24] As such, successful engagement involves working with all stakeholders to learn cultures, norms, and lessons about each other and the collaborative process.[25] Community engagement was a vital component of planning the current project to understand the strengths and weaknesses of partners, and to identify key aspects of the project such as the study questions, research design, and data collection procedures in order to study the feasibility and outcomes of a pharmacist-provided falls prevention MTM intervention.

*Objectives*

One objective of this article is to highlight the process of community engagement we experienced to plan and implement a pilot test of a pharmacist-provided MTM intervention, and to present the research methods that emerged from the community engagement process that will be used to evaluate the feasibility, acceptance, and preliminary impact of the intervention. An additional objective of this article is to present important lessons we learned from the community engagement process that community stakeholders and pharmacy researchers could use if they implement a community engagement process to develop and evaluate the impact of pharmacist-provided services in the community.

**Process of Community Engagement**

*Relationship Building/Study Planning*

The PI for the current project (DM) initially was contacted by the program coordinator at ADRCBC (BM) to discuss a community-academic partnership to conduct research about activities the coalition was planning related to community pharmacist-provided medication management. A series of subsequent face-to-face meetings over six months conducted in Green Bay focused on several topics including introductions to group members, potential research ideas, knowledge gained from previous activities, capacity for new activities, comfort with the research process, and the feasibility of expanding activities into new areas. There were four core members of the planning group (DM, BM, JK, and a retired psychiatrist at ADRCBC). The academic partner helped the community partners write two grants to obtain support for new projects.

Discussions related to planning, implementing, and evaluating a pharmacist-provided MTM intervention for older fallers became more focused about 6 months into the partnership. The community partners had a long term vision of connecting various pharmacy provider organizations in the community to older adults in order to provide needed services. The community partners were interested in developing such a program that could be disseminated, implemented and sustained in the community after any evaluation was complete. Based on this information, the academic partner (DM) adopted the RE-AIM framework to guide broadly the planning process.[26] The RE-AIM framework was chosen since it can be useful to translate research into practice and to help plan public health programs and improve their chances of working in "real-world" settings. Additionally, the RE-AIM framework addresses issues related to patients who will be targets for a program and issues related to organizations that will provide the program.[26] The planning process focused on various topics within and outside of the RE-AIM framework.

The first topic discussed was the research questions that could be addressed and questions that were of most interest to the group. Past successes and failures related to medication management in older adults, the role of pharmacists in medication management, as well as a vision for the future were discussed. The group was able to list key questions that needed to be researched and to prioritize the order of the key questions. The group determined that a pilot study to examine the feasibility of implementing a program as well as show preliminary impacts of the pharmacist was a top priority since a pilot study was small in scale and could best capitalize on available resources.

The next topic discussed in the planning phase was the patient population to study. Ultimately, the group decided to focus on older adults who completed the Stepping On falls prevention workshop. This population was targeted mainly due to the experience of the ADRCBC in offering and providing Stepping On workshops; ADRCBC began offering the Stepping On workshop in 2008. Stepping On is promoted by the Centers for Disease Control and Prevention[27] and is an evidence-based, multifactorial, small-group based, behaviorally oriented educational program to prevent falls among at-risk older adults.[28] One of the seven, two-hour classes that make up the Stepping On workshop focuses on medication education and the pharmacist in our planning group (JK) provided these classes in the workshop. A large-scale evaluation showed the medication education classes to be ineffective at modifying drugs associated with falling.[29] Our group wanted to show that expanding the role of a pharmacist beyond the medication education class could be effective at modifying drug use.

Next, the group focused on the capacity of each partner to perform various procedures associated with the research, and to plan how the procedures would be accomplished. During these discussions it was important for partners to learn what relationships and/or processes had been developed and/or could be improved to facilitate the development and evaluation of the current project. The goal was not to re-invent resources, but rather identify and modify, if necessary, resources that currently existed. The academic partner's role during these discussions was to highlight how various procedures would impact the quality of the evidence produced from the project.

Next, the group discussed the value of evaluating the processes to implement the procedures that were developed for the project. Process evaluation was important for the group as there was a desire to understand what would work and why it worked. One motivation for implementing process evaluation was to ensure that the project could be expanded to serve additional older adults in the future. After several face-to-face meetings, telephone conference calls and email were used to refine study processes (e.g. recruitment, data collection), and to develop all of the study materials (e.g. consent forms) and data collection tools (e.g. surveys, falls calendars). In total, the relationship building and planning process took about 12 months.

*Advisory Panel to Review Procedures and Finalize Research Plan*

After all study processes, study materials, and data collection tools were developed, we sought input into the concept and process of the intervention from older adults who represented the likely targets of the MTM intervention. We created an advisory panel of six people who were 65 years and older and completed the Stepping On workshop between 2008 and 2010. ADRCBC mailed letters to potential advisory panel members informing them about the advisory panel, their roles and responsibilities, and information if they wanted to participate. Older adults wishing to participate were telephoned and a meeting time was established. The study PI (DM) and the ADRCBC's program coordinator (BM) met with the advisory panel. The panel discussed the concept of medication management, the role of the pharmacist in medication management, and reviewed and commented on all study processes and study materials. Handwritten notes were used to document the discussions.

The panel thought the concept of medication management specifically focused on medications related to falling was needed, would be very useful, and would augment the medication class that was part of the Stepping On workshop. A common theme from the advisory panel was that they viewed the pharmacist as a very important health provider that should be involved in their care. However, several panel members said they often don't notice the pharmacist when they go to the pharmacy or cannot identify the pharmacist at their pharmacy. Often times they were afraid to ask questions of the pharmacist as they felt the pharmacist was too busy to answer their questions or they were afraid the pharmacist did not want to be interrupted. The panel said they would welcome the opportunity to have a pharmacist meet with them to review their medications. Additional panel comments about the study processes and materials that resulted from the planning process were incorporated to develop the final study methods (i.e. processes and materials) that are described next.

**Study Methods Derived from the Community Engagement Process**

*Study Design*

A randomized, cluster, controlled experimental design is being used to assess the feasibility, acceptability and effectiveness of a pharmacist-provided MTM intervention focused on reducing the use of medications associated with falling. The unit of randomization is a Stepping On workshop rather than an individual patient. We were informed that older adults who enroll in the Stepping On workshop often are friends outside of the class and likely would talk with each other about which experimental group they were assigned. Thus, to avoid any contamination of the study groups, the randomization unit is the Stepping On workshop. Participants in each workshop randomized to the intervention group receive an MTM session and direct feedback from a pharmacist regarding their medication use (as described below). One pharmacist at one retail pharmacy in Green Bay, Wisconsin provides the intervention. The MTM intervention is incorporated into usual practice and daily activities at the pharmacy via scheduled appointments. Participants randomized to the control group receive usual care, consisting of a mailed pamphlet describing medication use and falls. The study was approved by the Health Sciences Institutional Review Board at our institution.

*Recruitment and Randomization*

Study sampling occurs from a population of Stepping On workshop participants. English speaking participants, 65 years and older, who have fallen in the past 12 months or have a fear of falling, who complete at least four of the seven curriculum classes in the Stepping On workshop, and are capable of providing their own consent are eligible for the study.

Our goal is to enroll 80 participants in this pilot study who complete the Stepping On workshop, with each study group consisting of 40 participants from workshops randomly assigned to each study group. The primary factor considered when deciding on the sample size was the number of Stepping On workshops that would be offered by ADRCBC and the likely number of older adults that would sign-up for each workshop. ADRCBC is coordinating nine Stepping On workshops throughout the year and aims to enroll 15-18 participants in each workshop. At the last meeting of each workshop, two IRB-trained study recruiters who volunteer at ADRCBC meet with Stepping On workshop participants to introduce the study and answer any questions. Each prospective study participant receives a packet of information that describes the study, outlines participation expectations, and asks for participation. The packet contains a consent form that prospective study participants must sign and provide to ADRCBC to enroll in the study.

About 4-5 days after the last meeting of each workshop, an IRB-trained study recruiter, who coordinates programming at ADRCBC, will telephone prospective study participants who have not enrolled in the study to answer any questions, to determine their willingness to enroll, and to instruct them how to return the signed consent form. All consent forms

returned to ADRCBC are faxed to the PI at the School of Pharmacy. A staggered enrollment period is planned corresponding to the ADRCBC Stepping On workshop schedule.

*Procedures*

Following enrollment, trained third-year student pharmacist telephone interviewers are assigned to each study participant. Only male student pharmacists will be assigned to male study participants based on feedback from the advisory panel that older males can hear male voices better than females. Only the student pharmacist assigned to a study participant will contact that study participant throughout the study. This decision was made based on feedback from the advisory panel that they preferred to not be contacted by several different people during the study as there could be uncertainty whether the contact was related to the study. All telephone contacts and interviews will use a standardized script developed by the study team and all student interviewers will be blinded to study group assignment.

The study timeline is outlined in Figure 1. After establishing a time for the pre-intervention survey, the student pharmacist informs the project manager that a time for the pre-intervention telephonic interview has been established. The project manager then mails the study participant Packet #1. A cover letter in the packet thanks them for participating in the study, contains a reminder of the time for the pre-intervention telephone survey, and instructs them to complete the pre-intervention survey form and drug (prescription, OTC and herbal) therapy lists so they can be used during the pre-intervention telephone survey.

After the pre-intervention survey is completed, the project manager provides the name and contact information for each intervention group member to staff at the retail pharmacy. Each intervention group member will be contacted by an employee of the retail pharmacy to arrange a date and time for the MTM session with the study pharmacist. The MTM session will take place at the pharmacy with the study pharmacist, unless another location is requested by the study participant. After the MTM session, the study pharmacist will give the participant Packet #2 containing a pamphlet describing the role of medications in falls.[30] The monthly falls calendars, and instructions to complete them, are to be used to document falls that study participants experience. The schedule grid will help remind study participants of upcoming interviews with the student pharmacist. The first follow-up telephone interview with intervention group participants will take place approximately six weeks after the MTM session. We allotted two weeks for the MTM session to have an impact on the medications used by the study participant.

All control group participants will receive Packet #2 by mail after the pre-intervention survey. The first follow-up telephone interview with control group participants will take place approximately 44 days after a control group member was assumed to have received the pamphlet. We allotted two weeks for the pamphlet to have an impact on the medications used by a study participant.

For each follow-up telephone call, the student pharmacists will contact study participants about 7 days before the call to reconfirm the time and date for the follow-up telephone call. During the follow-up telephone calls participants will be asked to refer to the falls calendar to provide information about falls and will be asked about current medications they are taking and any medication-related changes. For the intervention group, the study pharmacist will provide a follow-up telephone call 90 days after the medication assessment. At the end of each call a time and date for the next follow-up call will be established.

The post-intervention survey will take place approximately 6 months after the initial MTM session by the study pharmacist (intervention group) or 6 months after receipt of the pamphlet (control group). Participants will be given $50 for participating in the study: $25 after pre-intervention survey completion and $25 for completing the entire study.

Information collected during all of the telephone interviews will be entered by the student pharmacists into an electronic, web-based patient medical record (EMR) created by the study team. The study pharmacist also will enter information collected during the MTM session and the 90-day follow-up telephone call into the EMR. Student pharmacists and the study pharmacist can access each patient's EMR, download the file, update the file with new information, save the file, and upload it back to the server.

*Intervention*

The one-hour MTM session with the study pharmacist will follow the core components of MTM.[31] The goal of the MTM session is to identify and modify the use (i.e. remove drugs, switch drugs, and lower doses) of any FRID and provide education to the patient about disease management and falls prevention. Prior to meeting with the patient, the study pharmacist will access the EMR for the patient to review the

information collected during the pre-intervention survey. When the patient and the study pharmacist meet, the study pharmacist will conduct a medication therapy review (MTR), talking with the patient about the appropriateness of each medication (prescription, OTC, and herbal), identifying any adverse drug events experienced by the patient, and providing education to improve medication self-management. Based on the MTR the study pharmacist will develop a medication-related action plan and communicate recommendations for medication modification to patients and corresponding prescribers. It is expected that the MTM session will take no more than 60 minutes. The study pharmacist will document in the EMR and follow-up on all recommendations made to prescribers to determine whether they are accepted or rejected.

The study pharmacist (JK), a geriatrician with expertise in falls prevention (JM), a geriatric pharmacotherapy expert (RB), and a researcher with expertise in adult education (BM) worked with the PI (DM) to develop an evidence-based clinical algorithm for the study pharmacist to follow during the MTM session. The study pharmacist has extensive experience as a nursing home consultant and is a certified MTM pharmacist in Wisconsin, which includes motivational interviewing (MI) training. The geriatrician contributed expert information related to geriatric disease management and falls education. The geriatric pharmacotherapy expert provided information related to the inclusion of FRID for the MTM session as well as assessment and modification for FRID to the clinical algorithm. A total of five therapeutic categories of drugs (neuroleptics, benzodiazepines, anti-depressants, sedative/hypnotics, and antihypertensives), as well as certain additional drugs [cyclobenzaprine, carisoprodol, sedating antihistamines (e.g. hydroxyzine, meclizine, dicyclomine, diphenhydramine) oxybutynin, carbamazepine, methocarbamol, prochlorperazine, benztropine, and trihexiphenidyl] with good literature support showing association with falls among persons 65 and older are included in the clinical algorithm.[7-10]

To be successful in modifying medication, a pharmacist must effectively communicate recommendations to patients and/or to prescribers and have the recommendations accepted. The study pharmacist has extensive experience communicating medication recommendations to physicians in nursing homes. For this project, we developed a form that the study pharmacist will fax to prescribers to communicate medication recommendations.

*Student Pharmacist and Pharmacist Training*

Guided student pharmacist protocols and interview scripts for the pre- and post-intervention surveys and the monthly follow-up telephone calls were created and reviewed for content validity. The protocols and scripts were used by the study team to train student pharmacists and will be used to assess fidelity to the protocols of the actual interviews between student pharmacists and study participants. Student pharmacist training consisted of a thorough review of the guided interview script with simulated practice and feedback. After a discussion about interviewing for research, each section of the script was reviewed with suggestions for handling specific scenarios (e.g. participants asking medication-related questions which the student pharmacists were not permitted to answer). Student pharmacists were trained to ask open-ended questions in appropriate situations, to ask probing questions when necessary, and were trained not to provide any health or medication-related advice if asked by study participants. In such a situation, student pharmacists were trained to tell participants to ask their pharmacist or physician about any such questions or issues. After the student pharmacists had time to review the script and listen to an example, they participated in simulated practice with a study member (BM). Student pharmacists were trained to enter all information obtained during the interviews into the EMR.

To facilitate pharmacist training and assessment of fidelity, a Falls Medication Review Session protocol was developed. The protocol contains checklists for the pharmacist to use in preparing for, conducting and completing each MTM session. The protocol also contains detailed checklists for the 3-month follow-up telephone calls, including a discussion of recommendations and changes. In addition to traditional MTM session content, the protocol purposefully incorporates components of the OARS framework[32] within motivational interviewing including establishing rapport, using open-ended questions (i.e. “O”), providing affirmation and positive feedback and reinforcement for positive participant choices and behaviors (i.e. “A”), reflective listening (i.e. “R”), involving the participant in decision-making, , and summarizing key points (i.e. “S”).

A 4-hour, live, training session with the pharmacist and the research team was conducted. The evidence-based clinical algorithm and Falls Medication Review Session protocol were reviewed in detail and the pharmacist was instructed to refer to them during each MTM session. Due to study-related outcomes, the pharmacist training also emphasized the importance of prioritizing participant-directed interventions, with the order of preference being identifying FRID use using

the clinical algorithm, recommending FRID modifications, identifying and resolving adverse drug events, and recommending fall reducing lifestyle management. Additionally, the study pharmacist was introduced to the web-based electronic medical record and instructed how to access study participants' EMR, write to the EMR, save them, and upload them to the secure server. A user's guide to using the web-based electronic medical record system was created for the pharmacist to use if needed.

*Process and Outcome Evaluation*

Table 1 contains a summary of the process and outcome evaluations that will be conducted as part of the study. All interactions (i.e. telephone interviews and face-to-face communication) between the study participants and the student pharmacists and the study pharmacist will be audiotaped. The audiotapes will be used to conduct some of the process evaluations. Periodic phone conversations with the pharmacist will be used to obtain feedback about the usefulness of the EMR and any barriers to providing the MTM sessions. The program coordinator at ADRCBC will tabulate Stepping On participation and we will combine this with enrollment data to determine accrual rates and attrition rates. Reasons for not enrolling in the study as well as dropping out of the study will be assessed.

Outcome evaluation will include participant outcomes as well as what happens with recommendations made by the pharmacist. Primary outcomes include the proportion of study participants that stop using FRIDs and the number and type of FRIDs that are stopped. Secondary outcomes are changes in the proportion of study participants who fall and the number of falls in the post-intervention time period, and a tertiary outcome is the acceptance rate of pharmacist medication recommendations. Participant information will be collected using a 109-item pre-intervention survey and a 70-item post-intervention survey. Both surveys contain items to ascertain a complete medication list (prescription, OTC, and herbal supplements). The purpose of the follow-up telephone calls is to determine the frequency and severity of any falls experienced by participants and to identify any changes in medication use since the last study contact.

The use of any FRID and the quantity of FRID use in the pre-intervention period will be assessed by the MTM pharmacist (intervention group) and a study clinical pharmacist (control group) by comparing the clinical algorithm developed for the study with the list of medications patients reported in the pre-intervention survey. The MTM pharmacist will document in the EMR all medication recommendations made to prescribers and participants as a result of the MTM session and whether the recommendations were accepted by prescribers and participants. The study clinical pharmacist will document in the EMR all medication recommendations for control group participants. Changes in the use of FRID for both intervention and control group study participants will be assessed by study staff by examining documentation in the EMR about changes in medication obtained from study participants during the follow-up telephone calls and by comparing names and dosages of medications participants reported using in the pre- and post-intervention time periods.

The number of falls in the post-intervention period will be assessed through the use of falls calendars completed by study participants and follow-up telephone interviews.[36,37] The post-intervention survey includes items to assess participant satisfaction with the pharmacist (data collected by the trained student pharmacist)[38] and participant satisfaction with the student pharmacist (data collected by a non-student, study staff member).

*Analysis*

Descriptive statistics (mean, standard deviation, frequencies) will be reported for all variables collected at baseline and six months by study group. Differences at baseline and from baseline and month six will be compared by study group using appropriate statistical tests. The descriptive statistics will be used to inform sample size calculations for a similar, larger trial. Accrual rate will be estimated by the average number of Stepping On workshop participants that enroll after each workshop and overall. The study dropout rate will be estimated by the number of enrolled study participants lost to follow-up divided by the total number of enrolled study participants.

**Lessons Learned from the Community Engagement Process**

The community engagement process is important as it can inform the adoption, implementation, and sustainability of effective, evidence-based programs in communities to better serve clients. The process of academic researchers and community-based public health organizations engaging with each other for the purpose of planning and conducting evaluations of health care service delivery models likely will become more common. Table 2 contains a list of nine lessons we learned from the community engagement process and a description/examples for all nine lessons. One important lesson from the community engagement process was discussing and coming to agreement on the importance of including both process and outcome evaluation in the pilot study. It is important to note that both types of evaluation

were important to all community partners engaged in the process. There was consensus among the community partners that the results of the evaluations would provide information related to decisions that were made during the community engagement process and would inform a future larger-scale version of the pharmacist-provided intervention. The following paragraphs provide more details about our community engagement process and highlight some of the lessons learned during the community engagement process.

An important decision from the perspective of both the academic and community partners is determining the research questions to pursue. One barrier to this decision is academic partners proposing to do too much, too fast, before completely understanding the capabilities of the community partners. Academic and community partners must take time to discuss the activities that have been tried in the past, the process used to implement activities, problems with the process, and the results of the activities, both successes and failures. In the present situation, the ADRCBC had been working on falls prevention for a relatively long time and had involved other partners in the community. The Brown County coalition had tried many approaches to falls prevention and had experimented with the process and feasibility of a pharmacist meeting with patients and reviewing medications. They were ready to expand services to study the pharmacist's impact on modifying FRID use. We found face-to-face meetings facilitated this process. Partners need to provide information, ask questions, and listen to each other in order to identify mutually agreeable research questions.

Another important issue we discussed was the research process and determining which research components the community partners were comfortable performing. A key facilitator in this step was the community partners' understanding of the value of good evidence to show program impact. Further, the community partners understood the relationship between research processes and the quality of evidence produced from the processes. We worked together to identify resources and processes that could be used to facilitate proper execution of important elements of the research design, research procedures, and data collection. We worked to gain consensus on who would perform various research activities and how those activities would be accomplished. Since we were doing new things, it was easy to reach agreement about the need to study what worked and did not work (i.e. process evaluation). Further, one advantage of conducting a pilot study is incorporating process evaluation to determine what aspects of the research procedures and data collection are operational.

ADRCBC will be coordinating the recruitment of study participants. We had numerous meetings, both in-person and via telephone, to discuss the recruitment process including the timing (before or after a workshop session and which workshop session) of recruitment, the content of the recruitment message, who should provide the recruitment message, and incorporating IRB standards into the recruitment process. Fortunately, ADRCBC identified two people, both over age 65, who volunteered to be present at the recruitment sessions, provide the message, and answer questions that potential participants may have about the study. Both of the recruiters were actively engaged in the discussions about the recruitment process. One of the recruiters is a retired psychiatrist who is an advocate for falls prevention and has first-hand experience about the role of medications in falling. The other is a Stepping On workshop leader and retired physical therapist with experience treating patients who had fallen. The study recruiters feel very confident that they will be able to address any concerns potential study participants have about participating in a study such as, sharing health care data and visiting with a pharmacist. The group agreed to monitor the recruitment process using accrual rates as well as obtaining feedback from the study recruiters after each recruitment session about what is working and not working during the recruitment sessions and what concerns potential participants have about participating in the study. All of this information will be used to improve the recruitment process.

Another study component that was discussed at length was who will collect data from study participants and how data will be collected. Based on previous experience, the pharmacist and the other community partners knew it was not feasible to have the pharmacist collect patient information about health status, falls history, and medication list data (i.e. name of drug, dose, frequency, problems, etc.). Also, there was consensus that providing the data to the pharmacist before the MTM session would allow the pharmacist to better utilize his time with the participants. The community partners had experience with using health care professional students from local community colleges to collect patient health-related data using various data collection forms and computer software in a previous project. Thus, they were aware of the relative advantages and disadvantages of having students collect data and, generally, were open to the idea of using trained student pharmacists for this project. The pharmacist is supportive of using student pharmacists due to their familiarity with drugs, drug names, and health care in general. As part of process evaluation, we

will obtain participants' reaction to the data collection process with the trained student pharmacists. Additionally, the pharmacist will assess the accuracy and completeness of data collected by the student pharmacists and entered into the EMR based on conversations he has with participants. Lastly, there was some concern that the number of telephone interviews will be burdensome for participants and that they will be hesitant to answer the telephone. Comments from the advisory panel were instrumental in finalizing the telephonic data collection procedures.

Another issue we discussed was whether a community pharmacy, with a myriad of potential interruptions, is an appropriate scientific environment in which the pharmacist must follow a protocol to provide the MTM sessions and to document the outcomes of the sessions in a retrievable form. The mutual decision among the partners to audiotape the MTM sessions will allow us the opportunity to listen to the MTM sessions after they occur and determine the fidelity of the sessions to the clinical protocol. Any deviations from the protocol will be communicated back to the pharmacist for adjustment in future sessions. It should be noted that the pharmacist that is involved in the project (JK) is trained to provide MTM and has over 20 years of practice experience working in a nursing home environment communicating drug therapy concerns to physicians. The willingness of the pharmacist to participate in these aspects of the process evaluation demonstrates his commitment and motivation to participate in the study and learn how to improve the program.

After the pilot is complete, the current plan is to expand the model of a pharmacist-provided MTM focused on falls prevention to additional counties. The expansion process will involve identifying and engaging with additional community partners and using the lessons learned from our community engagement process in the expanded project. We will continue to involve ADRCBC as we expand our model, as ADRCBC is an advocate for the model and the community engagement planning process. Our experience suggests that following a community engagement process is an important step in promoting the dissemination, implementation, and sustainability of pharmacist-provided patient services in the community.

**Conclusion**

Pharmacist involvement in falls prevention is an area for future research that could include partnerships between academic researchers and community partners. Successful community engagement will be important to develop both formative and summative evaluation processes that will help to produce valid evidence about the effectiveness of pharmacists in modifying drug therapy and preventing falls as well as promote adoption and implementation of the intervention in other communities. The lessons learned and the research methods developed through a community engagement process outlined and discussed in this article will be used to develop a similar, expanded trial to study the effects of community pharmacists on modifying drug therapy to prevent falls among older adults.

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**Table 1: Summary of Evaluation Process and Measures**

| Type of Evaluation | Purpose of Evaluation | Data Collection Method | Measures |
|---|---|---|---|
| Process | – Assess the feasibility of student pharmacist interviews<br>– Assess the fidelity of student pharmacists to the interview protocol | – Audit of contacts made with study participants<br>– Audiotape of participants -student pharmacist interviews<br>– Periodic meetings with student pharmacists<br>– Feedback from pharmacist about electronic medical record | – Number of contacts to schedule and complete interviews<br>– Length of time to complete interview<br>– Completeness of asking questions in interview protocol<br>– Accuracy of interview information documented in electronic medical record |
| | – Assess the feasibility of providing the MTM session<br>– Assess the fidelity of the pharmacist to the MTM protocol | – Audiotape of MTM sessions<br>– Periodic telephone conversations with pharmacist | – Completeness of covering topics in MTM session protocol<br>– Ease of using and completeness of documentation in electronic medical record<br>– Length of time to complete MTM session<br>– Barriers to providing MTM session |
| | – Assess the recruitment process | – Tabulation of both Stepping On participants who are eligible for the study and Stepping On participants who enroll in the study<br>– Audit of study completion by participants | – Accural rate<br>– Attrition rate |
| Outcome | Collect pre-intervention measures | – Telephone interview with study participants<br>– Review of patient prescription, OTC, and herbal medication list by clinical pharmacist | – Demographics<br>– Health Status<br>– Geriatric Syndromes<br>– Number of falls in previous six months<br>– Prescription, OTC, and Herbal medication list<br>– Fear of falling (the Modified Falls-Efficacy Scale, the Mobility Efficacy Scale, and the Falls Behavioral Scale)[33-35]<br>– Use of FRID |
| | – Collect monthly follow-up measures<br>– Assessment of pharmacist recommendations | – Monthly telephone interviews with study participants<br>– Monthly falls calendars<br>– Review of patient prescription, OTC, and herbal medication list by clinical pharmacist<br>– Review of pharmacist recommendations | – Health Status<br>– Changes in medication list<br>– Number of falls<br>– Use of a FRID<br>– Acceptance of pharmacist recommendations |
| | – Collect post-intervention measures<br>– Assessment of pharmacist recommendations | – Telephone interview with study participants<br>– Review of patient prescription, OTC, and herbal medication list by clinical pharmacist<br>– Review of pharmacist recommendations | – Health Status<br>– Number of falls<br>– Prescription, OTC, and Herbal medication list<br>– Fear of falling (the Modified Falls-Efficacy Scale, the Mobility Efficacy Scale, and the Falls Behavioral Scale)[33-35]<br>– Use of a FRID<br>– Acceptance of pharmacist recommendations<br>– Participant satisfaction with pharmacist<br>– Participant satisfaction with student pharmacist interviewer |

**Note**: Use of FRID determined by reviewing recommendations made by the study pharmacist (treatment group) or a clinical pharmacist (control group).

**Table 2: Lessons Learned from the Community Engagement Process**

| | Description/Example |
|---|---|
| 1. Assess capabilities regarding research project | Determine how comfortable partners are with conducting research. Identify strengths and weaknesses of partners in terms of resources available for a research project. |
| 2. Determine willingness of partners to conduct process evaluation | If the partners agree to develop/implement a new process as part of the research project, evaluation of the process will promote identification of barriers and facilitators and lead to process improvement. Process evaluation may require additional time and resources, but it is important for implementation and maintenance of a program. |
| 3. Assess the willingness of partners to adapt and make changes | Planning a research project may require partners to change the way they currently do things in an attempt to standardize processes. All partners have to understand the reasons for changes and buy into the changed process. |
| 4. Develop trust among partners | All discussions have to be honest, complete, and show no hidden agendas. All partners must work together and have a common understanding of the project. Reviewing past discussions and rationale/motivation for decisions made is a good way to promote common understanding. It is vital to follow through with assignments/tasks. |
| 5. Partners must understand the history/background of each other related to the research project | Establishing a timeline of each partners' activities related to the research project is a good approach to promote understanding. The timeline should include success as well as failures. Understanding reasons for success and failures is very important as it helps identify the strengths and weaknesses of each partner. The timeline also will provide an understanding of where in program development the partnership is located (i.e. early stages versus modifying a long-term successful program). |
| 6. Assess how comfortable partners are with the research process | Discussions need to occur that focus on each partner's perceived value/need for research, knowledge of research, and whether partners have conducted research in the past. All of this information is useful in determining each partner's comfort level with engaging in the research process. |
| 7. Promote face-to-face meetings | Making time to meet face-to-face, especially at the beginning of the engagement process, is very important as it shows commitment to the partnership. Also, seeing reactions of partners to various discussion points and ideas is vital to better understanding the comfort level of partners as it relates to the research process and program development. |
| 8. Recognize resources that partners are committing to the research project | Partners will be more willing to expend time and resources if they have a sense that all partners are committing an equal amount of time and resources to the project. Promote discussions about activities performed by each partner to promote better understanding among partners about resources devoted to the project. Be willing to consume resources to deal with any imbalances. |
| 9. Partners must listen carefully to each other | As described in the items above, much of the community engagement process is sharing past experiences with projects and ideas for future projects. It is important that partners pay attention and actively listen to what is said and acknowledge successes, failures, barriers, facilitators, etc. Partners have to be careful to not move ahead with new ideas without acknowledging and discussing past experiences. Much can be learned about how to proceed by listening carefully to each other. |

**Figure 1: Falls Prevention MTM Study Timeline**

| Initial Call and Packet #1 Mailing | Pre-Intervention Telephone Interview | MTM Session for Intervention Group | Packet #2 Mailing | Follow-up #1 | Follow-up #2-#5 | Post-Intervention Interview |
|---|---|---|---|---|---|---|
| Within 5 days of study staff receiving signed consent, call from student pharmacist to participant to establish interview time. Mailing includes: cover letter, copy of signed consent form, survey and blank medication list. | Student pharmacist conducts pre-intervention survey interview with intervention and control group participants. | MTM pharmacist conducts face-to-face MTM session with each intervention group participant | Mailed to control group after pre-intervention survey. Given to intervention group by pharmacist after MTM session. Packet includes: drug pamphlet, 6 falls calendars, blank telephone follow-up scheduling grid. | 44 days after pre-intervention survey interview for control group. 44 days after MTM session for the intervention group. | 30 days between follow-up calls for intervention and control group participants. Pharmacist conducts telephonic follow-up for intervention group 104 days post-MTM session. | 30 days after follow-up #5 for control and intervention group participants. |