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A Pharmacist-led Pilot Program to Facilitate Deprescribing in a Primary Care Clinic

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Declaration of Conflicting Interests

Dr. Scott V. Monte declares an equity interest in Mobile Pharmacy Solutions.

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Abstract

Objective: To develop and pilot test a model in which a community-based clinical pharmacist was incorporated as part of a Medicare Annual Wellness Visit (AWV) to make deprescribing recommendations targeted at potentially inappropriate medications (PIMs) in the elderly.

Setting: One family medicine Patient-centered medical home (PCMH) clinic in Buffalo, NY.

Practice description: Implementation and evaluation of a pilot program incorporating a pharmacist provided medication review targeting PIMs in the elderly as part of a Medicare AWV.

Practice innovation: A community pharmacy-based clinical pharmacist provided face-to-face medication reviews for patient's over 65 years old as part of their AWV with a focus on deprescribing PIMs. No clinical pharmacy service existed at the practice when this program was implemented.

Evaluation: Identified PIMs, pharmacist recommendations, recommendation acceptance rate, time spent on intervention, healthcare utilization at 6 months post visit, and barriers to implementation.

Results: Of the 21 patients enrolled, the pharmacist provided a total of 20 deprescribing recommendations for 13 unique patients. The overall acceptance rate for pharmacist recommendations was 20%. The pharmacist spent a mean (standard deviation) of 34 (6) minutes per patient encounter. One patient in the intervention group was hospitalized and 1 was seen in the emergency department (ED) during the 6-month follow up period compared to 1 patient in the control group who had an ED visit. We identified multiple logistical and organizational barriers to implementation of the intervention.

Conclusion: In this prospective pilot study, a workflow to include a pharmacist medication review to facilitate deprescribing in the primary care setting was tested. We encountered a number of barriers integrating the pharmacist into AWV workflow to deliver the intervention. Future pragmatic clinical trials are warranted to improve provider awareness and comfort with deprescribing PIMs medications in the elderly.

Background

Polypharmacy is the concurrent use of multiple medications by a patient. While the definition used in research and clinical practice varies, it is often defined as use of 5 or more medications.¹ Potentially inappropriate medications (PIMs) in older adults are those in which the potential risks of use outweigh the expected benefits. Both polypharmacy and PIMs pose a significant risk to the health and safety of older patients.² As patients age, the prevalence of polypharmacy increases along with the rate of adverse events related to

inappropriate prescribing.² Additionally, receipt of PIMs has been identified as a risk factor for hospitalization in the elderly.³

Deprescribing has been defined as a “systematic process of identifying and discontinuing medications in instances in which existing potential harms outweigh existing or potential benefits within the context of an individual patient’s care goals, current level of functioning, life expectancy, values, and preferences.”⁴ The recognized harms related to polypharmacy and PIMs has led to research and practice innovations targeted at deprescribing PIMs.^{5,6} Examples of clinical interventions that have been implemented include clinician (pharmacist or other trained provider) medication reviews, patient education and activation, and use of clinical decision support tools.^{7–12} The concept of deprescribing is gaining traction as a formalized approach to improving medication safety for older adults.

Previous studies have demonstrated the feasibility of deprescribing interventions in community dwelling patients.^{13,14} Iyer et al conducted a literature review of trials designed to deprescribe individual agents or classes of agents.¹⁵ This work suggested that deprescribing could be done successfully in most cases without causing harm. In addition to deprescribing specific interventions, multiple studies have evaluated interventions to address polypharmacy and medication safety. A Cochrane systematic review conducted in 2015 summarized data on interventions designed to address polypharmacy.¹⁶ The results of this review suggest improvement in appropriate prescribing per validated instruments, but insufficient evidence regarding improvement in hospital admissions or drug-related problems. A more recent meta-analysis of 13 randomized controlled trials designed to reduce adverse reactions in the elderly (including 8 pharmacist driven interventions) suggested that implementation of these strategies reduced the risk of serious adverse events.¹⁷ Despite the evidence in favor of these interventions, there remains significant provider and patient barriers to deprescribing.^{18–20} Commonly cited barriers include lack of time, lack of published clinical guidance of when and how to stop medications, and fear of poor outcomes related to stopping medications.

Primary care providers (PCP) are chiefly responsible for the management of chronic health conditions of their patients. Thus, it is logical to develop formal deprescribing processes within primary care practices. Pharmacists are uniquely skilled to support deprescribing efforts in this setting.²¹ We designed and pilot tested a workflow for a pharmacist provided medication review during a Medicare annual wellness visits (AWV) as this is a routinely scheduled and billable visit for the practice.²²

Objectives

The primary objective was to develop and pilot a workflow in which an on-site pharmacist was incorporated as part of an AWV to make deprescribing recommendations targeting PIMs in older adults. Secondary objectives were to evaluate the type of clinical recommendations made by the pharmacist and the acceptance rates for those recommendations, assess healthcare utilization within 6-months of the intervention, and to describe the time required by the pharmacist to complete the intervention.

Setting

This pilot program took place at one family medicine patient-centered medical home (PCMH) in Western New York between August and December of 2017.

Practice description

The practice is an academically affiliated, National Committee for Quality Assurance recognized PCMH that provides evidence-based medical care to patients of all ages. Services offered by the practice include well care and preventative visits, diagnosis and treatment of chronic and acute diseases, office-based procedures, women's health services including gynecological visits, pregnancy and delivery services, mental health counseling, and a chemical dependence program. Approximately 20 percent of the patients seen at the practice are over the age of 65 years.

Practice innovation

The clinical service offered as part of this program was innovative for several reasons. First, the focus of the pharmacist-led intervention was the deprescribing of PIMs in the elderly. One of the commonly cited barriers to implementing deprescribing in primary care is lack of provider time to devote to the activity. We sought to delegate this task to the clinical pharmacist who could evaluate the patient prior to being seen by their PCP. Second, the additional clinical services were provided by a clinical pharmacist in conjunction with regularly scheduled Medicare AWW. Previous studies have demonstrated that pharmacist provided AWW or team-based approaches including a clinical pharmacist can lead to medication and non-medication interventions, improve use of preventative services, and increase reimbursement for medical practices.^{23–26} To our knowledge, this is the first report of an intervention specifically targeted at deprescribing PIMs implemented as part of an AWW.

During the implementation period, no clinical pharmacy service existed at the practice and the intervention was conducted by a clinical pharmacist from a local independent community pharmacy. The pharmacist conducting the intervention was a residency trained clinical pharmacist and Board Certified Ambulatory Care Pharmacist with extensive experience providing Chronic Care Management and AWW services within the primary care setting.²² While no contractual agreement was established during this pilot program, there are evolving payment models that exist that would allow for such an agreement to be made between the PCMH and community pharmacy that would allow for reimbursement of pharmacist provided services.²²

Intervention development

Prior to enrolling patients in this pilot program, the principal investigator (RGW) met with both the practice's medical director and chair of the family medicine department to secure administrative buy-in. Next, investigators (CMC, RS, RGW) met with the practice's providers to explain the study and elicit participation. Likewise, meetings were held separately with the practice manager and nurse manager to describe the proposed workflow.

After enrolling approximately 10 patients, the principal investigator and research team requested a staff meeting with nurses and front office staff to address logistical barriers encountered regarding the integration of the pharmacist's intervention into the clinic workflow without interrupting patient visits.

Patient inclusion

Initially, patients were included if they were greater than or equal to () 65 years of age, were living in the community (not a resident of a nursing home or other skilled nursing facility) and were identified through a registry from the practice's electronic medical record (EMR) to have 2 potentially PIMs per the 2015 Beers Criteria.²⁷ However, due to limited enrollment, the inclusion criteria was modified to include all patients 65 years old living in the community. Patients were considered for enrollment if they were scheduled for an AWV within the study period. Only patients who were scheduled for an office visit at a time in which an exam room was available for the pharmacist were eligible. All other patients not meeting these criteria were excluded.

Intervention workflow

Study personnel prospectively reviewed provider schedules to identify potentially eligible patients in the weeks prior to their scheduled visit. Potentially eligible patients received a call from study personnel prior to the visit to introduce the study and to ask them to bring their medications with them to their appointment.

When a patient met the inclusion criteria, presented for their AWV and gave consent to be seen by the pharmacist, the front office staff printed a current medication list for the pharmacist to use to perform medication reconciliation. The patient was first roomed with the pharmacist who performed the medication reconciliation and comprehensive medication review. Medication reconciliation included reconciling all for the medications the patient was taking at home with what was documented in the practice EMR. Patients were also assessed for issues with adherence and for potential side effects. The pharmacist additionally documented an assessment of the risk to benefit ratio for each medication. The comprehensive medication review included a review of all of the patient's medications and other patient-specific information in order to identify any medication related problems in which to discuss with the PCP. At the conclusion of the patient interview the pharmacist provided the reconciled medication list to the nursing staff who updated the EMR. Pharmacist identified PIMs were discussed with the patient and therapeutic alternatives were discussed. Recommendations were developed by the pharmacist based on the patient interview and were presented verbally to the patient's PCP, using the Situation, Background, Assessment, Recommendation (SBAR) technique, prior to his or her meeting with the patient.²⁸ The patient's PCP determined whether or not the suggested deprescribing interventions would be implemented. The intent of this model was to apply a shared decision making process involving with the patient, their caregiver (if applicable), the pharmacist, and provider.²⁹ Following communication with the patient's provider the pharmacist documented the encounter on a standardized template for the study files which included reconciled medication list with pharmacist risk-assessment for each medication, recommendations and pertinent information gleaned from patient and provider encounters.

Evaluation

Our primary goal was to describe the implementation of a workflow in which an on-site pharmacist is incorporated as part of an AWV to make deprescribing recommendations targeted at PIMs in older adults. We additionally evaluated the type of clinical recommendations made by the pharmacist and the acceptance rates for those recommendations. The pharmacist documented the patient encounters, including identified PIMs, recommendations, time spent on all aspects of the intervention, and notes from the patient encounter on a standardized template. Since recommendations were verbally communicated to the patient's PCP prior to their patient encounter, acceptance of pharmacist recommendations was assessed retrospectively by research staff with access to the practice EMR. A recommendation was considered accepted if the recommended medication changes recommended were present in the EMR on the date of the visit. If recommended changes were made within the 6-month follow-up period this was also noted but not considered to be an accepted recommendation. We also assessed healthcare utilization, including emergency department visits and hospitalizations, reported within a 6-month follow-up period. The pharmacist's documentation of each visit was reviewed and examined for themes related to provider and patient acceptance of recommended deprescribing recommendations. Logistical barriers encountered during the execution of the program are also described in more detail. This pilot study was approved by the institutional review board at the University at Buffalo.

Results

A total of 21 patients were seen by the pharmacist during the implementation of this project. Enrollment was stopped at this point due to practice level barriers to pharmacist integration in existing AWV workflow. Of those seen, 13 (62%) were male and the average age was 75 ± 6 years. Subjects were prescribed an average total of 10 ± 3.5 medications (6 ± 3 prescription and 4 ± 2 over the counter) and were prescribed 2 ± 1 PIMs per the 2015 Beers criteria.

Of the 21 patients enrolled, the pharmacist provided a total of 20 deprescribing recommendations for 13 unique patients (Table 1). The overall acceptance rate for pharmacist recommendations was 20%. Accepted recommendations including transitioning from an oral to topical non-steroidal anti-inflammatory agent, discontinuation of rapid acting insulin, discontinuation of niacin, and dose reduction of aspirin from 325mg to 81mg for primary prevention of cardiovascular events.

Seven (33.3%) of the patients seen were not prescribed any medications identified by the pharmacist as PIMs. Five patients (23.8%) were resistant to at least 1 medication modification discussed with the pharmacist. These medications included benzodiazepines (n=2), non-benzodiazepine hypnotics (n=1), proton pump inhibitors (n=2), histamine 2 receptor antagonist (n=1), nonsteroidal anti-inflammatory agents (n=1), and antihistamines (n=1). Healthcare utilization outcomes are reported to the practice through a regional health information exchange as part of the standard of care for the practice and information was available for all study participants. One patient in the intervention group was hospitalized

and 1 was seen in the ED during the 6-month follow-up period. The pharmacist spent a mean (standard deviation) of 34 (6) minutes per patient encounter. This included 5 (1) minutes to prepare, 15 (3.8) minutes to interact with the patient, 5 (1.6) minutes to discuss recommendations with the PCP, and 8.3 (4.3) minutes to document the encounter.

Barriers

The initial phases of pharmacist integration into clinic workflow were disruptive to patient visit workflow due to lack of adequate awareness of all clinic staff as to the roles and responsibilities of all staff during these visits. This workflow was new to the practice for this study and varied between providers in efficiency. The pharmacist had to physically locate the provider to give recommendations verbally prior to the provider seeing the patient which was sometimes logistically difficult. Additionally, medication reconciliation was typically a task performed by nursing staff, which could have contributed to some reluctance to relinquish this task to a new person in the workflow. Lack of pharmacist access to the EMR limited the pharmacist's ability to make recommendations as the patient's history could not be reviewed beyond information gained from the interview. The lack of documentation with the patient's chart may have negatively impacted the PCP's ability to address the recommendation either at the present visit or in the future.

Discussion

Frequently cited barriers to deprescribing include lack of provider time during a visit to address the problem and lack of a specific funding mechanism to support deprescribing itself.¹⁸ Pharmacists are well suited to help address these gaps in the primary care setting. Provider acceptance rates for MTM services provided by community pharmacists have been reported to be between 40 and 75%.^{30–33} Doellner et al conducted a retrospective study that looked at a group of 100 patients with recommendations for medication changes due to high risk medications (HRMs) per the Medicare Part D start rating measure for HRM in the elderly.³⁰ Of these patients, 59% refused changes and recommendations were never communicated to the provider. Of the remaining 39 recommendations sent to the provider, 23 (59%) were accepted. The acceptance rate of recommendations was lower in the current study. Reasons for this are likely multifactorial and related to both provider and patient characteristics. At the time of this study there was no clinical pharmacy service at the practice so the lack of established relationship with the research pharmacist may have influenced acceptance rates.³⁴ Providers were largely unwilling to attempt deprescribing in situations in which their patients were not actively complaining of adverse events. The process of deprescribing is best implemented as a proactive approach as opposed to reactively changing medications when an adverse event occurs.⁴ This pilot study identified that further provider education in this area may be beneficial.

With the shift in third party payments to value-based initiatives and quality-driven performance, the expertise of pharmacists has become increasingly utilized in the primary care setting.^{22,35} While our attempt to include a pharmacist medication review as part of an AWW faced significant barriers to implementation, previous studies have suggested

pharmacists providing medication reviews as part of an interdisciplinary care team can lead to higher rates of deprescribing.

Whitman et al recently conducted a pilot study to determine the feasibility of a pharmacist-led polypharmacy assessment in a geriatric oncology clinic.³⁶ While this study occurred in a higher risk population, the authors found that pharmacist assessment using the Beers Criteria, Screening Tool to Alert doctors to Right Treatment/Screening Tool of Older Persons' Prescriptions, and the Medication Appropriateness Index led to deprescription of 73% of PIMs and improvement in symptoms in two thirds of patients. These results suggest that deprescribing interventions in complex patients with polypharmacy are both feasible and lead to improvement in patient reported symptoms. Similar to our study, this intervention took an average of 30 minutes to complete. However, it is important to note the difference between practice settings methodologies used between the two studies.

Ammerman et al. conducted a retrospective cohort study to assess the impact of a clinical pharmacy specialist on deprescribing PIMs as part of an interdisciplinary team in a geriatric primary care clinic within the Veterans Affairs system.¹² These authors saw a significant increase in deprescribed PIMS (26.8% vs. 16.1%, $p < 0.001$) in the intervention group compared to usual care. There was also a much higher rate of documented risk benefit discussions with patients regarding PIMs in the intervention group (65.2% vs. 0.003%, $p < 0.001$). In a recent review of deprescribing interventions in primary care settings, Dills et al suggest that successful deprescribing requires intensive ongoing interventions by clinical teams and that evidence is still lacking that correlates these interventions to improvement in clinical outcomes such as reduced hospital admissions, reduced falls, or improved quality of life.¹⁴ Our results support these conclusions as we undoubtedly would need to implement a program with ongoing pharmacist interventions and monitoring before we saw a meaningful impact on clinical outcomes. Larger studies with more rigorous experimental designs and longitudinal follow up are still required to elucidate if such an intervention may impact these outcomes.

Practice implications

The low acceptance rate of pharmacist recommendations seen in this study highlights the importance of established relationships and multidisciplinary approach to achieve successful deprescribing. We encountered significant barriers related to pharmacist integration into existing clinic workflow for an AWW. The successful implementation of new clinical services requires the buy-in from all involved stakeholders, including practice administrators, clinicians, and non-clinical staff and all parties should be included in the development and implementation of proposed interventions. Targeting the patients most likely to benefit is also important to successful implementation. One such approach is to use practice-based risk stratification algorithms to develop registries of high-risk patients most likely to benefit from clinical pharmacist interventions.

Establishing an integrated clinical pharmacy service was identified as a necessary component of future interventions. The ability for pharmacists to follow-up with patients to facilitate ongoing interventions is essential. Since the time that this study was completed, a clinical pharmacy service has been established in the study practice. The pharmacy service is

supported by a clinical faculty member from the school of pharmacy who is on site twice weekly (8 hours/week) and continuous coverage of fourth professional year (P4) student pharmacists. The pharmacy team has established a workflow in which they work with the nursing staff and providers to complete medication reconciliation for complex patients. The pharmacy service has access to document encounter within the EMR and can be tasked within the same to follow up with patients or other healthcare professionals as necessary. Future studies developed based on these methods will benefit from established pharmacist-provider and pharmacist-patient relationships. Lessons learned through this pilot study will inform future iterations of this model.

Limitations of this study include the small sample size and single center nature of the study population. Due to liberalization of the inclusion criteria, many patients were on lower risk regimens and no recommendations were offered by the pharmacist. Ideally, follow up would have been in person to assess medication changes and healthcare utilization during the follow up period. Since we did not have access to documentation from hospitalizations or ED visits it was not possible to attribute healthcare utilization to medication related causes. Future research should attempt to directly connect patient outcomes using modalities other than just EMR data, such as contacting the patient for follow-up to hear their own version of events. In the future, the practice's risk stratification algorithm will be employed to identify high risk patients who may be more likely to benefit from pharmacist intervention. Low rates of acceptance of recommendations limits the potential impact of intervention on healthcare utilization outcomes.

Conclusion

Deprescribing is a complex task that requires both clinical expertise and buy-in from both clinicians and patients to be successful. Lack of established pharmacist role as part of the current PCMH workflow was identified as a significant barrier to the implementation of the service. Future pragmatic clinical trials are warranted to improve provider awareness and comfort with deprescribing PIMs in older adults.

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Table 1.

Pharmacist Deprescribing Recommendations

Subject	Pharmacist identified potentially inappropriate medications	Deprescribing recommendations	Accepted	Comments
1	Clonazepam	None	N/A	Patient unwilling to change medications.
8	Clonazepam, hydrocodone, tizanidine, pantoprazole	Taper clonazepam and start buspirone	No	Patient reported dizziness and feeling like she might fall. Patient was unwilling to attempt medication changes.
		Consider acetaminophen for pain in place of hydrocodone and tizanidine	No	
		Consider as needed antacids or H2RA in place of PPI	No	
9	Naproxen	Acetaminophen or topical diclofenac in place of naproxen for knee pain	Yes	Provider changed naproxen to topical diclofenac for knee pain.
14	Glimepiride and basal insulin, pantoprazole, amlodipine	Alternative agent for diabetes to reduce risk of hypoglycemia	No	Amlodipine was discontinued within 6-month follow up period.
		Antacid or H2RA as needed in place of PPI	No	
		Trial off amlodipine with continued blood pressure monitoring	No	
16	Rapid acting insulin, niacin	Discontinue rapid acting insulin	Yes	Patient's diabetes was considered controlled so rapid acting insulin was discontinued. Niacin discontinued due to flushing.
		Stop niacin	Yes	
26	Ibuprofen	Acetaminophen or topical diclofenac as alternative to ibuprofen for arthritis	No	
36	Rapid acting insulin per sliding scale	Stop sliding scale insulin in favor of GLP1-RA	No	Patient noted to be non-adherent with sliding scale insulin.
37	Hydrochlorothiazide, testosterone	Stop hydrochlorothiazide with close blood pressure monitoring	No	
		Discontinue testosterone	No	
45	Naproxen	Switch naproxen to acetaminophen for pain	No	
47	Aspirin	Reduce dose of aspirin from 325mg to 81mg daily	Yes	
51	Omeprazole, zolpidem	Taper zolpidem and start melatonin	No	Patient previously did not tolerate withdrawal of PPI. Provider felt small dose of zolpidem was less risky than melatonin.
55	Terazosin	Switch terazosin to alternative agent for BPH	No	No hypotension noted so provider not willing to change therapy.
56	Hydroxyzine, ibuprofen, oxybutynin, ranitidine	Stop hydroxyzine and start melatonin or trazodone	No	Patient not willing to make medication changes to pain or reflux management.
		Discontinue oxybutynin due to anticholinergic properties	No	
62	Diphenhydramine	Stop diphenhydramine in favor of alternative therapies for sleep	No	Patient hesitant to try alternatives as melatonin was ineffective.

Abbreviations used: H2RA, histamine 2 receptor antagonist; PPI, proton pump inhibitor; GLP1-RA, glucagon-like peptide-1 receptor agonist