FINAL REPORT

Promoting Pharmacy Services through Development of and Academic / Community Pharmacy Cooperative Targeting High-Risk Cardiovascular Patients"

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Background

The value of community pharmacists in the provision of Medication Therapy Management (MTM) services has been widely established in the literature and is known within the pharmacy community.[1-3] Nonetheless, referral to community pharmacies by physicians and knowledge of such services is not widely known in the East Tennessee area. Several community pharmacies perform comprehensive medication therapy management including diabetes management, hypertension screening / counseling, and tobacco cessation services, however these pharmacies have little referral from the physician practices. Patients with risk factors of age greater than 50, diabetes, hypertension, and tobacco abuse are at high risk for a condition known as peripheral arterial disease (PAD).[4] PAD is a known indicator for disease in coronary and cerebrovascular beds.[4,5] The presence of PAD can be detected by a screening known as the Ankle Brachial Index (ABI) [5,7]. Knoxville, Tennessee has a total population of approximately 430,000. Of those, 39% are over the age of 45, 32% have been told they have hypertension and 16% abuse tobacco.[6] Heart disease, stroke, and diabetes are the 2nd, 5th, and 8th leading cause of death in this county accounting for 3,290 deaths between 2007 – 2009.[6] The number of deaths from heart disease more than triples the 3rd leading cause of death accounting for 2,424 deaths in that time period.[6] A recent position statement by the United States Preventative Task Force (USPTF) summarizes existing literature to state that a low ABI score is associated with future coronary artery disease (CAD) and cerebrovascular disease (CVD) events regardless of other existing risk factors.[7] If disease exists in a patient then targets for preventative management become more aggressive per standards of care. Therefore identifying PAD by ABI tests is a valuable component of prevention of CAD and CVD events.[4,5,7] Knowledge of existing disease rather than simple knowledge of risk factors for disease is a more motivating impetus for lifestyle change for patients. Once it is known to both patients and physicians that community pharmacists are key providers of risk factor reduction through provision of MTM and disease management programs this may prove to be a very strategic method for targeting patients, particularly high risk patients into community pharmacy programs. The model for ABI screening in a community pharmacy has been piloted by community pharmacists.[8]

Both ABI screenings and provision of MTM cannot be performed without comprehensive education and training.[5] The American Heart Association guidelines for PAD screening point specifically to a need for proper training that includes didactic and experiential methods. The University of Tennessee Medical Center, Knoxville (UTMCK), the hospital most closely affiliated with the UTCOP and offered the services and support of the UTMCK Noninvasive

Vascular Lab to train students in the technical aspects of performing the ABI. The outreach was strongly supported the physician director and the technical director of the lab.

Purpose

The purpose of the study was to target direct physician referral of high risk cardiovascular patients (age>50, hypertension, tobacco abuse, diabetes) to community pharmacies performing cardiovascular risk reduction services. Patients, upon receipt of comprehensive medication therapy management services including a 1) comprehensive medication review 2) counseling about risks specific to patient 3) optional ABI screening test, were evaluated at baseline for baseline knowledge and ABI. A patient could elect to participate in all 3 components or only one. The specific aims of the study were to evaluate 1) changes in patients' knowledge of risk factors following intervention 2) change in adherence to medication following intervention 3) change in barriers to adherence following intervention 4) increase in physician referral of patients to these community pharmacies. In addition to physician referral, patients with qualifying risk factors could also self-refer. Comparisons between outreaches in the 2 community pharmacies

Methods

This is a prospective study included patients were referred by direct physician referral and self-referral. If patient met inclusion criteria they were asked to participate in the study during their scheduled community pharmacy visit. All patients ≥18 years< English speaking and who have one or more risk factors for peripheral arterial disease (PAD). These are: age >50 diabetes, hypertension, and tobacco abuse. Patient follow-up occurred within one year following enrollment in this study. Following the initial visit, two follow-up visits were completed by telephone by study pharmacists and faculty primary investigator. Following this period, the patient was be referred back to the care of their community pharmacist.

Process and Recruitment

Funding for this project was received January, 2014. Though one cycle of outreach was proposed with the original grant, it was extended for one more year to attempt a greater outreach to physicians, promotion of events, and success. Therefore references to Year 1 and Year 2 may be made throughout this manuscript.

Two pharmacies were identified as participating pharmacies. One was located in East Knoxville and the other in West Knoxville; both had differing demographics and patient populations. Each practice was asked to identify 5 physician groups that constituted the highest volume of prescriptions to their stores. These physician practices were targeted for referral to the events and to be educated on clinical pharmacy services.

Promotional Materials

During both years, physicians were prepared promotional folders that included copies of pertinent sections of the ACC/AHA ABI guidelines, a section of the ADA Standards of Care, endorsement letters by the physician and technical director of the Heart, Lung, Vascular Institute, and a referral form with contact information. For Year 2 of the study, preliminary data (27 patients) was included in the promotional folder. The 2 participating pharmacies were given educational flyers for 1) all pharmacists in the practice and 2) for all eligible patients to recruit for the event that described what was an ABI and what would be expected during the process. A greater effort was made in the second year to educate all pharmacists within each practice rather than only the pharmacist champions.

Student Education

Second year pharmacy students were provided with reading material about medication therapy management, hypertension, diabetes, and tobacco cessation. A quiz was given prior to inclusion on the project which required an 80% pass rate. Following completion of the quiz, students completed 2 hours of focused education of disease states including practice with simulated patients. In addition 4 hours of hands on training by the Director of UT Vascular Lab was given. In addition, all students had to complete CITI training (IRB training) to be a part of the study. In Year 2 of the study, the competency exam was eliminated and all training was done by the principal investigator.

Pharmacy Requirements

Background checks were required for all participants at the West Knoxville location

Surveys

Physician Knowledge and Willingness to Refer Survey

Physicians were given a 5 question survey prior to the outreach that assessed their 1) knowledge of clinical pharmacy services 2) value of ABI, and 3) willingness to refer patients to pharmacists performing ABI. This survey was done prior to any outreach in Year 1 and then again following presentation of data of 57 patients in Year 2.

Patient Satisfaction Survey

In Year 2, patients were surveyed the day of the outreach event to evaluate perception and satisfaction with the event as well as willingness to pay for such a service.

Results

Spring 2014	Training of Class of 2016 student volunteers (n=17) Promotion of Events to Physicians (Direct Office Visits; 5 physicians met face to face) Physician Survey #1 (baseline)
Fall 2014	Outreach (Saturdays only) West Knoxville (2 days) East Knoxville (2 days) 27 patients seen 1 referral
Spring 2015	Training of Class of 2017 student volunteers (n=9) Promotion of Events to Physicians (Direct Office Visits; 2 lunches conducted; 5 physicians met face to face)
Summer 2015	Outreach (Fridays and Saturdays) West Knoxville (2 days) East Knoxville (2 days) 30 patients seen 2 referrals Physician Survey #2 (following completion)

Notable changes from 2014 to 2015 included outreach immediately followed training and in summer so students were free of classroom responsibilities and Fridays could be captured. Also, student volunteers were capped at 9. These changes resulted in increased efficiency for both training and outreach.

Patients (Physician referred and self-referred)

Category	**East Knoxville n=17**	**West Knoxville n=40**	
Female	82% (14/17)	55% (22/40)	
Race	100% Cau	93% Cau 5% AA 2% Hisp	
Known CV Disease	6%	10%	
DM	18%	25%	
HTN	47%	51%	
Current Tob. Abuse	35%	8%	
Age>50	65%	80%	
Of Patients on Whom Insurance Information was Obtained			
Medicare Insurance	38% (5/13)	36% (8/22)	
Private Insurance	62% (8/13)	64% (14/22)	

On Patients Whom ABI Was Performed			
Positive ABI* (≤ 0.9)	17% (2/12)	2.5% (1/40)	
Borderline Positive (0.9 – 0.99)	25% (3/12)	15% (6/40)	
Non-compressible‡ (≥ 1.40)	0%	2.5% (1/40)	
Borderline non-compressible (1.21 – 1.39)	25% (3/12)	38% (15/40)	
*Positive ABI indicates presence of peripheral arterial disease (coronary artery disease). Patients who are borderline positive are noteworthy. ‡ Non-compressible usually indicates calcification and is usually found in patients with uncontrolled diabetes.			

Physician Referrals

Category	**East Knoxville**	**West Knoxville**	
Baseline	0	0	
Fall 2014	0	1	
Summer 2015	1	1	
Total	1	2	

The above constitute referrals to the outreach and not an increase in referrals to the community pharmacy.

Education

The pharmacy was set up in 3 stations for every event: 1) intake with medication history 2) education station as described below and 3) ABI in a private consultation room. Education was provided at every contact with the patient from the first visit through the subsequent 2 follow-ups. The following areas of knowledge were assessed and educated depending on the co-morbidities of the patient.

CATEGORY	**DESCRIPTION**
Medications	
Comprehensive Medication Review	OTC, Herbal
Barriers	Dosing, timing, administration technique, need for additional OTC or Rx
Adherence	Morisky Scale
Patient's greatest perceived barrier	Per patient
Barrier categorization	Knowledge, cognitive deficits, financial, social, psychological, medication adverse effect.

Diabetes	
ADA Plate Method	Knowledge of Plate Method, effect of CHO on BG, CHO amt./meal
Hypoglycemia	Events per week; knowledge of s/sx, how to treat, when to re-check
Immunizations:	
Appropriate immunizations	Flu, Pneumovax
Hypertension	
DASH plan	Fruits, vegetables, low sodium, unsaturated fat, decrease sweets
Exercise	Knowledge of exercise benefit on HTN
Tobacco Abuse	
Evaluation of Stage of Change and movement to change stage	Pre-contemplative, contemplative, preparation, action, maintenance

Patients were provided education plus written educational material for every barrier or educational gap that was identified. Though education was provided at all follow-ups, written materials were only provided for the first visit since it was the only one that was face to face.

Patient Follow-up

Eighteen patients of the 57 who participated (32%) had gaps or barriers in their medication knowledge at baseline and were educated the day of the outreach. This was out of the total of 57 patients.

Of the 57 patients, 15 did not complete an informed consent for follow-up, one was excluded for follow-up due to lack of qualifying factors, and one withdrew consent following the first visit. The following depicts changes in knowledge from the 40 eligible patients.

Medications: 17 had identified gaps in their baseline medication knowledge and were educated. 5 (29%) were lost to follow-up and progress could not be assessed. Of the remaining 12, 10 (83%) showed improvement in resolution of their medication related barrier after 1 or 2 follow-ups.

Analysis of the benefit of risk factor education is underway.

Physician Survey

(Based on identifiers, only one physician answered the same survey twice)

	Survey #1 (prior to outreach) n=8	**Survey #2 (following outreach) n=7**
Perform ABI in their office: **Yes**	25%	30%
ABI is Valuable to my patients with risk factors for cardiac disease: **Agree / Strongly Agree**	88%	86%
If trained pharmacists were performing ABI at no charge, I would refer: **Agree / Strongly Agree**	38%	57%
Percentage of physicians that would refer 25% or greater of their patients to such an event	50%	50%
Aware that local clinical pharmacists can assist with managing some of the risk factors of PAD **(Moderately/Very/Extremely)**	25%	29%

Modest changes were observed with knowledge of clinical community pharmacists and their impact on risk factors for PAD. Meeting with primary-care physicians face to face was often a challenge, however many positive remarks were made about the outreach and physicians that were spoken to did verbalize a new knowledge and understanding of the extended services offered by community pharmacists. However survey data do not always reflect physician points of view. Some reflected a hesitancy to refer directly to the pharmacy but were willing to pass out patient flyers to eligible patients so they could self -refer. Concerns for physician protection of patient privacy could be involved.

Patient Survey

Key: 1= Strongly disagree, 2= disagree, 3= neither, 4=agree, 5=strongly agree

	East Knoxville (n=7)	West Knoxville (n=19)
I appreciated receiving the service from the pharmacist.	5.00	4.89
I am pleased with the service I received.	5.00	4.84
I am thankful for the time the pharmacist gave up to provide the service.	5.00	4.95
The pharmacist was unfriendly and unsupportive during the service.	1.00	1.63
The service motivated me to stay in control of my heart disease.	5.00	4.39
I understand my medications better since participating in the service.	4.63	4.12

The service gave me confidence to deal with my risks for heart disease.	4.75	4.72
I am satisfied with my understanding of what things can change my risks for disease	4.88	4.56
I do not know what types of things are beneficial to control my risk for heart disease.	1.13	2.16
I would be willing to pay for these services including an ABI	3.7	3.47
I would be only be willing to pay for an ABI.	3.14	3.16
I would be willing to pay $50 for an ABI screening.	4.25	3.31

Conclusions

This complex outreach project had a two-fold objective of enhancing patient care of high risk patients in the community setting and enhancing physician awareness of clinical community pharmacists through an academic / community pharmacy partnership that promoted value-added and risk reduction services to a physician practice that could be accomplished in the community. Though survey data may not fully reflect attitudes of all physicians from the major feeder groups, all physicians with whom direct contact was made reflected a new appreciation of a community pharmacist services as well as appreciation of the value of the ABI outreach program. The lack of translation to referrals cannot be elucidated however some feedback received indicated a reluctance to traverse the privacy of the patient. Notably some physicians would provide referral flyers to their patients encouraging them to attend however they would not send referral information to the pharmacy. More time is likely needed to further capture that much needed trust and information sharing.

The ABI test itself which is considered valuable by >85% of physicians surveyed is only performed in 30% of the physician practices surveyed. This is due in large part to the time of the test and the training required to perform this test[5]. Such an outreach is more easily accomplished by a 3rd party such as a pharmacy school or could be accomplished by any trained medical personelle that were willing to invest the time. It is noteworthy that patients have a modest willingness to pay for such a test. One previous study has indicated that the break-even charge for a community pharmacy to provide such an outreach is 25 dollars[8]. Our survey indicates that some patients are willing to pay 50 dollars for such a service therefore a fee-for-service charge somewhere in between could be profitable for a community pharmacy while enacting patient care and a valuable service to physicians.

The student education required to carry out such a project is a valuable experience for the students. This activity in terms of a valuable co-curricular activity will be further evaluated by a student survey. Should the data show positive results, such an activity can be more readily embedded in pharmacy curriculum which would further support a community pharmacy's initiatives.

The full value of the patient education is still being statistically assessed. However based on preliminary data, the benefit of patients is seen.

Continuation of such an outreach is feasible for not only a pharmacy school but also a community pharmacy that wishes to invest in one-time training in use of equipment and procedure. If done twice annually, for example, as a scheduled outreach it shows probability of being a profitable project for pharmacies, a beneficial outreach for patients, and an another avenue for increased referrals for physicians to community pharmacies.

VII. References

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