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The impact of care coordination on community pharmacist-delivered medication therapy management

Stephanie A. Gernant
Purdue University

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For the degree of Masters of Science

Is approved by the final examining committee:

Margie E Snyder, PharmD MPH

Chair

Karen Hudmon, PharmD MPH

Alan Zillich, PharmD

Jasmin Gonzalvo, PharmD

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Approved by: Alan Zillich, PharmD

Head of the Departmental Graduate Program

04/21/15

Date

THE IMPACT OF CARE COORDINATION ON COMMUNITY PHARMACIST-DELIVERED
MEDICATION THERAPY MANAGEMENT

A Thesis

Submitted to the Faculty

of

Purdue University

by

Stephanie A. Gernant, PharmD

In Partial Fulfillment of the

Requirements for the Degree

of

Master of Science

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This work is dedicated to my loving husband Harold Gernant. Thank you so much for moving so many times for my education.

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Jasmine D. Gonzalvo, PharmD, BCPS, BC-ADM, CDE. Clinical Associate Professor, Purdue University College of Pharmacy. Clinical Pharmacy Specialist, Ambulatory Care Eskenazi Health.

Karen Suchanek Hudmon, DrPH, MS, RPh. Professor of Pharmacy Practice, Purdue University College of Pharmacy.

Alison L. Huet, PharmD. Pharmacist, Kaup Pharmacy.

Anna Oman-Baker, PharmD. Pharmacist, Eskenazi Health Pharmacy.

Caitlin G. Morrow, PharmD, BCACP. Pharmacist in Charge, Penobscot Community Health Center.

Kelly J. Werling, PharmD. Pharmacist, Kaup Pharmacy

Sandi Sprunger, PharmD. Staff Pharmacist, Retail Pharmacy. Indiana University Health, Ball Memorial Hospital Southway Pharmacy.

Ashley Chambers, PharmD. Post-Graduate Year One Resident, Dr. Aziz Pharmacy.

Tracie Miller, PharmD. Pharmacist, Mash Pharmacy.

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LIST OF ABBREVIATIONS

CDC: United States Centers for Disease Control and Prevention

CITI: Collaborative Institutional Training Initiative

CMR: Comprehensive Medication Review

CMS: United States Centers for Medicare and Medicaid Services

IRB: Institutional Review Board

MRP: Medication-related Problem (also known as: drug-related problem and drug therapy problem)

MTM: Medication Therapy Management

MTR: Medication Therapy Review

PCP: Primary Care Provider

SOAP: Subjective, Objective, Assessment, Plan

TMR: Targeted Medication Review

USPSTF: United States Preventative Services Task Force

ABSTRACT

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Background: Care coordination is imperative to successful patient outcomes. However, community pharmacists are commonly excluded from health information exchange during care coordination. One of the ways pharmacists deliver care, through medication therapy management (MTM), could be optimized if pharmacists engaged in care coordination through review of unedited patient medical records in preparation for a section of the MTM, the comprehensive medication review (CMR).

Methods: This was a non-blinded randomized controlled trial undertaken within the Medication Safety Research network of Indiana, also known as RxSafeNet. RxSafeNet is a community pharmacy practice based research network. Pharmacists were randomized to deliver CMR's to adult patients under usual care, or with a care coordination intervention. The intervention consisted of soliciting the patient-identified primary care provider-held medical records of the last six months. Medication related problems (MRPs) identified and omissions in preventative care identified were recorded for each CMR delivered. Additionally, pharmacists were surveyed over their thoughts and opinions regarding utilizing medical records.

Results: Thirty seven patients were seen for CMR appointments. Intervention pharmacists identified more MRP's than usual care pharmacists. The intervention, while controlling for predictor variables included in a multiple linear regression model, had an adjusted $R^2=0.511$; $p=0.05$. Intervention pharmacists identified more omissions in preventative care (adjusted $R^2=0.136$; $p=0.027$).

Intervention pharmacists were more likely to agree they were confident they identified all of the patient's MRPs (47.1% vs. 15.8%), but neither group was more likely than the other to believe they had resolved all MRPs (41.2% vs. 42.1%). Lastly, intervention pharmacists agreed 100% of the time that the patient's health history helped them complete a better CMR as compared with only 69% of usual care pharmacists.

Conclusion: Community pharmacists identify more MRPs and omissions in preventative care when they engage in care coordination by reviewing the patient's PCP's unedited medical record in preparation for a CMR.

INTRODUCTION

One of the many ways community pharmacists deliver patient care is through Medication Therapy Management, otherwise known as “MTM.” MTM can be thought of as an umbrella term referring to a group of services pharmacists offer, such as medication therapy reviews and pharmacotherapy consults, which are utilized to identify, prevent, and resolve medication-related problems (MRPs)(American Pharmacist Association 2013). Effective MTM is imperative, as an estimated 1.5 million preventable medication-related adverse effects at an expense of \$177 billion occur each year in the United states(Ernst and Grizzle 2001). However, evidence of MTM’s effectiveness has varied extensively (Fox, Ried et al. 2009, Pindolia, Stebelsky et al. 2009, Welch, Delate et al. 2009, Winston and Lin 2009, Moczygemba, Barner et al. 2011, Ward and Xu 2011) and this variation can be attributed to a lack of service standardization and optimization. One of the Core Elements of MTM, the Comprehensive Medication Review (CMR), is a process that could be targeted for such optimization. CMRs consist of pharmacists’ review and reconciliation of a patient’s prescription and non-prescription medications to promote overall health and identify MRPs. Unfortunately the effectiveness of CMRs may be limited due to the lack of care

coordination (i.e. sharing of available patient health information) among health professionals (Hume, Kirwin et al. 2012). Thus the ability of community pharmacists to detect and resolve health-related problems, either medication related or preventive-care related, may be diminished.

Evidence from numerous studies show that when pharmacists engage in care coordination, positive impacts such as enhanced medication-related problem detection and resolution are realized. This has resulted in many hospitals including pharmacists in admission, discharge and follow-up programs (Bolas, Brookes et al. 2004, Schnipper, Kirwin et al. 2006, Kramer, Hopkins et al. 2007, Kwan, Fernandes et al. 2007, Varkey, Cunningham et al. 2007, Gorgas Torner, Gamundi Planas et al. 2008, Midlov, Holmdahl et al. 2008, Bergkvist, Midlov et al. 2009, Walker, Bernstein et al. 2009, Eggink, Lenderink et al. 2010, Hellstrom, Bondesson et al. 2011, Midlov, Bahrani et al. 2012). However, similar care coordination efforts in the community setting are limited. It is unknown how out-patient pharmacists in the community utilize medication records in preparation for a CMR.

Needs Assessment

The United States Agency for Healthcare Research and Quality (AHRQ), as a part of the Department of Health and Human Services, defines care coordination as “the deliberate organization of patient care activities between two or more participants (including the patient)...,” and “the exchange of information among participants responsible for

different aspects of care”(McDonald, Sundaram et al. 2007). The Centers for Medicare and Medicaid Services (CMS) and the Institute of Medicine (IOM) have identified poor care coordination as a major health problem within the United States, due to its staggering risk to patient safety: sixty-six percent of all medication-related errors are attributed to poor care coordination(Santell 2009). Consequently, standardized and effective mechanisms are needed to facilitate effective health information exchange and thus the 2010 Affordable Care Act (ACA) highlights care coordination measures. As a part of the ACA’s meaningful use of care coordination, the Office of the National Coordinator for Health Information Technology (ONC) has promoted state electronic Health Information Exchanges (HIE’s) which allow healthcare workers and patients alike to securely access medical information electronically. Specifically, as part of the ONC’s vision, pharmacies will participate in Health Information Exchange, but pharmacists are not eligible to receive any reimbursement for offsetting the cost of electronic health record (EHR) implementation under CMS’s Electronic Health Records Incentive Program(US Centers for Medicare and Medicaid 2015). The list of eligible professions under the EHR incentive program is quite lengthy, including dentists, nurse practitioners, nurse midwives, doctors of medicine, osteopathy, surgery, podiatry, optometry and chiropractors. Additionally, under CMS Meaningful Use stipulations, the above mentioned professionals are required to provide summary care records during all transitions among facilities, but not to community pharmacies or community

pharmacists. Furthermore, Indiana's HIE, the Indiana Health Information Exchange, does not engage community pharmacists.

Pharmacists are even further discouraged to engage in care coordination as they are not recognized providers under the Social Security Act and therefore ineligible to bill Medicare Transitional Care Management Services' CPT codes directly (Snow, Beck et al. 2009). Therefore, medication reconciliation during care coordination is billable by most healthcare providers except pharmacists, who are the medication experts. Despite being cited as the most trusted and accessible healthcare professional, and despite the fact that community pharmacies filled over 3.7 billion prescriptions in 2011, community pharmacists remain underutilized to contribute positively to care coordination.

Regardless of the barriers faced by pharmacists to provide patient care, opportunities exist for community pharmacists to identify and address health-related problems in the form of CMRs. Health-related problems can be medication-related in nature, but not necessarily so. Pharmacists also ameliorate health-related problems related to preventive-health, as community pharmacists regularly identify and correct missing preventive-care recommendations by delivering immunizations.

Indeed, one of preventive healthcare's recent and greatest success has been increased access to immunizations through community pharmacist-delivered vaccinations.

American community pharmacists began vaccinating in the early 1990's, and mass immunization education for pharmacists was endorsed by the US Centers for Disease

Control and Prevention (CDC) in 1996 (Terrie 2010). Today all 50 state legislations recognize community pharmacists' ability to vaccinate, and literature from national data shows that by allowing pharmacists to provide vaccinations, the rate of influenza immunization has increased (Steyer, Ragucci et al. 2004). Any time a pharmacist interacts with a patient is an opportunity to screen for missing vaccinations, especially during the one-on-one CMR. As such, community pharmacists may intervene on other preventive care measures, as prevention is reliant on availability and access to healthcare. Sufficient availability and access however is in stark contrast to the current state of American healthcare- with its challenges of quality, cost and access, amplified by a national shortage of primary care providers. Indeed, the Commissioned Corps of the US Public Health Service has identified pharmacists' contribution to increasing preventive care access by serving as extensions of public health infrastructure, increasing services' quality, and partnering with other healthcare providers (Scott Giberson 2011). Because of this, it is reasonable to believe that pharmacies might serve as care delivery or referral sites for other preventive measures above-and-beyond vaccinations.

In summary, despite pharmacists' ability to detect MRPs and omissions in preventive care, community pharmacists are underutilized in their ability to contribute to care coordination teams. Furthermore, American laws discourage community pharmacists from engaging in care coordination. Due to the paucity of literature related to- and policy hindrance of- community pharmacists' engagement in care coordination, a study

specifically analyzing community pharmacists' efficacy in detecting health-related problems when engaging in care coordination, in the form of health information exchange, in preparation for a CMR is warranted.

Study Hypothesis

It is postulated that when community pharmacists engage in care coordination and thus review patients' medical histories in preparation for a CMR, that immediate outcomes (i.e. detection of health-related problems) will improve, but this has yet to be tested. Touchette et al. studied the effect of pharmacists' review of medical record during a CMR on adverse drug event rates, but pharmacists in this study were not in community settings and information provided to the pharmacists were interpretations of the medical record (consisting of a two-page standardized synopsis) rather than the unedited and complete records (Touchette, Masica et al. 2012). Another study undertaken by Warholak-Juarez et al. within the Indian Health Services explored pharmacists' use of medical history. These researchers demonstrated that pharmacists provide better patient care (i.e. identify and resolve more problems) when given more complete patient medical histories on which to base their decisions. However, Warholak-Juarez et al.'s patient cases were also edited and standardized (Warholak-Juarez, Rupp et al. 2000). Understanding community pharmacists' interpretation and utilization of unedited and complete electronic medical records is warranted. While pharmacy curricula teaches students to identify health related problems through

evaluation of standardized medical histories, this model does not reflect current community pharmacy practice as medical histories HIE information exchange is limited. Additionally, in the rare chance that health information is shared with community pharmacists, the information is unedited and non-standardized. Consequently, research is needed to discern community pharmacists' effectiveness in discovering health-related problems during CMR delivery when engaging in care coordination activities.

Research Objectives

Specifically, our research team sought to determine if community pharmacists identify more health-related problems including MRPs, and omissions of preventive-care. We seek to answer: *“Do pharmacists who review medical records in preparation for a comprehensive medication review (CMR) identify more MRPs than pharmacists who do not?”* and characterize the types of MRPs identified between pharmacists who review medical records and those who do not. Additionally, we aimed to answer: *“Do pharmacists who review medical records in preparation for a comprehensive medication review (CMR) identify more omissions in recommended preventive care than pharmacists who do not?”* and characterize types of preventive care omissions found between community pharmacists who review medical records and those who do not. We also aimed to characterize the types of health records received from primary care providers and those records used by community pharmacists to discover health-related

problems. Lastly, we aimed to ascertain community pharmacists' perceived usefulness of available health history, be-it attained from unedited medical records or solely from the patient.

The research described below may provide evidence towards recognizing community pharmacists as an integral part of the healthcare team, and allow community pharmacists to engage in patient-centered collaborative care with prescribers and other healthcare workers. Long-term, we expect this research will (1) build on existing evidence demonstrating that pharmacists should be recognized as health care providers under the Social Security Act and as eligible providers for incentives under the CMS Electronic Health Record Incentive Program and improve quality and optimization of MTM services.

METHODS

This study was designed as a prospective randomized controlled trial to take place within the Medication Safety Research Network of Indiana (Rx-SafeNet). Rx-SafeNet is a state-wide community pharmacy practice based research network (PBRN), registered as an affiliate member with the U.S. Agency for Healthcare Research and Quality (AHRQ) PBRN Resource Network. The Network, comprised of 181 community pharmacies across Indiana, serves to facilitate collaboration among researchers and clinicians to research medication safety and advance community pharmacy. The mission of Rx-SafeNet is to “improve medication safety and advance community pharmacy practice in Indiana through the conduct and dissemination of collaborative, patient-centered, practice-based research.”

Outcomes Defined

Planning for the study began in July 2013 by defining the three outcomes measures. The primary outcome was total number of MRPs identified per patient as defined by the taxonomy described in Cipolle, Strand & Morley’s *Pharmaceutical Care Process: The Clinician’s Guide* (Cipolle RJ 2004.). A secondary outcome was total number of preventive care omissions identified per patient, as defined by the 2013 United States

Preventative Services Task Force A & B Recommendations (See Appendix)(United States Preventative Services Task Force 2013). The third and final outcome was pharmacist reported perceptions and beliefs towards utilizing patients' health history, despite how it was obtained (i.e. verbally for usual care pharmacists, verbally and from medical records for intervention pharmacists) for each CMR delivered.

Study Design Timeline

In July 2013, following the Network's policy for study selection, the project idea was proposed to the Rx-SafeNet Executive Committee, and approved the same month. Rx-SafeNet site coordinators voted to pursue the study after voting via an email survey in August, 2013. A preliminary protocol was developed and subsequently reviewed by the Rx-SafeNet project review team (PRT) in October 2013.

The PRT is a committee of 3 College of Pharmacy faculty who review draft study protocols submitted to Rx-SafeNet for feedback on protocol improvement. In September of 2013, the Purdue University Statistical Consulting service issued guidance on the protocol's data analysis methods, and the final protocol was approved by the PRT in January, 2014. Final approval by the Purdue University Institutional Review Board occurred on February 25th, 2014.

Intervention Design

It was decided that the intervention would not be tested in a pre-existing service, because although limited MTM services occur throughout Indiana and in Rx-SafeNet locations, use of these consultations for comparison would have been challenging due to a small number of patients receiving MTM and the wide variety in medication-related problem taxonomies routinely employed. Therefore, study pharmacists were trained to provide comprehensive medication reviews (CMRs) with and without care coordination, as applicable, to create an appropriate comparison group.

The intervention consisted of care coordination in preparation for the CMR by means of a HIPAA release soliciting the last six months of medical records to the patient-identified primary care provider by fax. The release itself not only requested records originated by the primary care provider, but all records obtained by the PCP through care coordination from other entities. This HIPAA release, explicitly requested release of protected health information for research purposes. This included the last six months of: (1) the patient's problems list; (2) laboratory test results; (3) allergies; (4) the patient's medication list; (5) immunization, surgical, device and family history and (6) the previous six months of known encounters, including any specialist, walk-in, care coordination, hospital or other healthcare provider encounter. The HIPAA waiver stipulated if the latest diabetic, osteo-, respiratory, lipid, endocrine, hepatic, hematological, and/or drug concentration(s) lab results fell outside of the previous six month window, to transmit the most recent results.

The six above criteria were chosen to be requested as they reflect information outlined at the time by CMS's Stage1: Eligible Professional Menu Objectives Core Measure 8. This Core Measure stipulated that any eligible provider who transitioned a patient to another care setting should provide a care summary to that setting. Currently, community pharmacists and pharmacies are not eligible providers under this CMS measure and neither transmit nor receive care summary sheets during transitions of care.

Thus, both groups of pharmacists received health information, but in two different approaches. Intervention pharmacists received the patient-health history verbally from the patient and from the PCP-provided medical record, whereas usual care pharmacists received health information solely from the patient.

Pharmacist Recruitment as Non-Key Personnel

Community pharmacists were eligible to assist with the study as non-key personnel if they certified that they did not routinely request medical records from patients' providers. It was believed that pharmacists who regularly requested patients' medical records would have a learning effect on reviewing such history. Recruitment of community pharmacists within Rx-SafeNet began in March, 2014. Twenty-three pharmacy site coordinators, representing the 168 pharmacy locations within Rx-SafeNet at the time, were contacted over the course of three months via email or telephone

from either the Rx-SafeNet Network Manager or Dr. Gernant. It was at the discretion of the pharmacy site coordinator to share the study's information to allow participation with the then existing recruitment pool of 312 network pharmacists. An estimated 125 pharmacists were informed of the study, as some site coordinators declined involvement. A total of 10 pharmacists within Rx-SafeNet representing 9 pharmacies, expressed interest in participating and agreed to undergo research training. However due to time constraints, only six completed training and three were lost to attrition (See Figure 1). Five replacement pharmacists were engaged, four of which were within RxSafeNet. Due to high attrition and low engagement, pharmacist enlistment was expanded outside the Network, and one non-member of Rx-SafeNet participated in the study.

Pharmacists were chosen to be the point of randomization as randomization at the patient level could have potentially contaminated the intervention by learning effects experienced by the pharmacists. Originally, the study was designed to stratify pharmacists based on their experience level, defined as year in practice, involvement in any post-graduate training, and number of CMRs completed in the previous year. However, this method of stratification was not used due to the high level of attrition; rather a simple binomial random number generator was used to randomize pharmacists to either the intervention or usual care group.

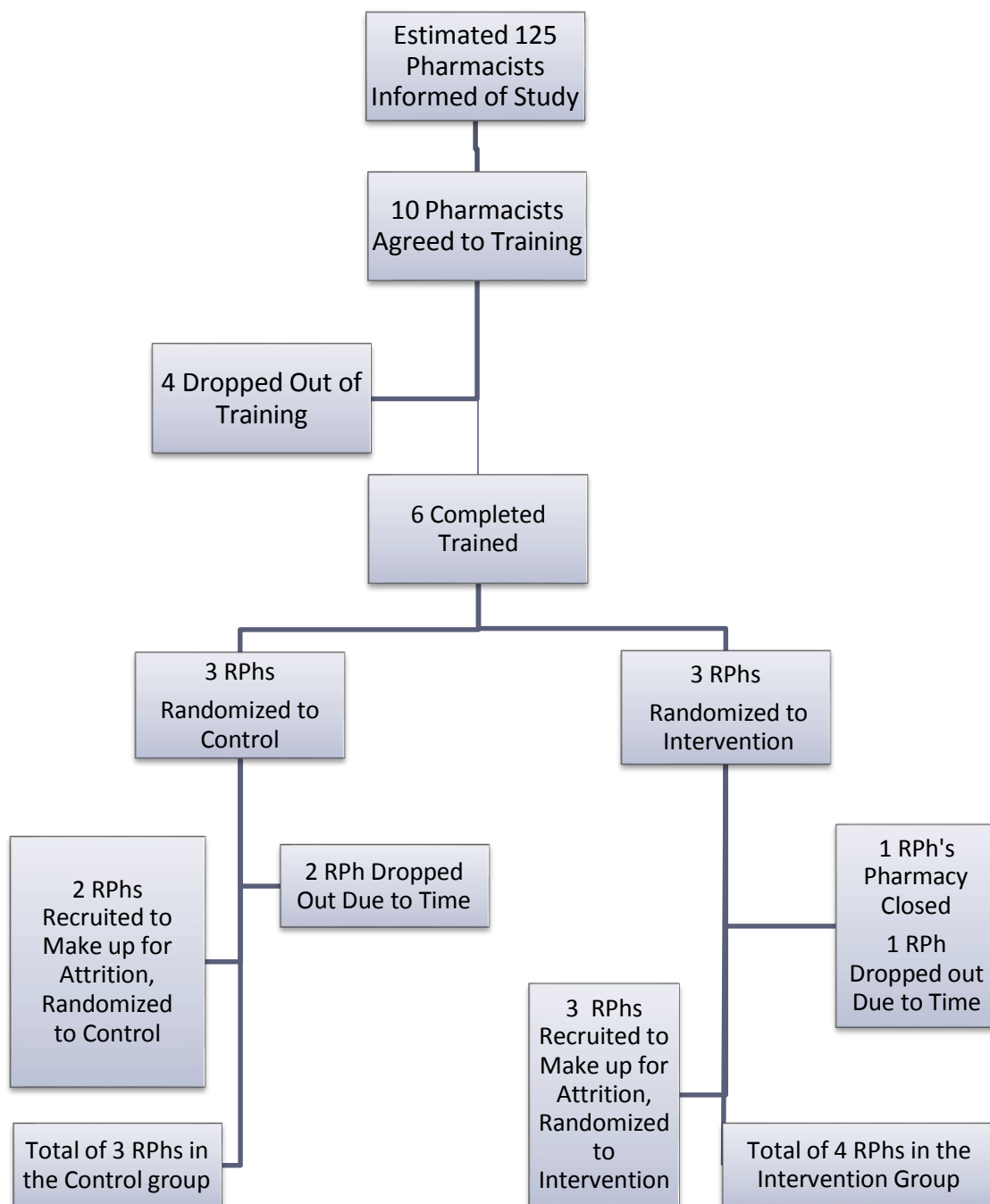


Figure 1. Study Pharmacist Recruitment and Attrition

Pharmacist Training

One-on-one pharmacist training sessions began after IRB approval in April, 2014. The

seventh and final pharmacist recruited for the study was trained in August, 2014.

Pharmacists were required to complete Human Subjects Research training online

through University of Miami's Collaborative Institutional Training Initiative (CITI)

modules and undergo one time face-to-face training with Dr. Gernant. Details of these

training sessions are discussed below.

CITI Module Training

All study pharmacists were required to complete Human Subjects Research Training for

Non-Key Personnel through the Collaborative Institutional Training Initiative.

Pharmacists were categorized as non-key personnel as they recruited and consented

patients, but did not contribute in a substantive, measurable way to the study's

scientific development. Pharmacists were required to complete an integrity assurance

statement certifying that they agreed to the ethical conditions required by CITI training;

namely, pharmacists certified that they would complete CITI training without assistance,

with one active account and without engagement in activities that would improve results

for themselves or others. Required training for non-key personnel included the

following nine modules: (1) A review of the Belmont Report and CITI course

introduction, (2) Students in Research, (3) History and Ethical Principles of Human

Subject Research, (4) Defining Research with Human Subjects, (5) Informed Consent, (6)

Privacy and Confidentiality, (7) Records-Based Research, (8) Populations in Research Requiring Additional Considerations and/or Protections, and (9) Conflicts of Interests in Research Involving Human Subjects. Completion of all eight modules were required, with an average score of at least 80% on post-module quizzes. Upon completion, a certificate was generated with the date completed and total score; Dr. Gernant collected these certificates before study pharmacists were allowed to begin patient recruitment.

Study-Specific Training

At the commencement of training, pharmacists signed an understanding certifying that they met all study criteria needed to act as non-key personnel (see Pharmacist Recruitment as Non-Key Personnel). Pharmacists underwent one-on-one study training with Dr. Gernant and were given a training manual that included a protocol regarding CMR delivery. The following sections explain the process of training study pharmacists on delivering CMRs, the study protocol, how to obtain informed consent and entering data.

Pharmacist Training: Protocol Training

Protocol training for study pharmacists included a step-by-step introduction to completing CITI module training, defining patient eligibility, classifying results and data entry. Additionally, the protocol for intervention pharmacists included instructions on

how to obtain HIPAA releases and medical records. Intervention pharmacists were instructed to fax the signed HIPAA release form to the patient-identified primary care provider at least 10 days before their scheduled CMR. If the pharmacists did not receive patient records within 48 hours of faxing the HIPAA release, the pharmacist was instructed to call the prescriber's office. If the pharmacist received nothing from the patient's prescriber's office within 72 hours before the scheduled CMR, the pharmacist was instructed to call the prescriber's office a second time. Intervention patients whose prescriber's office did not send records to the pharmacy were excluded from participation. All pharmacists were at liberty to schedule/reschedule appointments based on the convenience for the pharmacist and the patient. Pharmacists were instructed to call the patient 24 hours before their appointment as a reminder.

Pharmacist Training: Informed Consent

Informed consent training was critical as pharmacists participating in the study had no previous experience consenting patients. In addition to the informed consent training provided in CITI module training, Dr. Gernant role-played consent with each trainee. Furthermore, pharmacists were given a list of informed consent policies adapted by the guidance given by the Purdue University IRB, and reviewed this with Dr. Gernant. Examples of these policies include delivering informed consent in clear, understandable every-day language, and allowing the patient to ask questions throughout the process. The risk of unintended coercion was explained, specifically because the study

pharmacist may have had a pre-existing relationship with the patient. It was stressed to study pharmacists that even after reviewing the consent form, many patients may not yet understand basic information about the risks and benefits of study participation. Pharmacists were trained to have patients state the study's purpose and to specifically explain what was being asked of them in their own words. All pharmacists reported understanding that patients were ineligible for participation if the patient could not explain the study in their own words.

Pharmacist Training: Recruitment Logs

Study pharmacists were required to keep recruitment logs, itemizing potential participants who had been approached and consented for study participation. The recruitment log served as a record of the number of patients approached for IRB reporting purposes and CMR scheduling. The log also served as a reminder to intervention pharmacists to obtain medical records. The recruitment logs were gathered by Dr. Gernant at the end of the data collection period.

Completing a CMR

Regardless of the level of experience, all pharmacists underwent Medication Therapy Review (MTR) training delineating differences between a Comprehensive Medication Review (CMR) and a Targeted Medication Review (TMR). Additionally, pharmacists were

introduced to the concept of “pharmaceutical care”(Hepler and Strand 1990), in which pharmacists intervene to prevent, identify and resolve medication problems.

Pharmacists were asked to identify and resolve problems by considering the following four questions as reflected in the *Pharmaceutical Care Process*: (1) is the medication indicated?; (2) Is the medication effective?; (3) Is the medication safe?; and (4) Is the patient able to adhere to the medication regimen?

Completing a CMR: Extracting Information

Dr. Gernant refreshed pharmacists on the basics of extracting health information by reviewing the SOAP note process, and the difference between subjective and objective information. “SOAP” is an acronym for “subjective, objective, assessment, and plan,” and is a method employed by health care providers to document patient encounters. This training was included to highlight the difference between study data (identified MRP’s and preventive care omissions) and clinical decisions made at the discretion of the pharmacist. A blank SOAP template was provided to study pharmacists to facilitate reminders to review basic health history (e.g.: vitals, labs).

Completing a CMR: MRPs

Dr. Gernant introduced study pharmacists to categorizing and identifying MRPs by reviewing the taxonomy described in Cipolle, Strand & Morley’s *Pharmaceutical Care*

Process: The Clinician's Guide (Cipolle RJ 2004.)(see Table 1). In an effort not to limit pharmacists, examples of MRPs that did not clearly fall into a single classification were included in a case review. For example, a medication may need adjustment based on serum concentrations which had not been monitored. If an identified problem was not easily classified, pharmacists were instructed to choose the classification most closely related. Additionally, pharmacists were instructed to classify a problem only once, even if it applied to multiple categories.

Table 1. MRPs Classification

Category	Medication-Related Problem
Unnecessary drug therapy	No valid medical indication for the drug therapy at this time
	Multiple drug therapies are being used for a condition that requires single drug therapy
	Medical condition is more appropriately treated with nondrug therapy
	Drug therapy is being taken to treat an avoidable adverse reaction associated with another medication
Needs additional drug therapy	Drug abuse, alcohol use, or smoking is causing the medical problem
	Medical condition requires the initiation of drug therapy
Needs different drug product	Preventative drug therapy is required to reduce the risk of developing a new condition
	Medical condition requires additional drug therapy to attain synergistic or additive effects
Dosage too low	Drug product is not the most effective product for the indication being treated
	Medical condition is refractory to the drug product
	Dosage form of the drug product is inappropriate
	Drug is not effective for the medical problem
Adverse drug reaction	Dose is too low to produce the desired response
	Dosage interval is too infrequent to produce the desired response
	Drug interaction reduces the amount of active drug available
	Duration of drug therapy is too short to produce the desired response
Dosage too high	Drug product causes an undesirable reaction that is not dose-related
	Safer drug product is required due to risk factors
	Drug interaction causes an undesirable reaction that is not dose-related
	Dosage regimen was administered or changed too rapidly
Nonadherence	Drug product causes an allergic reaction
	Drug product is contraindicated due to risk factors.
	Dose is too high
	Dosing frequency is too short
Nonadherence	Duration of drug therapy is too long
	Drug interaction occurs in a toxic reaction to the drug product
	Dose of the drug was administered too rapidly
	Patient did not understand instructions
	Patient prefers not to take medication
Nonadherence	Patient forgets to take medication
	Drug product is too expensive for the patient
	Patient cannot swallow or self-administer appropriately
Nonadherence	Drug product is not available for the patient

Completing a CMR: Preventative Care Omissions; the 2013 U.S. Preventative Services
Task Force A & B Recommendations

All pharmacists who were involved in the study attained their PharmD, and thus had received basic training covering preventive care within the standard Doctor of Pharmacy curricula. Examples of preventive care measures pharmacists usually receive training on include colonoscopies, breast and prostate cancer screens, smoking cessation and aspirin use for myocardial infarction prophylaxis. However, despite their training, community pharmacists do not routinely engage in preventive care services aside from vaccination delivery. Therefore, a platform was required to justify the preventive care measures in which pharmacists could focus their care. Upon literature and policy review, it was decided that the United States Preventative Task Force (USPSTF) A & B Recommendations were the most complete and up-to-date list of preventive measures that applied to the study's target population.

Prior to training, all study pharmacists had never encountered the USPSTF's recommendations. During the section of this training, pharmacists were introduced to the history and reasons for the USPSTF's recommendations' development. Each recommendation related to adults and seniors were reviewed, however recommendations' related to pregnancy and children were excluded, as these patients were not included in this study for IRB purposes. "Women of child bearing age" was defined as any female 18-46 years old, in congruence with the USPSTF. "Intimate

Partner Violence” screening described screening for any physical, sexual, or psychological harm caused by a current/former partner/spouse occurring in either heterosexual or same-sex couples. As of 2013, this screening recommendation applied to women of child-bearing age only.

Completing a CMR: Preventative Measures; The CDC’s Advisory Committee on Immunization Practices

A refresher on the CDC’s Adult Immunization schedule was included in study training about preventive care (US Centers for Disease Control and Prevention, 2013).

Pharmacists reviewed information regarding the number of doses, intervals between doses, recommended vaccination schedule by age group, and important disease-related information.

Pharmacist Training: Data Recording

The data collection form was developed as an online survey with the Qualtrics® platform and all pharmacists were instructed to transmit data over the pharmacy’s secure wireless network, or the secure network identified by both the pharmacist and the Purdue researchers. The Qualtrics® survey collected data related to patient demographics, study outcome variables, and included a short survey of the pharmacists’

perceptions about using the health history obtained, either be it verbal from the patient, from the medical records or both. Pharmacists had the option of completing the Qualtrics® survey via iPad, or their work desktop computer.

During training to assure pharmacists understood data entry, Dr. Gernant gave pharmacists a simulated patient case that included a mock patient's medical history (including social/family history), recent labs, medication list, vitals and allergies. The pharmacist was instructed to review the case, and identify any MRPs and possible preventive care omissions. Once the case was reviewed, the pharmacist completed a mock data collection form for practice. If there was any discrepancy in the manner in which the pharmacists completed the mock data form, Dr. Gernant discussed this with the pharmacist until an agreement was reached on data transmission.

At the end of each Qualtrics® data collection form was a short survey measuring pharmacists' beliefs and attitudes towards utilizing health history in their CMR. Both intervention and usual care pharmacists were instructed to complete this section, as both groups did have some health history available to them- namely usual care pharmacists attained health history verbally from the patient, whereas intervention pharmacists attained health history from the patient, as well as from unedited medical records. However, only intervention pharmacists were asked to complete questions regarding their opinions on usability of certain parts of the medical records, as usual care pharmacists did not have access to these.

Patient Eligibility and Recruitment

After study power at 80% with an alpha of 0.05 was calculated to detect a minimum difference of two MRP's between groups, it was decided 90 patients would be sought for recruitment, 45 within each group. Patients were recruited face-to-face either by the study pharmacist or by Dr. Gernant when they visited their community pharmacy to drop off or pick up a prescription. Pharmacists were given a checklist inclusion and exclusion criteria and were instructed to ask each potential participant every question before the invitation for study participation.

Patient inclusion criteria was modeled after Medicare Part D MTM criteria, but expanded to all adults of all ages to increase the pool of patients for study. Thus patients were included if they agreed to undergo an CMR with the pharmacist and met the following criteria: (1) At least four chronic prescription medications scheduled for a chronic medical condition filled at the study pharmacy; (2) At least one of the following chronic disease states: hypertension, heart failure, diabetes, dyslipidemia, respiratory disease (such as asthma, chronic obstructive pulmonary disease, or chronic lung disorders), bone disease-arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis), or mental health conditions (such as depression, schizophrenia, bipolar disorder); (3) had an office visit with their Primary Care Provider within the last six months for any reason and; (4) understood and were able to give consent. Patients were

excluded if they met any one of the following criteria: (1) were under 18 years of age; (2) was a prisoner, or incarcerated; (3) was a university student; (4) was pregnant; (5) was unable to give informed consent or; (6) had received a CMR from a pharmacist within the previous six months. Patients were excluded from study participation if they had received a CMR within the previous six months from a pharmacist, as it was thought a lasting benefit would be experienced by the patient from their previous visit.

Data Collection Related to Pharmacists

Pharmacist demographics were collected at the time of study training and included number of years of active practiced, the number of CMRs completed within the previous year, and if the pharmacist had any post-graduate training/certification (Residency, Fellowship, or Board Certification). This data was collected to account for differences among pharmacists delivering the intervention as non-key personnel.

Exit Interviews

Upon study completion, pharmacists were invited to participate in an exit interview with Dr. Gernant. These interviews served as a quality improvement opportunity for study pharmacists to provide feedback regarding study logistics, and to discuss barriers and facilitators for CMR delivery. After consent, pharmacists underwent semi-structured

private exit interviews using an interview guide either telephonically or face-to-face at the pharmacists' pharmacy. Interviews were not audio-recorded, notes and quotations of pharmacists' responses were typed during the interview. These transcriptions were then reviewed for common and emerging themes.

Study Compensation

Pharmacists were compensated at a rate of \$75 per CMR, regardless of their assignment to intervention or usual care groups, which is comparable to market reimbursement for MTM (Mirixa 2013). If pharmacists in the intervention group did not receive any records from the PCP despite following procedures, the pharmacy was allowed to invoice the investigative team \$10. It was left to the pharmacists' discretion to continue and complete the CMR, however the patient's data were not included as a part of this study.

Patients were compensated for their time with a \$25 Visa gift-card. This compensation was approved by the Purdue University IRB, with the stipulation that a log of patient's identities be recorded to track payment receipt. Patient's compensation was sent via mail, with a note of appreciation from the researchers.

ANALYSIS

The research team consulted with Purdue's statistical consulting service to develop a data analysis plan. All analyses for this study were performed using IBM Statistical Package for the Social Sciences (SPSS) Statistics Version 22.

Pharmacist and Patient Demographics Analysis

Mann-Whitney U tests were used to detect differences in demographic variables (years practicing and number of CMRs delivered) between pharmacists groups, as pharmacists were acting as non-key personnel, and differences in experience would expectedly affect study outcomes. Differences among patient groups' comorbidities and race were tested with Pearson chi-square tests or Fisher's exact test for cells that had an expected count of less than five. Age, number of comorbidities, and total number of medications taken were compared between groups using Mann-Whitney U tests.

Primary Outcome Analysis: MRPs Identification

The primary outcome, total number of MRPs discovered, was analyzed using an independent sample Mann-Whitney U test, as the number of MRPs were not normally

distributed. Significance of the intervention was then tested with a multivariate linear regression model fit to relate study variables to the number of MRPs discovered. To do this, bivariate statistics were computed for each predictor variable; bivariate statistics on categorical data were computed using either a Mann-Whitney or a kruskal-wallis test. Correlation between continuous data and the number of MRPs identified was computed with spearman's rho. Variables with a p-value less than 0.2 were included in a multivariate linear regression model.

The assumptions of linear regression were verified- linearity was checked with a line of best fit in a plot of residual vs. predicted values. A correlation matrix and variance inflation factors/tolerance values were identified to assure that multi co-linearity was not present, and a durbin-watson test was run to ensure that the residuals were independent. A p-p-plot was used to verify Homoscedasticity.

The study team also sought to identify if there were differences between groups in the types of MRP's identified. Therefore, a Mann-Whitney U test was again used to test for differences in the numbers of each of the four types of MRP's (i.e., indication, efficacy, safety and adherence) identified between groups.

Secondary Outcome Analysis: Preventative-Care Omission Identification

The total number of applicable USPSTF recommendations was calculated for each patient based on the pharmacist-entered data. Determination of each patient's number of applicable recommendations was primarily based on the patient's age, gender and

reported comorbidities. If based on the available data it was uncertain to researchers if a USPSTF recommendation applied to a particular patient, then that recommendation was counted, as it could not be ruled out. This was done because the USPSTF recommendations' purpose is to both screen for and identify possible preventive care omissions. For example, the USPSTF has several preventive care screening recommendations for persons who are at risk for sexually-transmitted infections. Those at risk may be sex industry workers, injection drug users, or those who have multiple partners; this information was not specifically gathered by the Qualtrics® data collection form, and therefore could not be ruled out. Healthcare workers utilizing the USPSTF recommendations need assure patients' eligibility for each recommendation. Differences in the number of preventive-care omissions identified between groups were tested for significance using a t-test. A linear regression model was fit to isolate the effect of the intervention by the same methods outlined in section 3.1. The number of preventive care omissions identified for each recommendation was tested with a chi-square or fishers exact tests.

Secondary Outcome Analysis: Pharmacists' Perceptions of Utilizing Health History
Pharmacists' perceptions towards medical history's usefulness was characterized with descriptive statistics. Perceptions towards records received and utilized were characterized with descriptive statistics for intervention group only.

RESULTS

CMR Completion

Despite replacement for attrition, only four of the seven study pharmacists completed any CMRs. Due to the high attrition, the low recruitment and the overall slow rate of CMR completion, researchers decided to include all pharmacists who underwent training, whether they completed a CMR or not, in exit interviews to identify barriers and facilitators to study workflow and participation. Two usual care study pharmacists completed 19 CMRs and three intervention pharmacists completed 17 CMRs between June, 2014 and February 2015. Of the four pharmacists who completed CMRs, one usual care pharmacist and one intervention pharmacist had post graduate training. All pharmacists were female and opted to transmit data via their work desktop computer. There was no statistical differences in number of CMRs provided in the last year, nor years practicing between groups. Other demographics related to study pharmacists' experience can be seen below in Table 2.

Table 2. Study Pharmacists' Experience

	Usual Care (n=3)				Intervention (n=2)				p
	Mean	Min	Max	Std	Mean	Min	Max	Std	
<i>Number of CMRs Provided in Last Year</i>	6.7	0	20	11.5	2.5	0	5	3.5	0.80
<i>Number of Years Practicing</i>	5.0	2	7	2.6	5.5	5	6	0.7	1.00

Patient Demographics

Thirty-six patients were recruited and seen for CMRs during the intervention period; 17 were seen by intervention pharmacists and 19 by usual care pharmacists. The majority of patients were female (86%) and Caucasian (75%). Patients in the intervention group were more complex than patients in the usual care group, with significantly more comorbidities and number of medications, and were more likely to be diagnosed with asthma, dyslipidemia, obesity and osteoporosis (see Table 3 below). Additionally, there were significant differences in patients' race between groups; all intervention patients were Caucasian and usual care patients were either African American or Caucasian. There were no differences in the average total number of preventive care omissions applicable to study patients between groups (14.4 ± 1.89 vs. 14.5 ± 1.97 , $p=0.88$).

Table 3. Patient Demographics and Morbidities

Demographics	Intervention (n=17) Median (IQR)	Usual Care (n=19) Median (IQR)	p-value
<i>Age</i> [‡]	45 (39-52)	43 (33-49)	0.20
<i>Total # of Medications</i> [‡]	15 (11-16.5)	8 (6-11)	<0.01*
<i>Total # of Comorbidities</i> [‡]	5 (4.5-7)	3 (3-4)	<0.01*
	n (%)	n (%)	
<i>Female</i> [‡]	15 (88.2)	16 (84.2)	0.56
<i>African American</i> [‡]	0 (0)	7 (36.8)	0.01*
<i>Asian</i> [‡]	0 (0)	2 (10.5)	0.49
<i>White</i> [‡]	17 (100)	10 (52.6)	<0.01*
Comorbidities [‡]	n (%)	n (%)	
<i>Asthma</i>	4 (23.5)	0 (0)	0.04*
<i>Chronic Pain/Fibromyalgia</i>	5 (29.4)	4 (21.1)	0.71
<i>Congestive Heart Failure</i>	0 (0)	2 (10.5)	0.49
<i>COPD</i>	2 (11.8)	2 (10.5)	1.00
<i>Depression</i>	9 (52.9)	8 (42.1)	0.52
<i>Diabetes</i>	8 (47.1)	7 (36.8)	0.54
<i>Dyslipidemia</i>	14 (82.4)	9 (47.4)	0.01*
<i>GERD</i>	6 (35.3)	3 (15.8)	0.25
<i>Hypertension</i>	15 (29.4)	13 (68.4)	0.24
<i>Obesity</i>	4 (23.5)	0 (0)	0.04*
<i>Osteoporosis</i>	4 (23.5)	0 (0)	0.04*
<i>RA</i>	3 (17.6)	1 (5.3)	0.33

‡ Pearson chi-square or fisher's exact test

† Mann-Whitney U test

Outcome: MRPs Identified

Intervention pharmacists identified significantly more MRPs per patient than usual care pharmacists (11 [IQR: 7-14.5] vs. 6 [IQR: 4-9] problems per patient, p=0.02). Intervention pharmacists found more MRPs in every domain (indication, safety, adherence and

effectiveness) than usual care pharmacists; that is, intervention pharmacists identified more: (1) Medical conditions requiring the initiation of drug therapy; (2) Medication dosages too low to produce the desired response; (3) Medication interactions resulting in undesirable reactions that were not dose-related; (4) Patients who did not understand medications' instructions and (5) Preventative therapies required to reduce the risk comorbidity development.

Variables identified with bivariate analysis to predict the number of MRPs discovered included total number of medications, total number of comorbidities, asthma, and depression. All variables entered into the multiple linear regression model to predict number of MRPs were significant with the exception of depression, and the overall model was significant (adjusted $R^2= 0.511$; $p<0.01$). The intervention, while controlling for all variables included in the predictor model, was, $B= 0.351$, $CI: 0.005-13.96$; $p=0.05$. Furthermore, the model improved with the addition of intervention variable into the model (adjusted $R^2= 0.461$ vs 0.511).

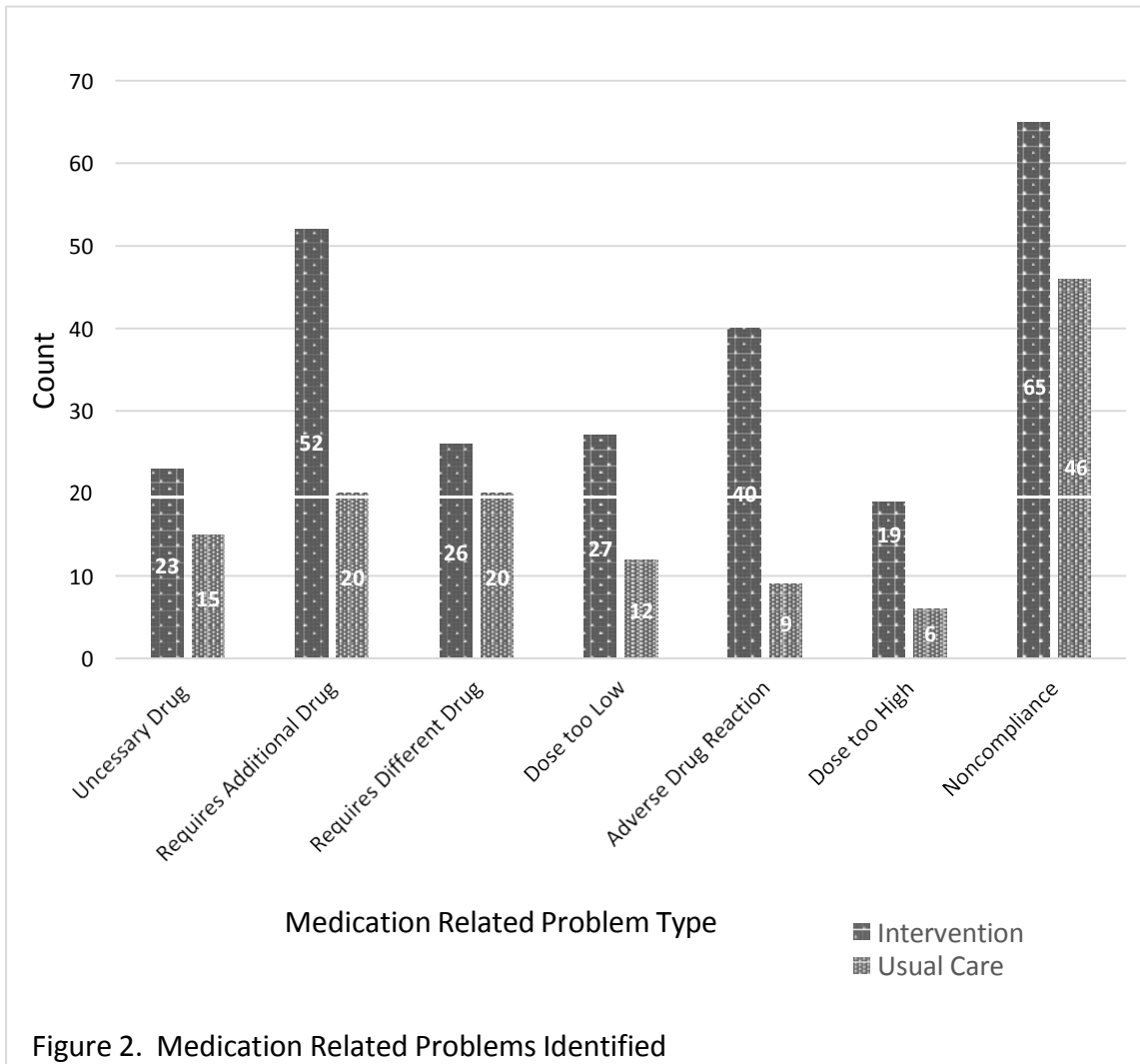


Figure 2. Medication Related Problems Identified

Table 4. MRPs Discovered[†]

MRP Category	Intervention		Usual Care		U	p
	# Discovered	Median (IQR)	# Discovered	Median (IQR)		
Unnecessary Drug Therapy	23	0 (0-1.5)	15	0 (0-2)	153.5	0.80
Needs Additional Drug	52	3 (2-4)	20	0 (0-2)	264.5	<0.01
Indication Total	75	0 (0-3)	35	0 (0-2)	239.5	0.01
Needs Different Drug Product	26	0 (0-3)	20	0 (0-2)	162.5	0.98
Dosage Too Low	27	2 (0-2.5)	12	0 (0-2)	218.5	0.07
Effectiveness Total	54	2 (0-4)	32	0 (0-2)	193.5	0.32
Adverse Drug Reaction Total	40	2 (0-5)	9	0 (0-1)	221.0	0.06
Dosage Too High	19	0 (0-0)	6	0 (0-0)	169.0	0.827
Safety Total	59	2 (0-6)	15	0 (0-2)	204.0	0.18
Adherence Total	65	4 (2-6)	46	0 (0-4)	218.5	0.07

[†] tested for with Mann-Whitney

Outcome: Preventative Care Omissions Identified

Intervention pharmacists identified, on average, 3.4 preventive care omissions per patient, compared to an average of 2.5 omissions per patients seen by usual care pharmacists (a median of 3 [IQR 3-4] vs. a median of 3 [IQR:1-3] omissions identified per patient; $p=0.04$). There were statistical differences in types of preventive-care omissions discovered between groups; intervention pharmacists were more likely than usual care pharmacists to identify a need for depression screening/counseling, healthy diet counseling, and missing immunizations. In contrast, usual care pharmacists identified significantly more patients who needed blood pressure screenings than intervention pharmacists. Other notable preventive care omissions identified by pharmacists, but not included in the United States Preventative Service Task Force A & B recommendations, pertained to healthy amounts of physical activity and accessing other healthcare resources (e.g., social workers, financial counselors, keeping all scheduled doctor appointments). Neither intervention nor usual care pharmacists ever identified preventive care omissions related to breast cancer medications, folic acid supplementation, intimate partner violence, sexually transmitted diseases, nor skin cancer behavior. See Table 5 below for a full representation of preventive care omissions identified by pharmacists.

Only two variables were identified with bivariate analysis to predict the number of preventive care omissions discovered: hypertension and CHF. When entered into the

multiple linear regression model to predict number of preventive care omissions discovered, the model itself was significant (adjusted $R^2 = 0.136$; $p = 0.027$). Hypertension was non-significant, but did increase the predicted model's r-squared, so it was retained in the final model testing the effect of the intervention. The model improved with the addition of the intervention variable from $R^2 = 0.136$ to $R^2 = 0.238$, and the model remained significant. The intervention variable itself was significant ($B = 0.367$, CI: 0.123-1.88, $p = 0.027$).

Table 5. Preventative Care Omissions Identified †

Preventative Care Recommendation	Usual Care # Applicable	Usual Care n (%)	Intervention # Applicable	Intervention n (%)	p-value
Alcohol Misuse	19	0 (0%)	17	1 (6%)	0.48
Aspirin Use	4	2 (50%)	9	3 (33%)	0.65
Blood Pressure	19	9 (47%)	17	2 (12%)	0.03
Breast Cancer Preventative Medicine	16	0 (0%)	15	0 (0%)	--
Breast Cancer	16	1 (6%)	15	2 (13%)	0.59
Cervical Cancer	16	1 (6%)	15	0 (0%)	1.00
Cholesterol	19	6 (32%)	17	3 (18%)	0.45
Colorectal Cancer	2	2 (100%)	5	6 (100%)	0.11
Depression	19	0 (0%)	17	4 (57%)	0.04
Diabetes	19	6 (32%)	17	5 (29%)	1.00
Falls Prevention	0	1 (-)	0	3 (-)	--
Folic Acid	11	0 (0%)	7	0 (0%)	--
Healthy Diet	19	4 (21%)	17	10 (59%)	0.04
Intimate Partner Violence	11	0 (0%)	7	0 (0%)	--
Missing Immunization	19	4 (21%)	17	10 (59%)	0.04
Obesity	19	1 (6%)	17	4 (24%)	0.17
Osteoporosis	16	2 (13%)	15	2 (13%)	1.00
Skin Cancer Behavioral	0	0 (0%)	0	0 (0%)	--
Tobacco Use	19	1 (5%)	17	1 (6%)	1.00
Sexually Transmitted Disease	19	0 (0%)	17	0 (0%)	--
Other Preventative Measure	19	6 (32%)	17	1 (6%)	0.09

† tested with chi-square or fishers exact test

Outcome: Records Received and Perceived Usefulness

Only one intervention pharmacist was denied access to the patient's medical record after multiple attempts, resulting in a 97% response rate from prescriber's offices. Additionally, 94% of the time, intervention pharmacists had access to at least one medical record note. Intervention pharmacists were most likely to receive active medication lists, allergy lists, problem lists, office visit notes and blood pressure readings. Intervention pharmacists cited drug levels, active medication lists, discontinued medication lists, problem lists, order notes, glucose/A1C labs, drug concentration labs, lung function tests and lipid panels as the most useful pieces of information (i.e., useful in $\geq 50\%$ of cases received). Additionally, pharmacists received, but never utilized the following medical records to discover MRPs: liver/kidney function; medication indication & start/stop dates; complete blood counts; thyroid stimulating hormone levels; walk in, care coordination & hospitalization notes; and family, surgical, device & social history. A graphical representation of perceived usefulness can be seen in Figures 3 and 4.

Pharmacists' Perceptions to Utilizing Health History

Intervention pharmacists were more likely to strongly agree or agree they were comfortable using the health history obtained to make patient specific recommendations than usual care pharmacists (70.6% vs. 36.8%). Also, intervention

pharmacists reported that patients' health information was clearer and more understandable more often than usual care pharmacists (93.7% vs. 21.1%).

Pharmacists who had access to patient medical records were more likely to agree that they were confident they identified all of the patient's MRPs (47.1% vs. 15.8%).

However, neither group was more likely than the other to believe they had actually resolved all the patient's medication problems (41.2% vs. 42.1%). Lastly, intervention pharmacists agreed that the patient's health history helped them complete a better CMR more often than usual care pharmacists (100% vs. 68.5%).

See Figure 5 for a full representation of study pharmacists' opinions in utilizing health history.

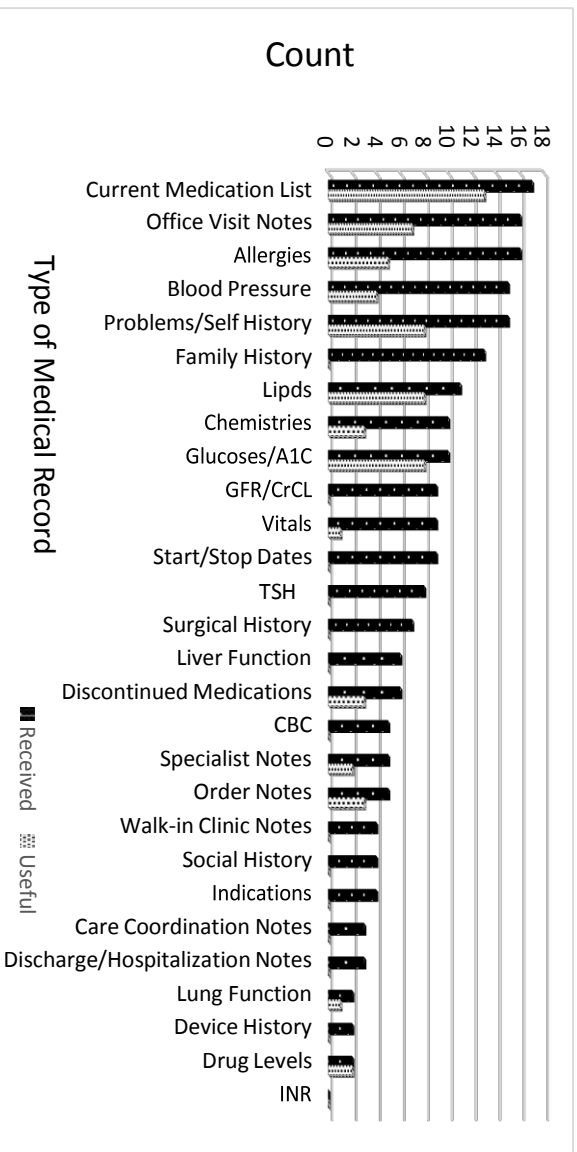


Figure 3. Records Received and Useful to Intervention Pharmacists

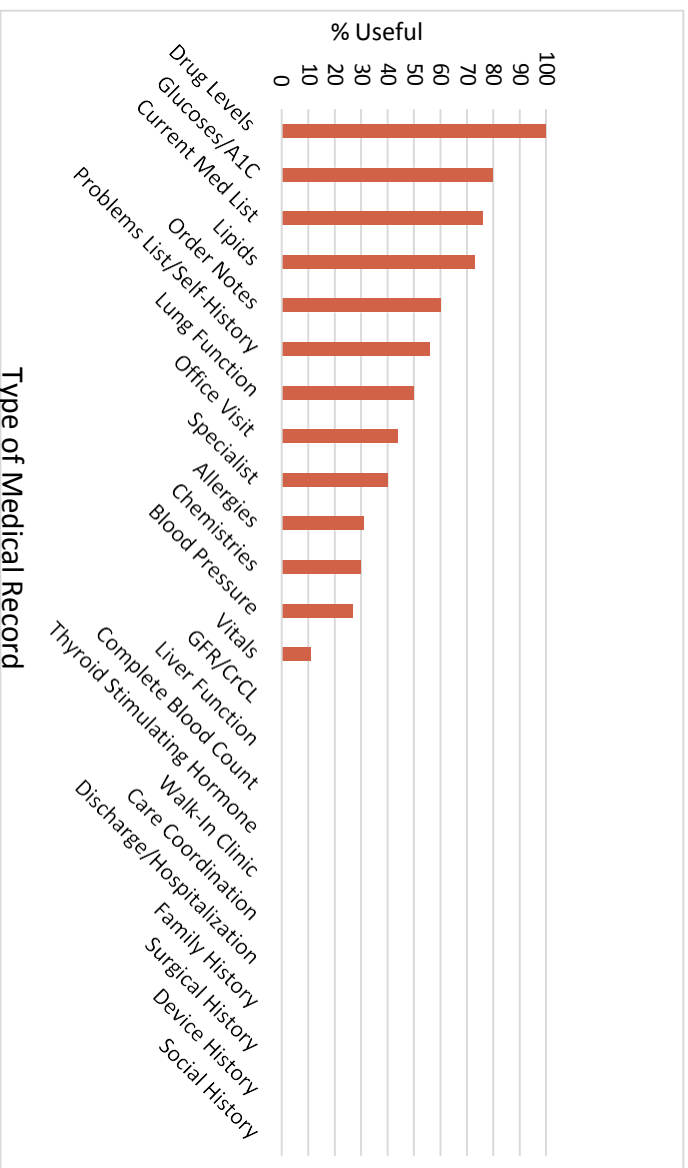


Figure 4. Medical History's Usefulness in Detecting Health Related Problems

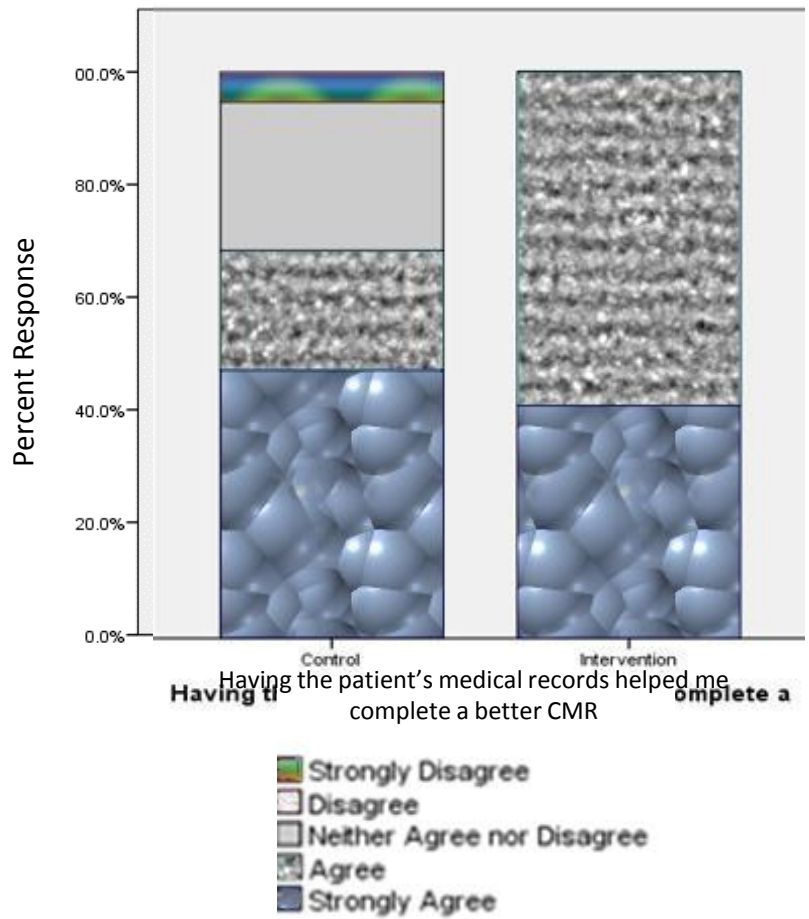
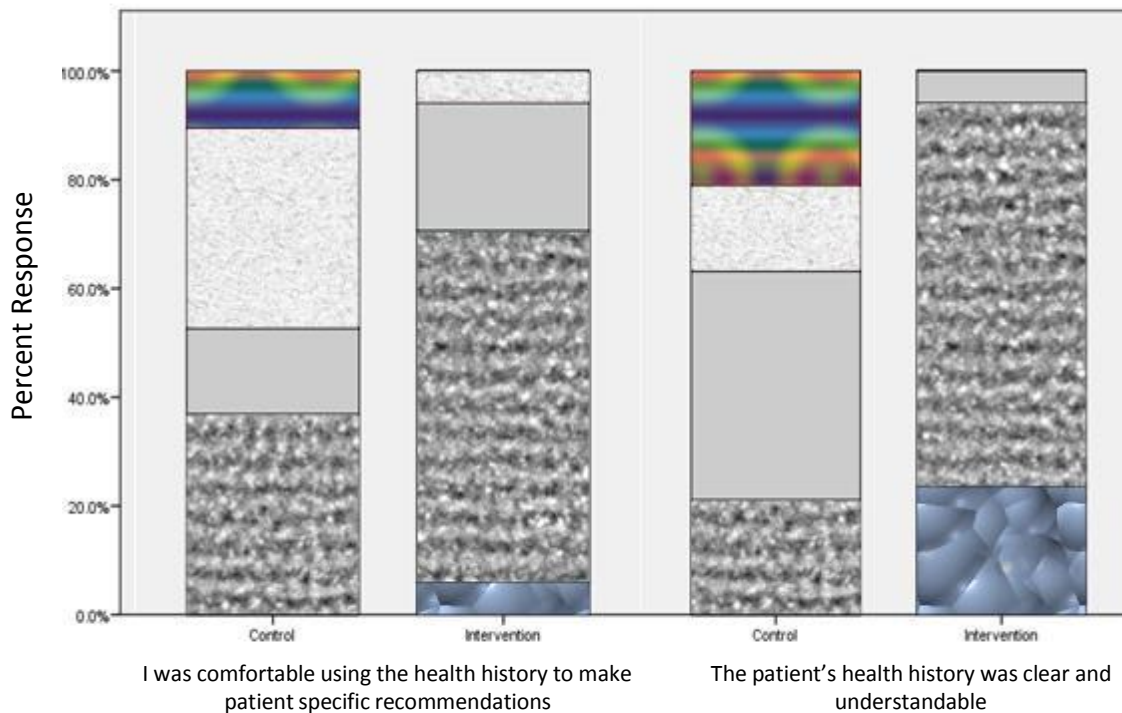
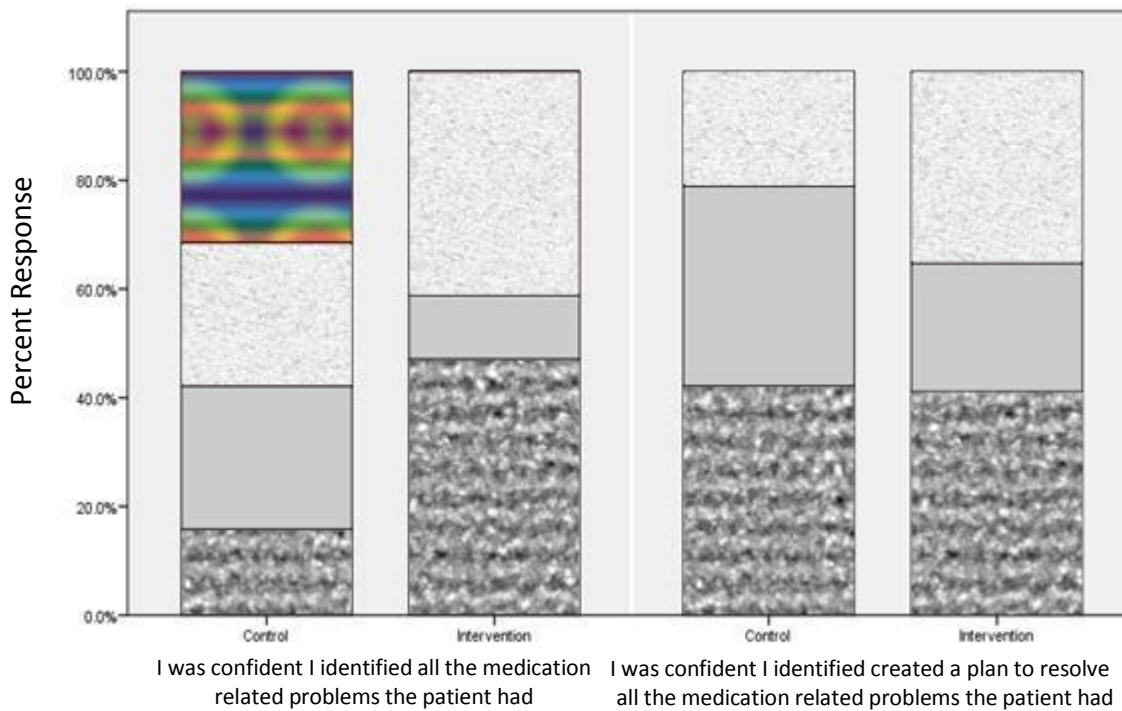


Figure 5. Pharmacist’s Opinions of Utilizing Health History



- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

Figure 5. Pharmacist's Opinions of Utilizing Health History Continued

Exit Interviews

After pharmacists were interviewed, themes related to barriers and facilitators emerged; there were a number of limitations due to the low recruitment rate and few CMRs completed. A major limitation identified by all pharmacists was finding time to fit in study activities (especially recruitment) into normal workflow responsibilities.

“Time was a huge issue. As a retail pharmacist, even with the overlap, you still have your own responsibilities.”

Pharmacists also reported limitations related to decision support tools, and identified confidence issues (concurrent with their feelings they had not resolved all identified issues) in regards to resolving identified problems.

“I looked up things I learned long ago but hadn’t used in practice. Interaction checks weren’t helpful. I would get a possible ‘serotonin syndrome,’ but I need more research on it. I didn’t know if I had to be worried about it.”

Time constraints were an emergent theme, and some pharmacists opted to perform the CMR directly after recruiting the patient, however this was only possible for usual care pharmacists, as intervention pharmacists had to wait for medical records to be released from the PCP. Pharmacists who opted to schedule patients, either in the intervention or usual care groups, identified patient reluctance to attending CMR appointments.

“You really have to sell it to the patients- it’s like I have to pull teeth to try and help you, and if [it] was your doctor asking, I think they’d be more likely to do it. I think it’s like, if you have an appointment with a

prescriber, and you don't come, you don't get your prescription....it's something that they just don't see that they need."

Additionally, pharmacists felt that patients may not have responded well to scheduling CMRs as this was an unfamiliar relationship with the pharmacist.

"People around here, MTM is new, and people aren't interested in sitting one on one with a pharmacist. It's just not a common thing. They're used to coming in and talking to us whenever they want."

"Patients just weren't interested, but they just kept avoiding us. I thought I had one, but they would never come in. I don't know why they weren't interested- maybe it was because they had to schedule instead of doing it on the fly."

Several other barriers mentioned by pharmacists were related to workflow issues and having to complete multiple projects simultaneously. Pharmacists who had devoted time away from the filling process in a private location found completing CMRs easier than those who participated in the study between checking prescriptions. By study design, intervention pharmacists had much more time-requirements; some pharmacists reported having to review full stacks of patient records before the CMR. However, none of the intervention pharmacists, upon direct questioning, reported that the records were ever cumbersome to review. Barriers related to time revolved centrally around stepping away from prescription filling responsibilities to speak with the patient.

“I would have to stop and restart because I was getting interrupted. I would forget what they took last.”

“We are trying to schedule at least one pharmacist as the MTM pharmacist per day. And they are away from dispensing in a room so it’s easier to contact people.”

There were few mixed themes reported by pharmacists; specifically pharmacists identified other pharmacy team members as barriers or facilitators based on whether the colleague would do extra work while the pharmacist was away from prescription filling responsibilities.

“I had great techs who could multitask while I was away. The techs would take the phone calls, type and adjust the pickup time. They were doing this on their own. Sometimes they would ask patients to come back tomorrow after dropping off.”

“My manager was supportive; they would cover when I was talking to patients and then went to a private area.”

Lastly, pharmacists felt positively about delivering CMRs. They voiced they were able to develop better relationships with patients, and appreciated being able to talk to patients whom they considered needed their services the most.

“I really liked that I wasn’t restricted in who I could provide the service to. I could pick people that I felt actually needed the service. The people I chose were frequent fliers, so it was very helpful to have their feedback.”

“In the future, I’ll do more med review to build rapport with the patients. Not in a room, but over the counter. “The more the patients get to know me, the more questions they ask. The study patients, they really stop by now. Even when they don’t have any prescriptions. They come by to show me their grandkids, and just talk to me personally.”

“I liked having the time to get to know the patients. I wouldn’t have known them at all. I feel like I’m more visible to the patients now.”

DISCUSSION

In this study, we hypothesized that community pharmacists would be more effective in detecting health-related problems if they had access to some of the patient's health history mirrored to information requested in CMS' Meaningful Use Stage 1, Core Measure 8: Transitions of Care Summaries. This core measure dictates that certain health history be transferred to a receiving healthcare entity; however only "eligible providers" are counted under this core measure, which exclude pharmacists.

Additionally, only eligible providers can receive incentives through CMS's Electronic Health Record Incentives Program which supports the adoption, implementation and improvement of EHR technology for providers who demonstrate meaningful use. We hypothesized community pharmacists could add benefit to HIE for two reasons: (1) pharmacies have the most up-to-date medication list and fill history; and (2) pharmacist-delivered patient care services (MTM), could be optimized when pharmacists engage in transitions of care (i.e.: reviewing health information generated by another healthcare entity). We confirmed that intervention pharmacists found significantly more MRPs than pharmacists who deliver CMRs under usual care.

Additionally, intervention pharmacists found more MRPs in every single domain (i.e., safety, efficacy, indication and adherence) than usual care pharmacists, however these

differences were only statistically significant for MRPs related to indication. A very recent study conducted by van Lint, Sorge and Sorensen, had similar results (van Lint, Sorge et al. 2015); in this study pharmacy residents completed MTM's without patient records, and then verified medication problems discovered with pre-existing health history. Over half of the MRP's discovered in the van Lint study were related to indication. MRP's related to indication may have been discovered most often because pharmacists are highly educated on indication, but very rarely receive indication information in usual practice. Nearly significant results related to adherence MRP's may have been discovered more often by intervention pharmacists, as patients' instructions may have been documented in the medical chart, but never transcribed to the prescription and subsequently cued the pharmacist to identify discrepancies between what the patient was instructed, and what the patient actually did.

In addition to discovering more MRP's, intervention pharmacists also identified more preventive care omissions than usual care pharmacists overall, however both groups had certain omissions identified more often than their comparator group. Intervention pharmacists were more likely to identify omissions related to depression, diet, and immunizations whereas usual care pharmacists were more likely to identify that the patient was missing preventive care related to blood pressure screenings. We suspect intervention pharmacists discovered more missing immunizations because community pharmacists are highly trained in adult immunizations, but rarely have access to the patient's immunization records. We suspect usual care pharmacists were more likely to

identify blood pressure preventive care omissions because hypertension is a condition regularly addressed in the community pharmacy setting; intervention pharmacists may have been more concerned with omissions discovered from the PCP-obtained health history, as this was not part of their usual practice.

Neither intervention pharmacists nor usual care pharmacists identified any preventive care omissions related to sexually transmitted diseases nor domestic abuse. We presume community pharmacists may have felt uncomfortable asking about highly sensitive subjects and/or may have felt inadequately trained to handle a positive identification. There is ample room for interventions and research for community pharmacist knowledge and communication related to preventive care. Specifically, future research and public health initiatives should focus on community pharmacies as a delivery point for more comprehensive preventive care, due to their easy access and employment of trained healthcare providers. Additionally, there were a few cases where pharmacists found more preventative care omissions than were calculated applicable by researchers (example: falls prevention and colorectal screening). This could be explained that pharmacists either identified patients' need beyond the stipulations of the USPSTF recommendations. For example, a patient may be at increased risk of falls if they are under 65, but on medications that cause dizziness and vertigo. Alternatively, it is possible that pharmacists did not understand the USPSTF recommendations and misapplied them.

Intervention pharmacists did find some health history more useful than others. Labs most useful were related to drug safety and monitoring, such as drug serum levels, A1Cs, lipid panels and lung function tests; this is expected as community pharmacists would be more likely to encounter ambulatory chronic diseases (as opposed to critical care situations with labs such as complete blood counts, and blood gases). Health history components most useful to the pharmacists were the active/discontinued medication lists as problem lists. We speculate community pharmacists are routinely trained to link indications with medications, and may seek out information on medication and problem lists specifically as community pharmacists rarely receive indications on prescriptions in usual practice. Indeed, pharmacists found more problems related to indications than any other medication-related problem. In regards to notes, order notes were helpful more often to intervention pharmacists than any other type of visit documentation, including office visits and specialist visits. This could be because community pharmacists are accustomed to taking orders from physicians, as part of their normal filling responsibilities. Interestingly, pharmacists perceived a lack of helpfulness of renal labs. This could be due to the fact that patients might have needed renal function

Pharmacists were more likely to report the health history they reviewed was clear and helpful if they received it from the PCP rather than from the patient alone. During the design of our study, we predicted the possibility that intervention pharmacists could feel uncomfortable utilizing real, unedited medical records, as certified they did not

routinely request medical records in order to participate. However, we detected the opposite, as intervention pharmacists were nearly twice more likely than usual care pharmacists to report they were comfortable using the health history attained to make patient specific recommendations. Utilization of real, unedited health information could particularly help community pharmacists especially when the patient is a poor historian, has no regular caregiver, and/or has communication/cognitive difficulties. This is further supported by the fact that usual care pharmacists (i.e., pharmacists who practice under normal conditions and received health history solely from patients) were less likely to believe they identified all of the patients' MRPs. Inferentially, community pharmacists under normal conditions cannot always be confident that they are aware of all of the patients' medications, conditions and needs. Van Lint, Sorge and Sorensen identified similar results, as pharmacists were more likely to report confidence in the validity of the MRP identified once they had reviewed the patient's medical records.

Intervention pharmacists were more than twice as likely than usual care pharmacists to confidently identify all of the patient's MRP's, but were no more likely than usual care pharmacists to confidently resolve the MRP's. There are several reasons that may explain this finding- First, we did not ask pharmacists to resolve problems in this study, but merely to identify them. Alternatively, this finding could be attributed to confidence or workflow issues related to the nature of community pharmacy. Namely, resolving problems identified within community pharmacies is limited as there is lack of standardization and agreement on community pharmacists' role, not only by other

healthcare providers, but within the profession itself. Future research should focus on why community pharmacists may identify certain healthcare related problems, but not necessarily act to resolve them.

This study had several limitations; mainly due to the small sample size, few if any remarks can be made to the clinical relevance to community pharmacy practice. The suggestions related to the results themselves may be promising, as some significant suggestions were found, however there may be a low external validity to this study, as pharmacists were allowed to choose patients themselves. This is not normal practice, as usually patients are referred to community pharmacists via their Medicare Part D, or other insurance provider.

Interest in participation of Rx-SafeNet pharmacists in this study was low, and only a handful of pharmacists expressed initial interest in training, with even fewer completing training. Pharmacists were compensated for their time, in the form of \$150 for training and \$75 per CMR, which is comparable to other common MTM payers' compensation, however we speculate that pharmacists may not have been incentivized to participate as the payment went to the pharmacy itself, and not the pharmacist. This payment method was utilized as Purdue University mandates individuals be paid only with the use of consulting agreements. We speculate if pharmacists had been compensated directly, then there may have been more incentive for study participation. Future research in community pharmacy PBRNs may find more success in study participation through direct incentives, and reducing total time spent in study participation by

reliance on technicians and other pharmacy staff for some study functions, such as the consent process. Regardless of compensation, pharmacists acting as study personnel in PBRN research may limit participation and feasibility; as such PBRN studies will be more successful if pharmacists act as the provider and not as study personnel.

Another limitation due to the lackluster enrollment of pharmacists and high attrition, was that we could not stratify and match pharmacists based on their experience and natural variation in ability to appraise medical history. To account for this variation in clinical skills to the best of our ability, we gathered some demographics on the pharmacists by asking their past post-graduate training experience and former experience with delivering CMRs. Experience between the two pharmacists groups was similar in the average number of years practicing (5.0 ± 2.6 vs. 5.5 ± 0.7), but differed in relation to CMRs reportedly provided in the last year. While both groups included members whom reported no experience ever delivering CMRs, usual care pharmacists had more experience than intervention pharmacists, with an average of 6.7 CMRs/year vs. 2.5 CMR/s year. One suggestion to reduce this variation was to have a researcher obtain the medical records, and reduce the pertinent patient information to a standardized form as previous studies have done, with positive results with regards to outcomes. However, we decided against an edited medical record form, as the purpose of this study was to have pharmacists directly review the medical information themselves, as this is an unusual current circumstance, but a plausible possibility as transitions of care initiatives are undertaken. We also chose to have pharmacists directly

review real, unedited medical records as we wanted to measure pharmacists' opinions related to the medical record's usefulness and usability.

Because usual care pharmacists had moderately more experience delivering CMRs, we would expect the opposite of this study's findings, however there was such a small sample size no definitive conclusions can or should be made.

Another limitation of this study is that the outcomes were not clinical in nature. Study pharmacists only reported the number of identified health related problems, and not the patient's outcome of any action taken (if any action was taken). Any steps taken to resolve identified health related problems were up to the sole discretion of the study pharmacist and their clinical judgment; additionally interventions made were not recorded for this study. Due to this, we are unsure if pharmacists' confidence in resolution of MRP's was low because steps to intervene were never taken, or because the steps taken were perceived inefficient.

Another limitation results as the quality of records received by intervention pharmacists was not recorded. No clinical verification was made in how far each medical record went back in the patient's history, nor the records' characteristics; we merely recorded each type of record received. If we had characterized the quality of the records received, we may have been able to study pharmacists' clinical rationalization more closely, and explain findings related to pharmacists' comfort and confidence. To characterize the value pharmacists' place in medical records more transparently and to mirror transitions of care efforts in in-patient healthcare, the study was originally designed to include only

patients who had a recent hospitalization for conditions targeted under CMS's Hospital Readmission Reduction Program- namely, CHF, COPD, Pneumonia and Hip/Knee arthroplasty. However, this was dropped from the final protocol as the patient recruitment pool would have been diminished. Future research should focus more specifically on pharmacists' value and rationalization of medical records in clinical decision making, and identifying best practices so that they may be taught to future pharmacists.

Lastly, this study was limited due to demographic differences between patient groups. Most patients seen in both study groups were females, which is not unexpected, as females utilize healthcare more often than males (Bertakis, Azari et al. 2000). However, differences emerged in that intervention patients had significantly more conditions and medications than usual care patients. It is possible intervention pharmacists were more aware of existent conditions and medications due to seeing them on the patient's medical record, and thus had a more complete list of medications and conditions. Usual care pharmacists would only know the conditions and medications reported to them by the patient, and since this study did not verify any information the pharmacists received, there is no way to assure that these differences identified between groups are valid. Future research should focus on the quality of transitions of care processes- namely that information being transmitted and appraised is accurate and concise. There is a wealth of opportunity for research, as the profession needs to understand how it utilizes electronic health information.

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APPENDIX

APPENDIX

U.S. Preventative Services Task Force Recommendations Adapted for Study Pharmacist Training

Topic	Description
Abdominal aortic aneurysm	One-time screening for abdominal aortic aneurysm by ultrasonography in men ages 65 to 75 years who have ever smoked.
Alcohol misuse	Clinicians screen adults age 18 years or older for alcohol misuse and provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse.
Aspirin	Use aspirin for men ages 45 to 79 years when the benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.
Aspirin	Use aspirin for women ages 55 to 79 years when the benefit of reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.
Blood pressure	Screen for high blood pressure in adults age 18 years and older.
BRCA screening, counseling about	Women whose family history is associated with an increased risk for deleterious mutations in <i>BRCA1</i> or <i>BRCA2</i> genes be referred for genetic counseling and evaluation for BRCA testing.
Breast cancer preventive medications	Clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.
Breast cancer screening	Screen mammography for women, with or without clinical breast examination, every 1 to 2 years for women age 40 years and older.

Cervical cancer screening	Screen for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.
Chlamydial infection screening: nonpregnant women	Screen for chlamydial infection in all sexually active nonpregnant young women age 24 years and younger and for older nonpregnant women who are at increased risk.
Cholesterol abnormalities	Screen men age 35 years and older for lipid disorders.
Cholesterol abnormalities	Screen men ages 20 to 35 years for lipid disorders if they are at increased risk for coronary heart disease.
Cholesterol abnormalities	Screen women age 45 years and older for lipid disorders if they are at increased risk for coronary heart disease.
Cholesterol abnormalities	Screen women ages 20 to 45 years for lipid disorders if they are at increased risk for coronary heart disease.
Colorectal cancer	Screen for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults beginning at age 50 years and continuing until age 75 years.
Depression	Screen adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.
Diabetes	Screen for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.
Falls prevention	Exercise or physical therapy to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.
Falls prevention in older adults: vitamin D	Vitamin D supplementation to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.
Folic acid	All women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.
Gonorrhea screening:	Screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk

	for infection (that is, if they are young or have other individual or population risk factors).
Healthy diet counseling	Intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.
Hepatitis C virus infection screening	Screen for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965.
HIV screening:	Screen for HIV infection in adolescents and adults ages 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.
Intimate partner violence screening	Screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services. This recommendation applies to women who do not have signs or symptoms of abuse.
Obesity screening and counseling	Screen all adults for obesity. Clinicians should offer or refer patients with a body mass index of 30 kg/m ² or higher to intensive, multicomponent behavioral interventions.
Osteoporosis screening: women	Screen for osteoporosis in women age 65 years and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.
Sexually transmitted infections counseling	Recommends high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) in all sexually active adolescents and for adults at increased risk for STIs.
Skin cancer behavioral counseling	The USPSTF recommends counseling children, adolescents, and young adults ages 10 to 24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.
Tobacco use counseling and interventions	Ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.
Syphilis screening	Screen persons at increased risk for syphilis infection.
