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Analysis of Telephonic Pharmacist Counseling

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This is to certify that the doctoral dissertation by

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Walden University
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Abstract

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BS, University of Illinois, 1974

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Public Health

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Abstract

Medication complexity and nonadherence are significant risk factors for avoidable hospitalizations and health care spending for older adults in the United States. However, limited empirical research has investigated pharmacist-run telephonic medication management programs as a potential solution to the problem of reducing medication complexity while improving medication adherence. This quantitative study employed the behavioral change model to analyze archival data from a sample of 1,148 participants, examining the relationship of a pharmacist-run telephonic consulting program on medication adherence and medication complexity for one pharmacy benefit management firm's Medicare Part D recipients. The primary research questions investigated the relationship of medication therapy management programs to medication adherence and complexity. Data were assessed using correlation and regression analysis to determine the association between receiving pharmacist counseling, medication adherence, and medication complexity, and to assess the strength of any relationships identified. No linear relationship was found between pharmacists' counseling, medication complexity, and medication adherence. However, the study found a weak correlation between medication complexity and comorbidities, and between medication complexity and medication adherence. This study promotes positive social change by identifying information that can be used to reduce pharmaceutical industry liability by improving proper management of medications, by reducing the burden of comorbidities related to poor management of chronic disease, and streamlining health services and improving their outcom

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Dedication

My mother, a teacher, always stated that I loved going to school. I may not have been the best student, but I always gave it my best. My parents were both college graduates. I thank both of them for giving me the tools to become a successful student throughout my years. Procuring a Ph.D. was part of my wish list that I told myself I would do someday after having children and seeing them through college successfully. I thank my daughter Norma-Jean for her research and time to introduce me to online education and Walden University, and for her continued support to see me through to the finish line. Finally, I would like to dedicate this degree to my husband of 23 years. His understanding of my missing family and friend events due to school assignments has been phenomenal. I thank him for his unending support, patience, and encouragement all these years. I love you.

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This was my journey, and like many others before me down this same path, mine required people with various roles of support, and I have many to acknowledge. I would like to thank Janice Moore and Mike Cline for their invaluable assistance in collection and management of patient data. In some cases, it was not what you knew, but whom you knew. Secondly, I would like to thank those who guided me through my dissertation process. I cannot say enough about the support and guidance I received from my chairperson Dr. Cheryl Anderson, and my committee members Dr. Hadi Danawi, Dr. Diana Naser and Dr. Basil Considine.

As with all great productions, many individuals behind the scene add to the success. I would like to express my gratitude to Dr. Heather Miller, who gave me clarity with my writing and Dr. Jeff Zuckerman who editing skills were indispensable. A thank-you to James Moore, a wonderful and patient statistician whose writing skills were instrumental in the preparation of this work. Through him, I found a new respect for SPSS, and hierarchical regression.

As with the more traditional platforms of educational learning, peer support is also very important. Classmates help ground one, lend assistance, and above all, help to keep one’s sense of humor. Many times humor was the best remedy. Therefore, I would like to thank Walden University students Dr. Gary “Bones” Longmuir (June 2015 PhD graduate) and Mary “Helena Handbag” Trimble RN, MPH for being there for me through the years.

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Chapter 1: Introduction to the Study

Managing chronic diseases is often challenging for older adults who are aged 65 years and older. Multiple comorbidities, numerous medications, multiple health care providers, and other factors contribute to medication nonadherence and self-management issues for all individuals, but they have an additional impact on older adults (MacLaughlin et al., 2005; NEHI, 2009; Smith, Catellier, Conlisk, & Upchurch, 2006). Medication nonadherence is responsible for $100 billion in avoidable hospitalizations and $290 billion per year in avoidable health care spending in the United States (NEHI, 2009; Osterberg & Blaschke, 2005). Managing a chronic disease such as Type 2 Diabetes Mellitus (T2DM) in older adults is especially challenging because of the complex medication regimens and the existance of comorbitities (ADA, 2013). For T2DM patients, reaching their clinical outcomes and goals is key to effective disease management (ADA, 2013). This study investigated methods to improve medication adherence for older adults with T2DM.

This study examined a U.S. pharmacy benefit management (PBM) company's medication therapy management (MTM) system and its impact on medication adherance. In this system, pharmacists use telephone consulting in order to decrease medication complexity and nonadherence to prescribed medications. While these management practices are designed to benefit the individual patient, this strategy has the potential to create positive, systemic changes for society. Increasing the proper management of medications will positively impact the pharmaceutical industry by reducing liability, improve public health by reducing the burden of comorbidities related to poor management of chronic disease, and streamline health services to imrpove their outcome (Lawrence, Qu, & Briskin, 2012; NEHI, 2009; Viswanathan et al., 2012).

Chapter 1 introduces the study topic and provides background information on T2DM, medication nonadherence, PBM companies, and MTM pharmacist counseling program. After presenting the problem statement, purpose and research questions, I will briefly summarize stages of change theory and how this theory applies to medication nonadherence. The chapter continues with the nature of the study, definitions, and a discussion of the study's assumptions, limitations, scope, and delimitations. The chapter concludes with a discussion of the study's significance and a chapter summary.

Background

Self-management of T2DM in older adults is challenging because of complex medication regimens and the coexistance of comorbidities such as hypertension and hyperlipidemia (ADA, 2013; Inzucchi et al., 2012). Successful management of treatment depends not only on achieving proper glycemic control but on achieving treatment balance between comobidities and quality of life (Pratley & Gilbert, 2012). The prevalence of T2DM increases with increased life expectancy for older adults (Inzucchi et al., 2012; Pratley & Gilbert, 2012). The Centers for Disease Control and Prevention (CDC) estimated that in 2010, 390,000 older adults in the United States were newly diagnosed with T2DM (CDC, 2011). Despite the high consumption of prescription medications by older adults, it is not age itself but the age-related comorbidities that have a high risk of polypharmacy (multiple medication use). Polypharmacy correlates with increased adverse events, medication nonadherence, health care costs, hospitalization, and mortality (Budnitz, Lovegrove, Shehab, & Richards, 2011; Mansur, Weiss, & Beloosesky, 2012). For older adults with T2DM, diabetes treatment is often intensive and complex, creating challenges with medication adherence.

Pharmacy Benefit Management Companies

Pharmacy benefit management companies are specialized firms that manage the prescription drug programs for most health plans (Lawrence et al., 2012). These companies provide cost-effective drug-related administrative services and improving medication adherence, resulting in positive patient outcomes. Pharmacy benefit management companies promote medication adherence and improve health outcomes by employing disease management (DM) programs that primarily focus on chronic conditions such as diabetes, hypertension, arthritis, hyperlipidemia, and heart failure. In PBMs, pharmacists may be at the leading edge for DM programs (Lawrence et al., 2012); these pharmacists attempt to work proactively to educate patients on chronic conditions and monitor programs designed to increase medication adherence.

Medication Complexity

There is a limited body of literature on PBMs' use of MRCI scores on medication nonadherence. Medication variables such as the number of medications, dosing frequency, instructions, and prescribed dosage forms can all negatively affect adherence (George, Phun, Bailey, Kong, & Stewart, 2004). These are measured in part by the Medication Regimen Complexity Index (MRCI), which provides a numeric value that reflects medication variables (formulation, dosing frequency, and special instructions) and patient-level variables (disease specific medication, other prescribed medication and over-the-counter herbals or supplements; George et al., 2004). A review of the extant research, detailed more thoroughly in Chapter 2, suggested that certain chronic disease medication regimens are more complex than others are. In addition, medication complexity has been positively correlated with medication nonadherence (Choudhry et al., 2011; Libbey et al., 2013; Moore, Shartle, Faudskar, Matlin, & Brennan, 2013; Pollack et al., 2010).

Medication Adherence

Medication adherence is a complex behavior that depends on self-efficacy to perform the behavior, confidence in one's medical providers, and a belief that the medication treatment will work (DiMatteo, Haskard, & Williams, 2007). Medication misuse and nonadherence result in the deterioration of a patient's chronic condition and increased hospitalizations and medical costs (Ho et al., 2006; Hughes, 2004; Mahoney, Ansell, Fleming, & Butterworth, 2008). Interventions that include simplyfing drug regimens, increasing patient education, and pharmaceutical counseling increases medication adherence (Rodriguez de Bittner & Zaghab, 2011; Viswanathan, 2012). Increasing medication adherence is complex, and may require more than one solution to be successful.

At the time of this study, pharmacy benefit management companies in the United States used two methods to measure medication adherence using pharmacy claims data: medication possession ratio (MPR) and proportion of days covered (PDC). Both MPR and PDC allow PBM pharmacists to monitor a patient's adherence and to intervene when deemed appropriate to ensure appropriate treatment (Brennan et al., 2012). In this study, I used MCRI scores to help identify medication complexity and MPR ratios to measure adherence in a cohort of patients receiving medications in the treatment of T2DM.

Medication Therapy Management Programs

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA 2003) was a U.S. Congressional health care reform bill that focused on preventive medicine for chronic diseases to develop a mechanism to improve the quality of medication management (Neuman & Cubanski, 2009). The centerpiece of this reform bill offered Medicare beneficiaries outpatient prescription drug benefits (Meyer & Cantwell, 2004; 108th Congress, 2003). To ensure drug safety and appropriateness for the targeted beneficiaries, MMA 2003 required that all Medicare plan sponsors establish and implement a medication therapy management (MTM) program.

Medication therapy management is a part of the family of DM programs and is a distinct set of services designed to optimize therapeutic outcomes for the Medicare Part D recipients (Schommer, Doucette, Johnson, & Planas, 2012). MTM programs are distinct from other DM programs because of they incorporate analysis of a patient's total medication experience, not just the single chronic condition (Pellegrino, Martin, Tilton, & Touchette, 2009). While many MTM programs deliver through face-to-face consultations, several studies have shown that this delivery system is not always optimal for the patient and the community pharmacist (Dolor, Masica, Touchette, Smith, & Schumock, 2012; Schommer et al., 2012). Feifer, Greenberg, Rosenberg-Brandl, and Franzblau-Isaac (2010) found that some patients are not always satisfied with consultations that take place at the point of service. Because of this lack of satisfaction, telephone consultations have been proposed as a viable alternative to deal with this dissatisfaction (Moczygemba et al., 2008; Ward & Xu, 2011; Wu et al., 2006).

Pharmacy benefit management companies are well-equipped to offer full clinical pharmacist services, including MTM programs via telephone, to all Medicare health maintenance organizations and other private insurance companies (plan sponsors) that provide Medicare covered benefits (Neuman & Cubanski, 2009). The availability of complete patient medication profiles via electronic data claims enables PBM MTM pharmacists to remotely identify individuals who have the propensity to be medication nonadherent. Telephone MTM services are an option to deliver patient-specific care for health care plans offering MTM services to Medicare recipients. Pharmacists' direct patient care interventions have been shown to improve health care outcomes (Rodriguez de Bittner & Zaghab, 2011; Schnipper et al., 2006; Moczygemba, Barner, Gabrillo, & Godley, 2008). However, this study's review of the literature indicated a gap in the research investigating PBM MTM pharmacist counseling on medication complexity and improved adherence.

Problem Statement

As the U.S. population ages, more people are being diagnosed with Type 2 Diabetes Mellitus (ADA, 2013). T2DM is a complex and lifelong chronic disease that requires multiple medications, effective self-management, and medication adherence to achieve therapeutic success (ADA, 2013). Many older adults with T2DM have existing comorbidities such as hypertension, hyperlipidemia, and coronary heart disease, which complicates treatment regimens and increases nonadherence (ADA, 2013). Older patients with T2DM who are medication nonadherent are at greater risk for hospitalizations, emergency department visits, and all-cause mortality (Ho et al., 2006; Lau & Nau, 2004; Yang et al., 2009). Complex medication regimens also have documented negative effects on medication adherence and therepeutic outcomes (Choudhry et al., 2011; Libby et al., 2013; Pollack, Chastek, Williams, & Moran, 2010). Medication complexity and nonadherence have the propensity to undermine effective treatments in complex chronic diseases such as T2DM.

There is a gap in the literature on the effectiveness of PBM telephonic systems that pharmacists use to engage patients; however, several previous studies suggest that this is an important area for research. Several studies have suggested that lack of patient engagement in their health care is affected by embarrassment, inadequate reading comprehension, and poor communications skills, posing a challenge to dispensing pharmacists at the store level (Kirsh, Jungeblut, Jenkins, & Kolstad, 2003; von Wagner, Steptoe, Wolf, & Wardle, 2009). Inadequate patient engagement has been correlated with a decrease in self-management, affecting decisions in self-care (Mosen et al., 2007). Counseling older adult patients in an environment without barriers can increase patient engagement and medication adherence (Schnipper, et al., 2006; Tkacz, Metzger, & Pruchnicki, 2008). Other researchers have evaluated hospital-based pharmacists using telephone calls for consultation and was deemed successful as a communication medium for increasing patient involvement with their treatment (DeWalt et al., 2006; Nazareth et al., 2001; Wu et al., 2006). This study was designed to address this research gap.

Medication therapy management programs in the United States are designed to be distinct from medication-dispensing services and other DM programs. While studies have been completed using community pharmacy-based DM programs on patient medication adherence (Chawla, 2012; Fox, Ried, Klein, Myers, & Foli, 2009; Planas, Crosby, Mitchell, & Farmer, 2009), there has been little research on the impact of MTM pharmacists on medication complexity and medication adherence from a PBM system using telephonic consulting. More research is needed to study the impact of MTM programs on medication complexity and medication adherence in the older adult population.

Purpose of the Study

The purpose of this quantitative study was to examine the effects of a pharmacist PBM MTM telephonic consulting program on medication adherence and medication complexity for a selected PBM's Medicare Part D recipients. In this study, I used MRCI scores as an indicator for medication complexity, and MPR ratios as an indicator for medication adherence. I specifically examined an MTM telephonic program used by one PBM for Medicare patients with T2DM (these indicators are further examined in Chapter 3). I sought to analyze whether MTM pharmacist counseling is a means to improving medication adherence and compliance in an older adult population. Increased medication adherence and compliance could help stem the high costs of unscheduled hospital and emergency room visits while increasing positive health outcomes and decreasing health care costs.

Research Questions and Hypothesis

In this study, I evaluated the association of MTM pharmacist telephonic support with medication complexity and nonadherence in a group of T2DM Medicare–D beneficiaries enrolled in a specific PBM's MTM program. The independent variable was the PBM MTM pharmacist-counseling program, and the dependent variables were medication complexity (as measured by a decrease in MRCI scores) and medication adherence (as measured by an increase in MPR percentages). This investigation was guided by two primary research questions.

Research Question 1: Is there an association between receiving medication therapy management pharmacist telephonic support and medication complexity in Medicare Part D beneficiaries having T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities?

H_{01}: There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

H_{A1}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

Research Question 2: Is there an association between medication therapy management pharmacist telephonic support and medication adherence in Medicare Part D beneficiaries having T2DM as measured by a change in MPR percentages after controlling for MRCI scores?

H_{02}: There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

H_{A2}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

The Theoretical Framework

This study used the stages of change (SOC) theory for its theoretical framework. SOC is a frequently used theory to explain behavior change (Prochaska & DiClemente, 1983). This model describes the stages of readiness, the decisional balances, and self-efficacy used by individuals in making a behavior change. Changing behavior such as starting a new medication or taking medication on a daily basis for a chronic illness is difficult for many individuals. Pharmacists can assist individuals who may require information, education, guidance, or a combination in order to be medication adherent. The five stages of SOC theory are instrumental in identifying a patient's readiness for and barriers to change; SOC has been applied extensively where change in behaviors has been warranted (Prochaska, Redding, & Evers, 2008) and to explain medication adherence behavior (Johnson et al., 2006a, 2006b; Willey et al., 2000).

Pharmacists can lessen patient frustration and improve patient success by understanding the patient's stage of change, anticipating barriers to change, and identifying patients who have relapsed (Prochaska, 2008). As pharmacists identify patients in the different SOC stages, pharmacists can take specific actions by recommending an appropriate intervention aimed at increasing adherence. For long-term behavior change (e.g., chronic medication adherence), potential change strategies are individualized and applied at every stage (Prochaska, 2008). As a patient's skill and confidence, increases in managing medication use, challenges, and health crises decline (Hibbard, Mahoney, Stock, & Tusler, 2007).

Nature of the Study

In this quantitative study, I analyzed secondary data from a quasi-experimental match-control study on older adults who had T2DM and associated comorbidities (Moore, Shartle, Faudskar, Matlin & Brennan, 2013). The original study population consisted of older adults (≥ 60 years) from a large employer group, with data collected from October 1, 2007 through November 12, 2008. Through the present study, I sought to evaluate the effectiveness of a pharmacist MTM program on medication adherence (as measured by a change in MPR) and medication complexity (as measured by change in MRCI scores) in one PBM's employer-based Medicare population. The archival data were obtained from a PBM, and multiple regression was used to test the hypotheses.

Definitions

Health literacy: "The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (IOM, 2004 p. 32).

Medication adherence: "The collaborative relationship between the patient (and or caregiver) and his or her health care providers, leading to the patient's or caregiver's medication behavior coinciding with medical advice" (MacLaughlin et al., 2005 p. 232).

Medication complexity: The number of drugs, dosage frequency, administration frequency, and the prescribed dosage forms that make up a patient's medication regimen (George et al., 2004).

Medication therapy management: "A distinct service or group of services that optimizes therapeutic outcomes for individual patients that is independent of, but can occur in conjunction with, the provision of a drug product" (APhA & NACD, 2005 p.3).

Patient-centered service: Health care providers who work one-on-one with patients to understand their perspectives, needs, and concerns regarding their medications (Oliveira, 2012).

Pharmacy benefit managers (PBM): "Third-party administrators responsible for administrating clinically based services that enable them to manage drug spending for their clients by improving price competition and increasing the cost-effectiveness of the medications covered under client plans" (PCMA, 2003 p.iii).

Self-management education programs: "Patient education in preventive and therapeutic health care activities, usually consisting of organized learning experiences designed to facilitate adoption of health-promoting behaviors" (Warsi, Wang, LaValley, Avorn, & Solomon, 2004 p. 1641)

Targeted population: "Beneficiaries who have multiple disease states (typically chronic conditions), use multiple Part D – covered medications, and are expected to research (and exceed) the spending limit for the year" (Siecker, 2010 p.2).

Assumptions

Several assumptions informed this study. I assumed that all the pharmacists used the same technique when reviewing the patients' medication records and lab values and assessing any initial primary drug therapy concerns. Differences in techniques used could influence the patient's decision to opt in to the program. Another assumption was the data entered into the PBM's database were accurate. An additional assumption was that all the individuals took their medications as reflected by the MPR scores from the original data. Finally, I assumed that there was no pattern to any missing information. Overt inaccuracies and a pattern of missing data could have biased the study results.

Scope and Delimitations

The scope of this study was dictated by the source of the archival data: one PBM's MTM pharmacist telephonic counseling service and related changes in medication adherence, complexity, and patient engagement collected from older diabetic patients from October 1, 2007 through November 12, 2008. For this study, the archival data from the PBM were delimited to adults 60 years and older who had a diagnosis of diabetes, were high-end prescription users, and have documentation in their patient profiles showing the absence of recommended therapy in treating diabetes or the presence of drug therapy contraindicated in the treatment of diabetes. High-end prescription users were identified as participants having 14 or more prescriptions within a 120-day period. Exclusionary delimitations were those participants with dual coverage from Medicare and Medicaid or without active prescriptions. This study was delimited to the examination of MTM counseling service on medication adherence and medication complexity, and I did not consider any association with health care costs, as Moore et al. (2013) covered their study. I measured medication adherence by using MPR ratios, and MRCI scores to measure medication complexity. The results of this study were intended to be generalizable to adults 60 years and older with T2DM.

Limitations

The most important limitation in this study was the use of archival data from a previous study of health care in a large PBM (Moore et al., 2013). Selection, quality, included variables, and the method of data collection were not under my control, and validation was not possible. The data set includes both intervention and control group. The control group was formed from patients who declined to participate in the opt-in MTM counseling service. Moore et al. (2013) used propensity scoring, matching the control to the intervention group on several characteristics: age, gender, baseline days supply of medications, baseline plan-paid pharmacy costs, physician visits, inpatient visits, outpatient visits, and number of pharmacy derived conditions. Another limitation was that individuals who chose to accept the invitation for the opt-in program might have been inherently different in some immeasurable characteristics that could have contributed to changes unrelated to pharmacist counseling. Lastly, the variable MRCI index was added to the data set and was not used by the pharmacists initially in the evaluation of patient profiles.

Significance

Medication complexity and medication nonadherence have been implicated in undermining effective chronic disease management. This, in turn, leads to poor medication management and increases in health service users. Medication nonadherence has been implicated as a major contributor to health care costs in the United States. Costs due to medication nonadherence and the ensuing morbidity and mortality are primarily borne by insurers, self-insured employers, and government agencies (Shrank, Porter, Jain, & Choudhry, 2009). Pharmacy benefit management MTM telephonic programs provide a unique opportunity to promote health by assisting patients to receive the appropriate medication and to adhere to their medication regimens.

Pollack et al. (2010) demonstrated that as the regimen complexity increases, medication adherence decreases, adding to disease burden in patients with T2DM. Identifying medication complexity was designed to provide PBM MTM pharmacists a more efficient approach to identifying high-risk patients. As a result, targeted interventions could improve adherence and achieve optimum outcomes in diabetes management, potentially reducing morbidity and mortality. Using medication complexity as an indicator to identify medication nonadherence may be a useful strategy for PBMs to reduce long-term costs and decrease downstream costs to payers. Pharmacy benefit management companies have a key opportunity to improve patient health care directly as many patients are under, over, or inappropriately prescribed medications for chronic conditions, which may lead to nonadherence.

Summary

For older adults, barriers such as treatment regimen factors (treatment complexity, side effects, and dosing schedule) are more difficult to traverse than other factors such as disease factors (symptom prominence and disease response), or environmental factors (lack of family and social support), adding to medication nonadherence (Ingersol & Cohen, 2008). Medication nonadherence could contribute to adverse events and reduce the patient's self-management of their chronic medical condition.

Medication therapy management programs, a product of MMA 2003, are designed to be distinct from other chronic disease programs and could be delivered face-to-face or via the telephone. Pharmacy benefit management companies are in an excellent position to delivers MTM programs, as these companies have the tools necessary to deliver prescription benefits while controlling prescription drug costs. Medication therapy management programs, part of the DM programs, is but one of the tools used by PBMs to control medication utilization and decrease health care costs. Medication therapy management programs use a comprehensive patient-centered approach in order to increase patient education on prescription medications, improve treatment regimen factors, increasing medication adherence and reduce adverse events.

This chapter contained an overview of the research objectives, theories, and detail of the specific research questions for this study. The aim of this study was to evaluate pharmacists run MTM telephonic services on medication nonadherence and patient engagement in the Medicare Part D beneficiaries. Descriptions of the nature and purpose of the study, study design, scope, limitations, and significance of the study were provided.

Chapter 2: Literature Review

Introduction

The purpose of this study was to assess a specific type of pharmacy benefits management's (PBM) disease management (DM) program service known as medication therapy management (MTM). The MTM pharmacist counseling program examined in this study was part of a PBM telephonic system for providing MTM services to Medicare recipients. Pharmacy benefit management MTM pharmacist counseling is based on increasing patient engagement and medication adherence to optimize therapeutic outcomes. The stages of change (SOC) model was used to guide the overall research framework.

This chapter discusses the current literature related MTM programs for older adults, and is divided into eight sections. The first section investigates the stages of change model of health behavior change and this theory's application to MTM programs. The second section examines literature pertinent to medication nonadherence. The third section provides the underpinnings of MTM and community pharmacists as related to increased patient engagement and medication adherence in targeted Medicare beneficiaries. The fourth section focuses on key elements of treating chronic diseases and its relationship to patient self-management and medication nonadherence. The fifth section provides background on PBMs and pharmacists' responsibilities for the various clinical services. The sixth section briefly examines the health care of older adults and provides the foundation of the Medicare Prescription Drug, Improvement, and Modernization Act 2003. The seventh section provides a description of Medicare Part D (prescription drug benefit portion of MMA 2003) and the offerings of MTM services to older adults. The eighth section examines MTM's pertinence to medication adherence. MTM use by PBM pharmacists is used to improve medication compliance and adherence in older adults. This service originated from the Medicare Modernization Act of 2003 and the Medicare Part D prescription drug benefit that began on January 1, 2006. At the time of this study, there was a limited body of peer-reviewed literature directly related to MTM delivered by PBM pharmacists using telephonic consulting modes.

Literature Search Strategy

The literature search for this study was conducted using several multidisciplinary databases available from Walden University. These databases included Academic Search Complete/Premier, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Health & Medical Complete, Medline, ProQuest Central, PubMed, Sage Premier, and Science Direct. The search primarily focused on articles published between 2004 and 2015; older articles were incorporated when deemed necessary. The search keywords included chronic disease management, health literacy, Medicare Modernization Act 2003, medication adherence, medication management, medication regimen complexity index, medication therapy management, pharmacist, pharmacy benefit management, self-efficacy, and telephone consulting. Multiple books, book chapters, and relevant articles were also consulted with a specific focus on the SOC model.

Theoretical Framework

Changing medical behaviors such as starting a new medication or continuing to take a maintenance medication can be daunting for many individuals. Medication nonadherence is a significant problem in the United States, especially for individuals with chronic disorders requiring maintenance medications, such as heart failure, diabetes, and HIV infection (ADA, 2013; Pratley & Gilbert, 2012). The reasons for intentional medication nonadherence are numerous (Doggrell, 2010; Lehane & McCarthy, 2006; Santhosh & Naveen, 2011). To improve medication adherence, the causes of nonadherence must be understood and addressed using numerous multifactorial strategies employed by health care professionals (Brown & Bussell, 2011). Ultimately, however, the degree of adherence depends on a patient's involvement in their own treatment decisions.

This study is guided by the SOC model, which was originally developed to guide research on how to quit smoking (Prochaska & DiClementi, 1983). The results from that research revealed that behavior change is gradual, continuous, and occurred in stages (Frankish, Lovato, & Poureslami, 2008; Prochaska & DeClemente, 1983). SOC theory was used by researchers in public health, health promotion, and addiction studies because the theory incorporated various processes and principles of change from leading psychotherapy theory (Ficke & Farris, 2005; Prochaska, Redding, & Evers, 2008). When applying SOC theory, a matched strategy to help the individual successfully use a new behavior is identified according to their state of readiness.

The core constructs of SOC are precontemplation, contemplation, preparation, action, maintenance, and termination (Prochaska, 2008). The theory's central premise is that individuals move through these stages as they initiate a new behavior, but that this movement is not necessarily in a linear fashion, as individuals may need several attempts before behavior change is achieved (Prochaska et al., 2008). As individuals move forward, individuals increase their self-efficacy in managing health decisions while adopting positive health behaviors (Wiley et al., 2000).

Studies have suggested that individuals' self-efficacy and decisional balance are major influences on medication and health care utilization (Hibbard, Mahoney, Stock, & Tusler, 2007; Johnson et al., 2006a; Johnson et al., 2006b). Self-efficacy comprises two interrelated components: self-confidence, the ability to make and sustain changes; and temptation, the impulse to relapse to a former stage (Johnson et al., 2006b). As the individual builds self-efficacy, the individual's decisional balance has a positive shift forward, propelling the individual to the next stage (Prochaska et al., 2008). Increasing self-efficacy is important to maintaining a new behavior.

Behavior results from the interaction of three distinct factors (also known as *triadic* factors), personal, behavior, and environment (Zimmerman, 1989). Self-efficacy is part of a self-regulatory process related to how individuals use and combine the triadic factors in an attempt to achieve a specific goal or behavior (Clark & Dodge, 1999). Drawing from personal factors (information and beliefs), environmental (e.g., advice from experts, role models) and one's own behavior to make a decision to attempt a new behavior (e.g., starting a new medication). If the trial of starting a new medication and outcomes are successful, then another attempt is made. Individuals with greater self-efficacy, have a greater likelihood of repeating new behaviors than individuals with lower self-efficacy (Clark & Dodge, 1999). Patients who maintain new behaviors are predicted to see an increase in self-efficacy and reduced symptoms of the disease.

A significant problem in effecting long-term change is that feelings of self-efficacy for some behaviors may diminish over time. This lack of self-efficacy may, in turn, translate into negative changes of behavior, health status, and self-medication management (Lorig & Holman, 2003), which are particularly prevalent in older adults with chronic diseases (Johnson et al., 2006a; Lee, Grace, & Taylor, 2006). Treating chronic diseases is limited by barriers that challenge older adults, reducing their self-efficacy and self-management, leading to nonadherent behavior (Lee, Grace, & Taylor, 2006). This study specifically investigated the effectiveness of pharmacists using telephone or face-to-face services to assist patients in overcoming these barriers to adherence.

In SOC theory's precontemplation stage, an individual has no serious thought about changing or initiating a new behavior. At this stage, an individual's self-efficacy and management skills are insufficient to initiate any behavior changes, rendering many individuals frustrated, or discouraged (Berger & Grimley, 1997). This lack of self-efficacy also manifests in a lack of individuals' awareness that they must be active participants in their own health care (Hibbard, Mahoney, Stock, & Tusler, 2007). There is a positive correlation between self-efficacy, management skills, and health care engagement (Barlow, Wright, Sheasby, Turner & Hainsworth, 2001; Hibbard, Mahoney, Stock, & Tusler, 2007).

In the contemplation stage, an individual gives serious thought to behavior change. Individuals at this stage are usually medication nonadherent because they lack a full understanding of their illness and the importance of their medication regimen, and may also be experiencing various types of barriers such as medication side effects, health beliefs, finances, and medication complexity (Hibbard et al., 2007; Konkle-Parker, 2001). Pharmacists may be instrumental moving the patient to the next stage by educating the patient and removing the environmental barriers.

Preparation is the stage where individuals may have taken some steps already by setting a date when to start their new medication. The individual's self-efficacy and self-management skills have improved but may not be sufficient to initiate a new behavior (Fick & Farris, 2005). Any nonadherence problem would be most likely unintentional. At this stage, pharmacists would encourage patients to associate taking their medication with a daily event or events (Fick & Harris, 2005). Success at this stage is seen when strategies are used to enhance commitment.

In the action stage, behavior change has taken place; however, individuals may become nonadherent because of unresolved issues because of the medication, or they may be experiencing other health problems (Fick & Harris, 2005). Individuals may lack necessary social or community support needed to continue the new behavior. Follow-up phone calls from a pharmacist to resolve any residue medications issues would assure the success of the patient to move to the next stage (Konkle-Parker, 2001). Therefore, any interventions in this stage should be geared toward supporting the new behavior.

In the maintenance and termination stage, the new behavior is now more than 6 months old and the individual has sufficient self-efficacy and management skills to continue without fear of relapse (Prochaska et al., 2008). In this stage, patients are consistently adherent to their medications. Pharmacists need to be vigilant concerning medication refill patterns and intervene as needed.

Konkle-Parker (2001) identified four different types of factors relating to medication adherence:

1. Medication related: medication side effects, regimen complexity, size and taste of medication, dietary restriction, and duration of treatment regimen.
2. Client related: health literacy level, health beliefs, health status, self-efficacy, and medication self-management.
3. Provider related: relationship with physician, appointment frequency, and communication skills with provider.
4. Environmental: finances, transportation, and social support.

Pharmacists' skills and interventions differ from one stage to another stage depending upon the medication adherence factors (Ficke & Farris, 2005; Konkle-Parker, 2001). In the precontemplation stage, the pharmacist experiences more client and provider related factors. In the contemplation, preparation, or action stage, the majority of factors are medication related and some client- or provider-related factors (Konkle-Parker, 2001). Improving adherence is difficult, and the key for the pharmacist is to move the individual one stage at a time for optimal success (Berger & Grimley, 1997; Prochaska et al., 2008). Patient's self-efficacy is improved when barriers to medication adherence are lessened or removed.

Medication Nonadherence

Medication adherence is one of the most intriguing and complex behaviors demonstrated by patients (Hughes, 2004). Adherence is influenced by many social and behavioral factors and is significant in influencing treatment outcomes (Brown & Bussell, 2011; Martin, Williams, Haskard, & DiMatteo, 2005). Poor adherence can render the best treatment ineffective and continues to be a source of frustration to health care professionals (Osterberg & Blaschke, 2005). Numerous efforts have been undertaken to change the current findings of medication adherence

Medication nonadherence is a widely acknowledged and a pervasive problem that involves all health care providers. A key to proper chronic disease management is being adherent; yet nonadherence is observed in approximately 50% to 55% of older adults (≥ 65 years) with chronic conditions (Doggrell, 2010; Lehane & McCarthy, 2006). This population is exemplified by multiple chronic conditions, requiring complex medication therapy and compounded by cognitive deficits, low health literacy, and inadequate oral and written communication skills (Hughes, 2004; Ngoh, 2009). Poor disease management may represent a greater risk for older adults due to multiple co-morbidities and medication complexity.

Although the terms compliance and adherence are often interchangeable compliance is associated with a more passive behavior where the individual agrees with the physician’s advice but the individual is not fully engaged with treatment (Osterberg & Blaschke, 2005). Being adherent, the individual is more actively engaged and in accord with the physician’s recommendations (Doggrell, 2010; Vermeire et al., 2001; WHO, 2003). Being adherent implies that there is cooperation and an established relationship between the health care team and patient (collaborative care). Adherent behavior for chronic diseases dictates self-management, an individual's ability to take prescribed medication appropriately, filling the prescribed medication, scheduling and attending follow-up appointments, and having the self-efficacy to manage therapeutic behaviors (Lorig & Holman, 2003;WHO, 2003). The focus of effective treatment adherence is based on not only actions of health professionals but equally and more importantly by the patients themselves. The more actively engaged patients are with their health care provider and in their own health care, the more successful they are in their self-management skills (Barlow et al., 2002; Hibbard & Cunningham, 2008). An adherent patient is actively engaged, making daily decisions that affect their health and costs (Hibbard & Greene, 2013). Ultimately, the level of adherence correlates with patient engagement.

Medication complexity has been implicated in undermining effective chronic disease management leading to poor medication management. Choudhry et al. (2011) studied the relationship of therapeutic complexity on adherence and chronic disease (e.g., cardiovascular disease). This large retrospective cohort study used data prescription claims from 1,827,395 patients. The mean age of the patient was 63 years. Therapeutic complexity was defined as the total number of prescriptions, number of fills for medications in different drug classes and for maintenance use, the number of physicians who wrote the prescriptions, the total number of pharmacies, and number of different pharmacies at which prescriptions were filled, the number of pharmacy visits, and the consolidation of these refills. The Choudhry et al. (2011) study results highlighted complexity but also implicated variables such as multiple trips to pharmacies and multiple physicians, which added to medication nonadherence.

Nonadherence is divided into intentional nonadherence (active and reasoned decision process) and unintentional nonadherence (passive process) (Lehane & McCarthy, 2006). Lehane and McCarthy (2006) identified unintentional medication nonadherence with three key factors: (a) drug (medication scheduling, drug regimen, drug side effects, and packaging); (b) patient (age and changing physiology, multiple comorbidities, cognitive ability, health literacy and personal beliefs); and (c) health-system (patient-provider relationship, medication access, and social support). Intentional nonadherence correlates to patients' beliefs in accepting or disregarding professional advice (Lehane & McCarthy, 2006). Unintentional and intentional factors are important when considering medication complexity and the influences over maintenance medication adherence.

From an economic standpoint, nonadherence to medication regimens can be costly, as poorly controlled chronic conditions can require additional medical therapy, increases in medical provider office visits, and nonscheduled hospitalizations resulting from drug-related adverse effects (Ho et al., 2006; Hughes, 2004; Mahoney, Ansell, Fleming, & Butterworth, 2008). The New England Healthcare Institute (2009) estimated that $290 billion per year or 13% of total health care is due to intentional and/or nonintentional medication nonadherence and $100 billion each year in excess hospitalizations.

Roebuck et al. (2011) compared medication adherence of four chronic disease states (heart failure, hypertension, T2DM, and dyslipidemia) to health care costs in a retrospective cohort study of 135,008 patients. The analysis included three measures of health services use: inpatient hospital days, emergency department visits, and outpatient physician visits. Across all conditions, there was a positive correlation between annual inpatient hospital days and adherence, ranging from six fewer days for older adults with heart failure to one fewer day for those with dyslipidemia. Finally, there was a reduction in emergency visits and increase in physician visits in the more adherent patients.

Medication nonadherence is a complex problem involving many factors; therefore, optimizing drug therapy outcomes needs a multipronged approach. Patient health outcomes have shown improvement when patients are encouraged to take a more active role in their health care (Coulter & Ellins, 2007). There is a positive correlation between increased patient's self-efficacy with treatment and medication management and use of services and cost (Evangelista & Shinnich, 2008; Osterberg & Blaschke, 2005). Collaborative drug therapy management by various health care providers (pharmacists, physicians, and other allied health professionals) in accordance with the patient became a viable solution to maximize the patient's health-related quality of life. The pharmacist would share the responsibility for patient outcomes. To assume this level of responsibility, the pharmacist's role needs to shift from purely pharmaceutical dispensing to more of a clinical role, where the pharmacist takes a more active role in drug monitoring, patient education, and counseling (Patwardhan, Duncan, Murphy, & Pegus, 2012). Pharmacists must now focus on patient and drug safety and develop relationships with other health care providers.

Pharmaceutical Care

Pressure from policy makers, along with other factors, influenced the pharmacy profession to undergo a number of substantial changes to increase the professions' responsibility to reduce preventable drug-related morbidity and mortality (Carmichael et al., 1997). During the 1990s both community and hospital pharmacists moved away from a more traditional pharmaceutical dispensing role to a pharmaceutical care model as drug-related problems (DRPs) were recognized as serious and urgent (Berenguer, LaCasa, de la Matta, & Martin-Calero, 2004; Chewning, 1997; Helper & Strand, 1990). This new model involved enhanced clinical skills of the pharmacist (drug therapy monitoring, patient counseling and drug information services) and increased patient engagement with their own care (Chewning, 1997). In the pharmaceutical care model, pharmacists provided services such drug therapy medication management: identifying problems, implementing solutions, monitoring outcomes. The desired outcomes were to optimize the benefits of an individual's pharmacotherapy and to improve the quality of life.

At this same time, policy makers included pharmaceutical care in the 1990 Omnibus Budget Reconciliation Act (OBRA 1990) (Fulda & Hass, 1992). OBRA 1990 was enacted to assist in reducing the U.S. federal budget deficit. OBRA 1990 also was instrumental in creating the Drug Utilization Review (DUR) boards (Fink, 2008). State specific, DUR boards managed drug purchasing and formulary decisions for programs such as Medicaid, injured workers, and state employee benefits (Fink, 2008). OBRA 1990 was also responsible for requiring pharmacists to counsel all patients receiving prescriptions. Pharmacists addressed items such as name of drug, intended use and therapeutic outcomes, side effects, proper storage, possible drug to drug or drug to food interactions, and any needed action in the case of a missed dose. Although originally designed to assist Medicaid recipients with understanding their medications, this act was quickly extended to all patients receiving prescriptions (Fink, 2008). OBRA 1990 was the government's comprehensive piece of legislation on medication process and drug and patient safety.

Another approach to preventing drug-related problems involves having pharmacists directly involved with monitoring drug treatments. In a community clinic and hospital settings, pharmacists monitored the effectiveness of medications by performing blood pressure, glucose, and cholesterol checks (Berenger et al., 2004). Studies have shown improved patient outcomes with chronic conditions such as heart disease, T2DM, hyperlipidemia when pharmacists increased patient engagement in their own health care (Bluml, McKenney, & Cziraky, 2000; Cranor, Bunting, & Christensen, 2003; Fischer et al., 2000). Fischer et al. (2000), using a quasi-experimental design, investigated if using pharmaceutical care services had beneficial effects on chronic diseases. The priori consisted of health management organization (HMO) enrollees (average age of 63 years) being treated for a chronic condition (asthma, COPD, or heart disease). The intervention group received pharmaceutical care with their prescriptions, and the control group did not receive this intervention. Pharmaceutical care consists of intensive counseling, education regarding medications, and regular monitoring. Fischer et al. (2000) demonstrated that pharmaceutical care increased self-medication management skills and awareness of medication side effects.

Community pharmacists were in an exceptional position to offer pharmaceutical care services. Community pharmacists could review prescriptions for age appropriateness, medical conditions, and concurrent medications. With their increased availability, pharmacists were available to counsel patients on medication, and stress the importance of medication adherence. Many times, it was the pharmacist who the patient saw last prior to their medication being taken. Although many pharmacists at the retail level openly embraced this new pharmaceutical care model (Berenguer et al., 2004) researchers have shown that pharmacist-patient communication interaction at the community level was less than optimal (Devraj & Gupchup, 2011; Flynn, Barker, Berger, Lloyd, & Brackett, 2009; Swarstad, Bultman, & Mount, 2004). Patient education is a vital intervention for older adults to be medication adherent.

Given the importance of providing clinical support to patients receiving medication, and that this may not be happening at the retail setting, telephonic communication could be a viable alternative venue for the pharmacist and the patient. Older adults are especially vulnerable to medication nonadherence when faced with a new diagnosis and medication treatment plan, and not being fully engaged in treatment (NCPIE, 2007). Disease progression with complications and decreased quality of life has been correlated with medication nonadherence (Hughes, 2004; Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011; Sokol, McGuigan, Verbtugge, & Epstein, 2005;

Yang et al., 2009). Telephone management by pharmacists was shown to be appropriate for many chronic conditions (Car & Sheikh, 2003; Dolder & Dolder, 2010; Rickles, Svarstad, Statz-Paynter, Taylor, & Kobak, 2005; Walker et al., 2011; Ward & Xu, 2011; Wu et al., 2006). In patients receiving antidepressant treatment where nonadherence is relatively high within the first 3 months, patient receiving telephonic support increased medication adherence and improved clinical outcomes (Rickles et al., 2005).

Hospital discharge can be stressful especially for the older adult, as the patient transitions to a new environment and then is expected to remember new medication instructions. In a study by Dudas, Bookwalter, Kerr, and Pantilat (2001), follow-up phone calls by pharmacists were shown to increase patient medication adherence. Chronic conditions such as diabetes and cardiovascular disease have better outcomes when treatment levels are at goal. Using telephonic interventions, pharmacists were successful in managing their patients and getting them to their stated goal (Dolder & Dolder, 2010; Walker et al., 2011). Phone-based settings may offer pharmacists and their patients a wider variety of opportunities to deliver pharmaceutical care.

Chronic Disease Management

As chronic diseases became the dominant leading causes of death, the distinct discipline and management of chronic diseases became a focus of public health (Davis, Wagner, & Groves, 2000). The treatment and management of chronic disease often changes over time according to fluctuations in patient symptoms and in the disease process. The key to managing chronic disease is to improve both short- and long-term health outcomes in the targeted population with the disease.

Chronic disease management is no longer treating chronic diseases as separate disease entities but rather is a team-based direct-patient care approach (Hibbard et al., 2007; Lorig & Holman, 2003; Norris, Glasgow, Engelgau, O'Conner, & McCulloch, 2003). Patients with chronic conditions make daily decisions concerning self-management (Lorig & Holman, 2003; Norris et al., 2003). For many, self-management is a life-long task. Clinical management of chronic disease shifted from a focus of primarily pharmacologic and technologic intervention, to include patient self-management behaviors and education with increased clinician-patient interactions (Norris et al., 2003). Pharmacists as members of a team-based approach for patient care saw success for meeting patient needs and improving health care quality.

Self-management programs, in conjunction with provider patient care, empower patients to solve personal health-related problems. The outcome is to increase quality of life while living with chronic disease. As members of a health care team, pharmacists are key to providing information on safe, effective, and optimal medication use (Carmichael et al., 1997; Patwardhan, Duncan, Murphy, & Pegus, 2012; Rodriguez de Bittner & Zaghab, 2011). In a collaborative care setting, the pharmacist and patient design health care decisions together, with the pharmacist assisting the patient with problem-solving skills to enhance self-efficacy and medication management (Bodenheimer, Lorig, Holman, & Grumbach, 2002). This collaborative approach would help assure that the patient needs would be met with improved health care quality. Using a pharmaceutical care practice, the pharmacist validates the patient-defined problems (Bodenheimer et al., 2002). Using multisite community pharmacies involving community pharmacists, Garrett and Bluml (2005) demonstrated that using consultations, clinical goal setting, monitoring, and collaborative drug therapy had significant improvements in diabetes management including improvement in reaching goals. Patients had increased satisfaction with their diabetes care provided by their pharmacists.

An example of a chronic disease that warrants close adherence to prescribed medications is T2DM. Type 2 Diabetes Mellitus is the seventh leading cause of death, with prevalence of 25.8 million people in the United States (Qaseem, Humphrey, Sweet, Starkey, & Shekelle, 2012). Type 2 Diabetes Mellitus can lead to long-term complications such as microvascular, macrovascular, and cardiovascular disease. Although medications have been shown to be efficacious in reducing short- and long-term effects of the disease, treatment goals are often not reached. Barriers leading to treatment goal failure are numerous, but complex medication regimens and convenience factors are prevalent for older adults (Nam, Chesla, Stotts, Kroon, & Jansen, 2011, Osterberg & Blaschke, 2005). Provider-defined problems versus patient-defined problems have also been implicated in medication nonadherence. For many patients it is more important to avoid the adverse effects of hypoglycemia caused from oral diabetic medications happening in the present than the possibility of kidney disease occurring in the future (Bodenheimer et al., 2002).

It is important to understand nonadherence from patients' point of view. It is through personal communication that patients' perceptions of treatment may radically differ from that of the prescriber (Grant et al., 2011; Ramalho-de Oliveira, Shoemaker, Ekstrand, & Alves, 2012). With diabetes, three main areas have been identified where patients' perceptions differed from those of the treating clinician and ADA guidelines (Grant et al., 2011; Ramalho-de Oliveira et al., 2012):

1. Medication initiation was viewed as a negative event as it reflected personal failure and an added burden.
2. Medication intensification was viewed as a risk factor for diabetes-related complication. Patients did not fully understand the disease process and progression.
3. Patients never voiced a concern regarding a delay in medication changes and/or additions. ADA recommends regular assessments and changes as needed (ADA, 2013). Most patients were focused only on the present and not the future. Patients however, favored individualized medication planning (Grant et al., 2011).

Type 2 Diabetes Mellitus treatment success depends upon medication adherence, self-monitoring of blood glucose, nutritional and physical therapy, and frequent laboratory and medical appointments (ADA, 2013). Pharmacy benefit management pharmacists have access to a variety of patient medical and laboratory data. The available data assists the pharmacist in looking for warning signs on poor treatment adherence. In the case of diabetes, indicators of poor treatment adherence may include blood glucose readings and blood pressure not at acceptable levels, erratic office visits, weight gain, and dietary and medication nonadherence (Dang, 2013). Patients with T2DM require a comprehensive treatment plan specially tailored to their needs, as treatment will vary from patient to patient (ADA, 2013). Pharmacy benefit manager pharmacists are in a perfect position through telephone consulting to use communication interventions to increase patient adherence and improve communication with a primary care provider.

There is no ideal method to improve medication adherence. Today's PBMs have innovative programs that plan sponsors can use to help maintain the overall health of company employees (Lawrence, Qu, & Briskin, 2012). Specific to this current study, T2DM is a chronic condition that is a focus of MTM programs used to educate customers. Currently, through personal communication with the patient, MTM pharmacists play a key role by creating personalized therapy that takes into account the patient's specific attitudes and concerns about their medication regimen, as well as their lifestyle factors (Lawrence et al., 2012.).

Pharmacy Benefit Managers

Pharmacy benefit managers are independent arms of many health plans whose function is to reduce health plan prescription-drug costs while maintaining high quality prescription-drug delivery and patient care (Lawrence et al., 2012). Pharmacy benefit management companies manage the prescription drug plans for health insurance issuers and plan sponsors (PCMA, 2003; Shrank et al., 2009). Pharmacy benefit managers create provider networks of pharmacies and inter-related services for the health plans. While some PBMs operate as independent entities selling PBM services to multiple types of health plans, other PBMs are wholly owned by the health plan (PCMA, 2003). Whether independent or owned, PBMs are one of the solutions to help curb with the rising healthcare costs.

When Congress voted to expand the Medicare drug benefit to include outpatient medication coverage, the overarching problem was how to pay, administer the benefits, and use cost containment measures (Huskamp, Rosenthal, Frank, & Newhouse, 2000). Congress received a number of different proposals with a common thread of allowing PBMs as the administering agent to employ a PBM model for these Medicare programs (Lawrence et al., 2012). Although the current PBMs were successful in reducing pharmacy costs and increasing net savings with Medicaid programs in various states, prescription drug costs are still on the rise (Lawrence et al., 2012).

Pharmacy benefit managers have not always been known for their clinical services but have been judged largely on their cost-saving methods (Mullins & Wang, 2002; Shrank et al., 2009). However, factors such as new expensive drugs, greater utilization of prescription drugs, the aging baby boom generation, and direct-to-consumer marketing all gave rise to increasing prescription drug prices (Garis, Clark, Siracuse, & Makoid, 2004). It was necessary for PBMs to design and integrate innovative programs that would address these issues.

In order to increase health outcomes and still continue to curb health care spending, PBMs needed to produce a more cost-effective pharmaceutical care system (Shrank et al., 2009). Pharmacy benefit managers underwent a clinical process redesign, integrating pharmaceutical care into clinical pharmacy services and medical services across locations (Mullins & Wand, 2002; Shrank et al., 2007). Studies have shown that multifactorial interventions that include better medication systems, education, and communication were more successful in improving medication adherence (Barlow et al., 2002; Chodosh et al., 2005; Inzucchi et al., 2012; Kripalani, Yao, & Haynes, 2007; Osterberg & Blaschke, 2005). With the use of electronic data, PBM MTM clinical pharmacists via the telephone can provide not only the essential counseling and patient education as mandated by the Centers for Medicare and Medicaid Services (CMS) but can also perform screenings and assessments (Moczygemba et al., 2008; Shrank et al., 2007). Essentially, electronic data have allowed pharmacists to assist patients with a variety of nonadherence issues and bridge patient-physician communication gaps.

Pharmaceutical care services, later known as DM services, expanded PBM pharmacists roles from mainly cost savings to covering safety, medication adherence, educational, behavioral, and informational resources leading to increased quality of care (Lawrence et al., 2012; PCMA, 2003). Clinical pharmacists proved to be well suited for medication management due to their expertise on medication use and specialized training on specific diseases (Sipkoff, 2007). Pharmacists running DM programs, including MTM programs, were proving to be successful in the treatment of chronic diseases and increasing therapeutic outcomes. By directly engaging the patient, PBM pharmacists could reduce any perceived barriers and increase adherence and health outcomes (Oladapo & Rascati, 2012; Shrank et al., 2009).

The Centers for Medicare and Medicaid Services allowed MTM services to be delivered via face-to-face interventions, telephone consultations, and educational mail campaigns. Feifer et al. (2010) found medication adherence increased when there was telephone support by a clinical pharmacist soon after filling with a new prescription. Pharmacists were able to identify and resolve medication-related problems, refer patients back to their medical provider for any new problems and fewer patients returned to the emergency room compared to the non-phone follow-up group (Feifer et al., 2010). Pharmacy benefit managers offering full services found that incorporating telephone MTM services could provide patient specific care resulting in improved health outcomes (Moczygemba et al., 2008). Medication therapy management services were effective in increasing patients self-management skills and medication adherence.

Health Care in the United States Prior to MMA 2003

Despite the positive contributions by the pharmacy profession over the years, there remained concerns about patient safety, drug therapy, and the quality of health care. Studies howed that the costs of adverse drug events (ADEs) exceeded the initial cost of medications (Ernst & Grizzle, 2001; Smith, 1993; Sullivan, Krelig, & Hazlet, 1990). ADEs, inappropriate medications, and medication nonadherence were responsible for increased rates of hospitalization (Brennan et al., 1991; Chutka, Takahashi, & Hoel, 2004; Fick, Nion, Beers, & Waller, 2008; Leape et al., 1991; Page & Ruscin, 2006). In a large retrospective study of 11,500 patients with diabetes mellitus, nonadherence accounted for 20% of the patients and was associated with elevated hemoglycolated blood levels, blood pressure and lipid blood levels. Nonadherent patients had significant risk for all-cause hospitalization and mortality (Ho et al., 2006a). Primary prevention is crucial in treating and preventing future adverse events in T2DM.

Inappropriate drug prescribing to older adults continued to be a major concern as it contributes to drug-related morbidity and mortality. Inappropriate medications are those considered ineffective, lack efficacy, and have the potential to exceed the medication benefits placing older adults at great risk for adverse events. In a retrospective small study of 390 patients, Page and Ruscin (2006) reported that 107 patients were prescribed an inappropriate drug, and 124 patients experienced ADEs. Fick et al. (2008), in a large retrospective study of approximately 18,000 older adults, identified 6,875 individuals (40%) with one inappropriate medication and 2,326 older adults (13%) with 2 or more inappropriate medications. The Fick et al. (2008) findings illustrated that inappropriate medication in the older adult can lead to ADEs, falls, and injuries, leading to a poorer quality of life.

Nonadherence can be due to skipping, reducing the dose, or not filling the prescription. In a 2-year time span prior to the enactment of MMA 2003, it was estimated that approximately two million Medicare beneficiaries were medication non-adherent due to cost (Mojtabal & Olfson, 2003). Medication nonadherence was highest among enrollees who had no or partial medication coverage. In a national survey of approximately 17,600 Medicare beneficiaries prior to the enactment of the Medicare drug benefit, 25% (4,400) of the enrollees reported medication nonadherence of one important medication due to cost (Safran et al., 2005; Soumerai et al., 2006). Approximately 50% (8,000) reported giving up basic necessities and groceries to be able to afford their medications (Safran et al., 2005).

Older age is significant as an independent variable for adverse drug reactions leading to hospital admissions. Older age is positively correlated to frailty, multiple comorbid conditions, and polypharmacy, leading to hospitalizations second to ADEs (Budnitz, Lovegrove, Shehab, & Richards, 2011). Gurwitz et al. (2003) examined the frequency of ADEs among 30,000 Medicare beneficiaries in an ambulatory setting. Amongst 1,523 identifiable ADEs, 421 (28%) were considered preventable, and 578 (38%) were identified and classified as serious, life threatening, or fatal. In a national surveillance of emergency department visits, older adults had the highest percentage of ADEs and second highest of ADEs leading to hospitalizations (Budnitz et al., 2006). Hospital admission was higher for individuals 75 years and older (11%) compared to individuals 65 years and older (26%) (Doggrell, 2010). Drug-related problems and ADEs are a prevalent problem seen in older adults with polypharmacy.

The overarching message from reviews of health care in the United States is that there were large gaps between those individuals who were receiving care and the care these individuals were receiving (McGlynn et al., 2003; Schuster, McGlynn, & Brook, 1998). Gaps in care were seen in all levels of care, from acute to preventative and chronic. Overall, individuals only received 50% of the recommended interventions that were involved in their care (McGlynn et al., 2003). For older adults, only 60% received the needed care for chronic conditions (McGlynn et al., 2003). It was estimated prior to 2003, that only 64% of older adults received the needed preventative vaccines, 38% received preventative cancer screenings and 25% did not have prescription drug coverage (McGlynn, et al., 2003; Schuster, McGlynn, & Brook, 1998; Steinbrook, 2002). The quality of medical care for the older adult falls short of acceptable levels for a variety of conditions important to this vulnerable subpopulation.

There were also a lack of structured programs and outpatient medical providers to provide assistance to older adults to help manage their medication regimens. This fragmented care led to increased chances for ADEs and poor adherence to treatment plans (Smith, Catellier, Conlisk, & Upchurch, 2006). It was evident to policy makers that newer approaches were needed to improve the quality of care and optimize health outcomes of all adults (IOM, 2000). The enactment of the MMA was a national milestone to improve health care and improve accessibility to prescription drug care to older adults and individuals living with disabilities (Smith, Catellier, Conlisk, & Upchurch, 2006).

The MMA of 2003

In 2002, the aggregate health care spending in the United States reached in all-time high of $1.6 trillion (Levit et al., 2004). Retail prescription drug sales accounted for the largest increase in health care spending, reaching approximately $163 billion (Levit et al., 2004). The current Medicare package did not include coverage for outpatient prescription costs, leaving older adults to garner continuously the resources needed to purchase medications and proper health care or do without some essentials (Mojtabel & Olfson, 2003).

In a landslide move by policy makers, the MMA brought Medicare beneficiaries health care and prescription benefits that would be consistent with those offered to working-age Americans (Mojtabel & Olfson, 2003). Initiated in 2006, older adults and individuals with disabilities could purchase a prescription drug plan (PDP) through a benefit designated as Part D (optional drug benefit for Medicare beneficiaries who remain in traditional Medicare Parts A or B) or as part of the Medicare Advantage program (Ma-PD) (i.e., managed care or private health plans) (Smith et al., 2006).

The new law also required the plan sponsors offering PDPs or Ma-PD to offer Medicare beneficiaries a new program called MTM. The CMS had expectations that MTM services would improve drug therapy and medication adherence while reducing prescription costs for older adults. Originally, CMS offered little guidance on the parameters of the MTM programs and did not mandate the involvement of a pharmacist; however, the CDC officially recognized the clinical experience of pharmacists as providers and that they receive compensation for MTM services (Centers for Medicare and Medicaid, 2005). Today, the vast majority of MTM programs use pharmacists to provide this service as pharmacists are the ideal health care professional based on their knowledge of drug therapy and accessibility to patients in the community (McGivney et al., 2007; Shoemaker & Hassol, 2011).

Disease Management Therapy

With the adoption of MMA in 2003, a voluntary (also called opt-in) prescription drug benefit program was offerred to all Medicare eligible recipients via the Medicare Part D program. To help with the perverse problem of ADEs and poor medication adherence in older adults at risk, MMA 2003 required that insurers provide an MTM program (Meyer & Cantwell, 2004). At-risk older adults are noted for numerouse chronic conditions, multiple medications, and physicians, leading to an increased risk for adverse events. For effective health care and positive outcomes for the patient, health information needs to be shared, and patient care must be a coordinated effort by all providers and the patient (Chodosh et al., 2005). The Centers for Medicare and Medicaid

Services required that MTM would be distinct from other currently offered programs (Pellegrino, Martin, Tilton, & Touchette, 2009). Medicatuion therapy management programs would be based on collaborative care and be patient centered.

Pharmacy practice at the retail level under OBRA 1990 required all pharmacists to counsel patients about their prescriptions (Fink, 2005). The inherent problems with OBRA 1990 were that the counseling represented a single event at the time of dispensing, the patient's history was not considered, and there was no follow-up by the pharmacist or other providers to to ensure patient adherence (Pellegrino et al., 2009). Essentially, patient counseling used to be a one-way conversation from pharmacist to patient, follow-up responsibility was placed upon the patient, and there was lack of patient engagement in their medication management. Pharmacists now need to use patient counseling as a tool to ensure that patients have the needed information to take a specific medication properly (McGivney, 2007).

Disease management programs were adopted by many organizations in the 1990s as patients with chronic diseases needed the coordinated efforts of various health care providors where patient-self efficacy and engagement was significant (McGivney et al., 2007). Many programs included physicians, nurses, nutritionists, and pharmacists. The key objectives of DM were to focus on a single specific disease, provide patient education, and increase patient self-efficacy and engagement in self care (McGivney et al., 2007). These programs were instrumental in meeting a variety of patient drug and disease specific needs. Pharmacist managed disease state programs included anticoagulation, hypertension, lipid, asthma, diabetes, and others. These programs were robust in meeting the patients disease stated goals, and decreasing hospital admissions and mortality (Chisholm-Burns et al., 2010; Chodosh et al., 2005). The success of these programs were due to the two-way conversations between pharmacist and patient and then follow-up to provider to create solutions to drug therapy problems. The main drawback to DM programs was that the provided tools and education were limited to that individual disease state.

Medication Therapy Management Services

The Centers for Medicare and Medicaid Services required three core outcomes to their new program: (a) optimize patient therapeutic outcomes, (b) improve medication adherence, and (c) detect and decrease ADEs and improper prescription medication use (Pellegrino et al., 2009). With limited outcomes available on MTM services and to encourage innovations and competition by pharmacy and other health care organizations, the CDC did not clearly define all MTM activities and service provisions to achieve these outcomes (Pellegrino et al., 2009). However, these services were to be developed as a collaborative effort between pharmacists and physicians. More than 25 leaders representing PBMs, health plans, health care organizations, and state and national pharmacies constructed a consensus definition of MTM services (Curtiss, 2005; Pellegrino et al., 2009).

Driven by the philosophy of pharmaceutical care, two major frameworks were developed from the consensus definition. The frameworks were viewed as a comprehensive drug-focused patient care service components for the pharmacist. Both

MTM frameworks incorporate patient counseling, motivational interviewing, patient assessment and education, documentation, and collaborative care (McGivney, 2007).

The American Pharmacist Association and the National Association of Chain Drug Stores Foundation developed a framework representing the community pharmacists. This platform focused on providing greater detail on the rationale and procedures for the core outcomes as specified by the CMS (Pellegrino et al., 2009). Operationally, this platform is for a face-to-face interaction; however, other routes (home-visits or telephonic) are acceptable.

The Academy of Managed Care Pharmacy (AMCP) developed a framework representing managed care and PBM pharmacies. This platform, focusing from an insurers' perspective, places greater detail on coordination of care, outcomes assessment, patient identification, and collaborative care with other heath care providers. Operationally, this platform is telephonic; however other routes (face-to-face or home-visits) are acceptable if supported by evidence (Pellegrino et al., 2009).

Medication therapy management service is distinct from the mandated counseling that occurs as a result of OBRA 1990 and is more comprehensive than DM programs. Specifically, MTM service has the following characteristics:

1. It is patient-centered rather than product-centered. The pharmacist considers each individual as unique, not only in how patients experience and understand their medical conditions, but also in their personal values and beliefs in regard to their care and treatment (Ramalho-de Oliveira, Shoemaker, Ekstrand, & Alves, 2012). Patients' medication adherence

improved with an increased understanding of their disease, and the perceived need for treatment and their medications (Maclaughlin et al., 2005). A patient's attitudes or concerns toward medication therapy will vary from patient to patient and are often the basis of drug therapy nonadherence. To resolve and prevent drug therapy problems, the pharmacist needs to comprehend the patient's medication experience. Only after understanding the patient's motivations and the root of their attitudes and decisions can the pharmacist assist the patient with the process of behavorial change, when warranted (Ramalho-de Oliveira et al., 2012). This is a key issue when treatment is targeted toward prophylaxis or asymptomatic treatment.

2. Pharmacists focus on the patients total medication experience and not just one from a particular disease state.
3. Pharmacist-patient communication empowers the patient and increases patient engagement in managing their own medications and health care (Sieckler, 2010). Low health literacy, self-efficacy, and medication complexity are factors that have been repeately recognized that impact medication adherence. Having low health literacy may impede a patient's ability to correctly intrepret their clinician's verbal and written instructions. Other studies have found that low health literacy was associated with an inability to read and comprehend prescription labels or correctly navigate through complex medication regimens (Cameron et al., 2010; Hughes, 2004;

MacLaughlin et al., 2005). Being medication adherent is more than just taking medication, but is a complex process for the patient and healthcare provider.

Service Delivery Mode

CMS did not specify regarding whether MTM should be provided face-to-face, telephonically, mailed interventions, or combinations (Pellegrino et al., 2009). Face-to-face MTM services may be performed at various different locations, as long as the medication evaluation can be conducted in a private area (Shoemaker & Hassol, 2011). Such MTM settings may include community pharmacy settings, ambulatory clinics, institutional pharmacy practice, private pharmacy consulting services, or other areas where there is a private area for the pharmacist-patient meeting (Shoemaker & Hassol, 2011). The Academy of Managed Care Pharmacy uses a combination of telephone and mail, where interventions are mailed to both patients and providers. As MTM programs have evolved, telephonic based services have increased in popularity as telephonic services could be provided in the privacy of the patient's home, provide patient-specific care and be more accessible to Medicare beneficiaries with travel logistic problems (Academy of Managed Care Pharmacy, 2008; Moczygemba, Barner, Gabrillo, & Godley, 2011; Shoemaker & Hassol, 2011). Medication Therapy Management telephonic services were an efficient solution for government and private insurers to reach MTM program eligible members.

While many community and clinic setting pharmacists found MTM rewarding, surveys identified challenges to the successful provisions of these services. These barriers have included time and staff management logistics, reimbursement issues (individual fee-for-service), patients' lack of interest, and lack of access to patient records (Dolor et al., 2012; Lounsbery, Green, Bennett, & Pedersen, 2009; McGivney et al., 2007; Oladapo & Rascati, 2012). According to CMS MTM guidelines, MTM services are considered as an administrative cost (Moczygemba et al., 2008). Health plans providing telephonic MTM services incorporate this cost into the Medicare Part D plan premium rather than having to bill for individual fee for service (Moczygemba et al., 2008). By incorporating administrative costs within the MTM program itself, government and health plans found a successful solution to reduce a barrier for MTM implementation.

Patients' Perceptions of Pharmacists as MTM Service Providers

The success of the MTM program was dependent upon two factors. The first factor was the new role of the pharmacist, from the traditional dispensing model to a clinician model. The second factor was the acceptance of the pharmacist in this new role by the patients and will the patients have the same trust (Hong, Liu, Wang, Brown, & White-Means, 2011; Moczgemba et al., 2010; Pellegrino et al., 2009). Patients have always viewed the community pharmacist in the more traditional dispensing role rather than in a clinical role (Law, Okamoto, & Brock, 2008).

Patients in general have found the pharmacist providing the MTM services as a useful resource, and the information and type of service very important (Hong et al., 2011; Moczgemba et al., 2010). Several researchers found a positive association in the patients belief that MTM services can improve their communication and relationship with the pharmacist and improve medication adherence (Doucette, Witry, Alkhateeb, Farris, & Urmie, 2007; Lauffenburger, Vu, Burkhart, Weinberger, & Roth, 2012; Law, Okamoto, & Brock, 2008; Truong, Layson-Wolf, Rodriguez de Bittner, Owen, & Haupt, 2009). Garcia et al. (2009) reported that patients did perceive some barriers to receiving MTM services at the retail level. Barriers included location, parking, time of day/ week, and fear that the recommendations may be contrary to their physicians plan of care (Garcia, Snyder, McGrath, Smith, & McGivney, 2009). As more private insurance companies and government turned to using a telephonic platform for MTM programs, many patient challenges were resolved.

Measuring Adherence

Never before has the American population included so many older adults using Medicare Part D drug benefits, increasing the importance of medications in the treatment of chronic diseases (Kaiser Family Foundation, 2010; NEHI, 2009). Nonadherence affects not only patients but also insurers, and employers as health care costs significantly increase because of disease related complications. The Congressional Budget Office (2010) predicted yearly expenditures on Medicare Part D medications would triple from $59 billion in 2010 to an expected $177 billion in 2020.

One of the most challenging elements of quality improvement is measuring the quality of care (Nau, 2009) and providing evidence whether prescription drugs provide net economic value to those who pay for health care (Sokol, McGuigan, Verbrugge, & Epstein, 2005). Adherence to medication is vital to quality health care and outcomes. Adherence can be measured in several ways, for example, surveying patients, direct observation method, measuring drug blood levels, or using electronic medication monitors (Osterberg & Blaschke, 2005). These direct methods can be labor intensive and costly, and can limit the number sample subjects (Hudson, Rahme, Richard, & Pilote, 2007). For large populations of patients, health service researchers and pharmacy PBM's use pharmacy retrospective databases (refill claims) to describe medication adherence and persistence in chronic diseases (Andrade, Kahler, Frech, & Chan, 2006; Choudhry et al., 2009). None of the methods for measuring adherence are considered as a gold standard (Hess, Raebel, Conner, & Malone, 2006). Two preferred methods of measuring adherence and persistence using pharmacy drug refill claims data are (a) medication possession ratio (MPR) and, (b) proportion of days covered (PDC) (Choudhry et al., 2009; Karve et al., 2008, 2009; Nau, 2012). Karve et al. (2008, 2009) found that MPR and PDC had the highest predictive validity for future hospitalizations and have formulas in which better adherence corresponds to higher values.

The MPR and PDC are ratios that reflect the proportion of days during a defined time period that a patient had possession of any of the drugs used to treat an illness. The MPR ratio is calculated by the sum of days of medication supplied within a defined time span divided by the number of days within that period (Nau, 2012). Although easy to calculate, this method has come under scrutiny for its propensity to overestimate the true rate of medication adherence as the numerator and denominator have been operationally defined in different ways (Peterson et al., 2007).

The PDC is a newer method of calculating adherence. Proportion of days covered, more operationally consistently defined, uses the number of fill dates and days' supply for each fill of a prescription (Nau, 2009). Yet PDC is more than a simple summation of the days' supplies (Nau, 2012). In a comparative study, PDC provided a more conservative estimate of adherence when patients were using dual therapy in a class of drugs or switched to another drug from the same class of drugs (Martin et al., 2009). This occurs frequently with antipsychotic and oral hypoglycemic medications.

Whether using MPR or PDC, the ratios are always between 0 and 1 and may be represented by a percentage (ratio multiplied by 100). A MPR or PDC percentage of ≥ 80% or ratio of ≥ 0.80 is the industry standard acceptance for adherence (Osterberg & Blaschke, 2005). Performance measures such as MPR or PDC, when used to report adherence rates of patients, the reported adherence rate reflects the percent of patients who achieved the acceptable industry standard of adherence to the target class of drugs (Nau, 2012).

Treatment adherence is key to better control of chronic conditions and is associated with decreased emergency department visits, and hospitalization rates with an overall decrease in morbidity and mortality (Roebuck, Liberman, Toyama, & Brennan, 2011; Yang et al., 2009). For patients with T2DM taking oral antidiabetic medications, antihypertensives, and statin medications, all cause-hospitalization rates were increased when adherence rates were < 80% (Ho et al., 2006; Yang et al., 2009). Lau and Nau (2004) found that diabetic patients with adherence rates ≤ 80% were at a higher risk for hospitalizations for the following year (odds ratio 2.53; 95% CI 1.38-4.64). In an observational study, Sokol et al. (2005) evaluated the relationships among medication adherence, medical utilization, and health care cost. The analysis covered four chronic disease states for which pharmacotherapy plays a key role in treating diabetes, hypertension, hyperlipidemia, and heart failure. Patients who maintained $\geq$ 80% medication adherence had the lowest rates for all cause hospitalization, which offset the higher medication costs (Roebuck et al., 2011; Yang et al., 2009).

Medication Therapy Management Outcomes

It has always been the responsibility of the physician to ensure appropriate treatment and medication adherence for their patients. With the rise of chronic diseases and resulting complex treatments, pharmacists are in a unique position to fill an important role in chronic care management (Patwardhan, Duncan, Murphy, & Pegus, 2012). Older adults are at increased risk for ADEs and medication errors due to a greater prevalence of chronic diseases, increased use of maintenance medications and greater dependency than younger individuals are (Institute of Medicine, 2000). Proper treatment of chronic diseases includes a variety of different modalities, including patient and life-style management and targeted pharmacotherapy taken consistently on a regular basis (Rodriguez de Bittner & Zaghab, 2011). Medication therapy management pharmacists are an excellent resource for medication related questions thereby helping patients to become more involved with their treatment decisions.

In a prospective cohort study, Brennan et al. (2012) used MTM service recommendations in concordance with both mail order and retail. Pharmacists assisted patients with medication adherence and the initiation of new medication orders. Patients received their medications from a retail location, mail order, or both. The PBM used information from both sources to develop interventions to improve medication adherence for the patient and encouraged the initiation of beneficial therapies. Patient visits and calls were documented, and all recommendations were forwarded to the patient's primary provider. The intervention improved patients' adherence rates and increased physicians initiation rates (Brennan et al., 2012).

The important issue Brennan et al. (2012) brought to focus is that physicians may erroneously assume that patients fill and take all prescribed medications. This problem may further be compounded when physicians make inappropriate medication and dosage changes leading to suboptimal health outcomes (Martin, Williams, Haskard, & DiMatteo, 2005). Thus, nonadherent patients may suffer from the lack of effective medications and risk further complications from the disease. Specific to this study, I focused on medication adherence.

Using a randomized controlled trial, Planas et al. (2009) evaluated a 9-month community-based MTM program on quality of care in hypertensive, T2DM patients. Clinical outcomes assessed were blood pressure and medication adherence. The intervention group received MTM services on a monthly basis. The intervention consisted of increasing patient engagement in diet, lifestyle modification, and medication management skills. The control group received counseling on blood pressure at 3, 6, and 9 months. All visits were documented and shared with the patient's primary physician. Adherence with medications used in the treatment of hypertension was determined using prescription claims data. At 9 months, the intervention group's systolic blood pressure (SBP) decreased by a mean of 17.32 mm Hg, and the control group SBP increased by 2.73 mm Hg. The mean adherence rate in the control group prior to the study was 79.5%

and at 9 months was 78.8%. The mean adherence rate of the intervention group prior to the study was 80.5% and increased to 87.5% at the end of the study. The intervention group was effective at improving blood pressure and increasing medication adherence (Planas, Crosby, Mitchell, & Farmer, 2009).

Planas et al. (2009) highlighted the importance of the MTM pharmacist as medication experts. The MTM pharmacists were successful in providing patient-centered care that resulted in medication adherence and better health outcomes. Planas et al. demonstrated the effectiveness of pharmacists in evaluating patient response to therapy, including safety and effectiveness. As the aging population and incidence of chronic disease increases, utilization of pharmacists as medication experts is significant to optimal healthcare delivery in the United States. In the current study, pharmacists as medication experts were utilized in conjunction with patients and/or their caregivers to promote the safe and effective use of medications and assist patients with medication adherence. The ADA (2013) has documented the growing societal burden of T2DM. Medication Therapy Management pharmacists are needed resources to aid patients with self-management education and support services to enhance patient understanding and appropriate use of medication.

Although the older adult represents only 13% of the population (USDHHS, 2010), the prevalence for drug-related problems is disproportionately large compared with younger individuals (Chutka, Takahashi, & Hoel, 2004). Drug-related problems are multifactorial arising most often due to the number of medications, fragmented systems of care, multiple co-morbidities, and the pharmacodynamic and pharmacokinetic changes seen in the older adult population (Fick et al., 2007). Older adults have more time that is difficult recuperating from acute insults such as ADEs as compared to younger adults (Hutchison, 2010). Multiple ADEs may lead to secondary fragility, increased disability and death (Hutchison, 2010). Budnitz et al. (2006) reported that 32% of hospital admissions were due to medications and drug interactions.

Moczygemba et al. (2011), in a quasi-experimental non-equivalent control group study, assessed the impact of pharmacist-provided telephone MTM on medication, and health-related problems (MHRPs), medication adherence, and Part D costs. The intervention group received the MTM service at the start of the study. The assessment of MHRPs in the control group was done using retrospective electronic chart review. MTM services consisted of a comprehensive medication therapy review, medication action plan and referrals. Action plans included MHRP recommendations regarding (a) medication or dose changes, (b) drug safety and efficacy, (c) preventative care; (d) medication education (individually tailored), and (e) cost/formulary interchange. All consultations were documented with follow-up to the patient's primary care providers. There were 4.8 MHRPs identified in the intervention group at baseline, and 2.5 unresolved MHRPs at the 6-month follow-up, a reduction of 48%. In the control group, 9.2 MHRPs were identified at baseline, with 7.9 unresolved MHRPs at follow-up, a reduction of 14%. The intervention and control groups had similar adherence rates at baseline, 67%, and 68%, respectively. At the 6 month, follow-up adherence rates remained unchanged at 67% and 70%, respectively. In the intervention group, the mean Part D drug cost decreased by $158.00 from baseline to 6-month follow-up and the control group increased by $118.00

from baseline to 6-month follow-up. Moczygemba et al. (2011) noted that more than one consultation and a longer follow-up period might have been necessary to determine differences in medication adherence.

The Moczygemba et al. (2011) study is important in demonstrating the success of a large private health plan using telephone and electronic medical records as an effective method to deliver MTM services. Specific to this study, the focus was on MTM pharmacists engaging patients to optimize therapeutic outcomes while promoting safe and cost-effective medications. Using electronic medical records MTM pharmacists are (a) able to evaluate patient medication adherence, and (b) assess whether medication use by the patient contributed to a MHRP or if medication had failed to achieve the desired outcome.

Moore et al. (2013), using a PBM medical claims database, researched the relationship of MTM services on plan-paid health care costs, utilization of medical services, overall days' supply of targeted medications, and changes in MPR for 5 different chronic diseases (asthma, depression, diabetes, dyslipidemia, and hypertension). This large retrospective study used a quasi-experimental pre- and post intervention design. Moore et al. studied the effect of MTM services on plan-paid health care costs, utilization of medical services, overall days of medication, and MPR. The program intervention consisted of three consultations with clinical pharmacists over a time span of one year to discuss drug therapy. The study found that the intervention group was effective in reducing health care costs across all five chronic disease states; however, only the conditions hypertension and dyslipidemia were statistically significant in increasing medication adherence.

Although the problems of medical complexity specifically were not addressed by the Moore et al. (2013) study, the results correlated with a previous study by Choudhry et al. (2011). Choudhry et al. concluded that as the number of medications an individual takes increases, the chance of medication nonadherence increases. T2DM is a complex, chronic disease because of the coexistence of other comorbidities (hypertension, dyslipidemia, heart failure, and/or depression). The treatment not only depends upon treating diabetes but the successful treatment of the comorbidities. The significance to the current study is the importance of the pharmacist to recognize disease and medication complexity as it relates to the patient and medication adherence.

Measuring Medication Complexity

Polypharmacy is correlated with older adults and women; however, researchers have found that age and gender do not contribute to medication complexity (Corsonello et al., 2009; Mansur, Weiss, & Beloosesky, 2012). George et al. (2004) asserted that when those who evaluate medications regimens for complexity should evaluate all the different variables of the regimen, just not the medication count. Different variables include number of medications, dosage frequency and administration, and the medication dosage form (George et al., 2004).

Until recently there was no industry standard to quantify medication complexity. To develop and validate the MRCI, information is used from medication charts, prescriptions, and from electronic databases (George et al., 2004). The tool comprises three sections; (a) information of dosage forms, (b) dosing frequency, and (c) additional directions. The complexity index is the summation of weighted scores from the three sections. The weightings are based upon the degree of difficulty. In Section A, tablets and capsules are the most convenient compared to other dosage forms (liquids, gargles, sublingual sprays/ tabs, ointment, inhalation etc.). Tablets and capsules are assigned a weight of 1; the other dosage forms are assigned a weight of 2 through 5. In Section B, a tablet or capsule taken once a day is used as the baseline (Weighting 1). Additional weighting of 0.5 was assigned for regimens that are administered at a fixed interval (twice a day versus every 12 hours). Section C includes additional instructions per the manufacturer or the physician (e.g., after or before meals, or at a specified time during the day). George et al. (2004) tested the tool on a 134 different medication regimens from patients who had moderate to severe, chronic obstructive pulmonary disease. This tool was shown to have an inter-rater and test-retest correlation reliability of ≥ 0.9 ($p < 0.001$) with respect to derived scores and expert panel rating medication regimen complexity (George et al., 2004).

Libby et al. (2013) modified the MRCI to include a patient level MRCI subtype. Many disease states include other comorbidities. Type 2 Diabetes Mellitus is often complicated with hypertension and hyperlipidemia. The patient level MRCI subtype includes disease-specific medications, other prescribed medications, and over-the-counter (OTC) medications. In their cross-sectional retrospective study, Libby et al. (a) compared patient-level MRCI scores across four chronic disease states (geriatric depression, hypertension, HIV and diabetes; and (b) examined the importance of disease specific medication, other prescribed medications, and OTC medications in relation to the total MRCI score. Geriatric depression had the highest total score, followed by HIV, diabetes and hypertension Libby et al. concluded that dosing frequency and other prescribed medications not related to the specific disease state heavily affected patient level scores. In managing chronic disease states, it is vital to consider all the medications that an individual takes and not just disease specific.

Conclusion

The studies reviewed in this section suggest that MTM services can lead to a reduction in overall health care expenditures through increased medication optimization and adherence and reduction in medication errors. Pharmacists today have an expanded role as clinical providers in assuming a professional responsibility for patient's medication therapy outcomes. The literature shows that pharmacist involvement in patient care improves medication adherence and treatment outcomes.

Proper treatment of chronic disease is dependent upon not only a health care system that recognizes the importance of the patient involvement in self-care; it also requires an extremely engaged patient (Remmers et al., 2009). A fully engaged patient has confidence and skills to promote personal health and to continue this behavior for the long term (Remmers et al., 2009). Studies show that supporting, teaching self-management, and self-efficacy skills for T2DM patients improve health with lower costs of care (Dixon, Hibbard, & Tusler, 2009; Remmers et al., 2009). Not all patients are on the same level of engagement, and as such, the pharmacists must tailor the patient intervention to meet the needs of the patient’s level (Dixon et al., 2009).

Chapter 3 provides an overview of the quantitative research study designed to bridge the gaps in literature on patient engagement and telephonic pharmacist run MTM service. Specifically, I will outline the techniques employed to explore the relationships between medication complexity, patient engagement, and medication adherence. This includes the study design, proposed research questions, a description of the sampling frame, and power calculations based on available sample size. I will also discuss the measures used to protect participants' rights and privacy.

Chapter 3: Research Method

Introduction

The purpose of this retrospective quantitative study was to examine the relationship of a pharmacy benefit management (PBM) company's medication therapy management (MTM) pharmacist telephonic consulting program. This program was designed to medication adherence and medication complexity for the selected PBM's Medicare Part D recipients. The study specifically analyzed the effectiveness of MTM pharmacist counseling as a means to improving medication adherence and compliance in an older adult population with type 2 Diabetes Mellitus (T2DM). The treatment of T2DM requires lifestyle modifications, pharmacotherapy, and frequent blood glucose monitoring. Achieving proper glycemic control requires education, motivation, and continuous support from health care professionals (ADA, 2013). Medication therapy management pharmacists are able to take an active role in patient education, provide counseling in proper medication use, and address any barriers to adherence in the treatment of T2DM.

This chapter details the research design and methods for this study, which analyzed a dataset consisting of PBM pharmacy claims data from a large, national employer prescription benefit plan in the United States. Within the research design and rationale section, I review each of the research questions and provide a rationale for using multiple regression and correlation to determine the relationship of receiving MTM pharmacist counseling on medication adherence and on medication complexity. The methodology section summarizes the study population, sample, and sampling procedures.

This includes the procedures for recruitment used by the PBM's researchers from the original study (Moore et al., 2013).

This discussion includes details on the predetermined sample size, my estimated power for the proposed analysis, and an explanation of the methods used in the power calculations. Next, I review the instrumentation used in the original study, including methods to improve reliability and validity and the methods used in merging the data and creating the variables used in this study. The data analysis section addresses the details of data review and cleaning, and describes the analytic methods in detail. In the final two sections, I discuss the threats to internal and external validity, including steps I took to minimize them, ethical procedures taken to gain access to the data, and procedures used to protect the data and participants.

Research Design and Rationale

This study used two primary research questions.

Research Question 1: Is there an association between receiving medication therapy management pharmacist telephonic support and medication complexity in Medicare Part D beneficiaries having T2DM as measured by a change in MRCI scores after controlling for comorbidities?

$H_{01:}$ There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

H_{A1}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

Research Question 2: Is there an association between receiving medication therapy management pharmacist telephonic support and medication adherence in Medicare Part D beneficiaries having T2DM as measured by a change in MPR percentages after controlling for MRCI scores?

H_{02}: There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

H_{A2}: There is statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

The first research question addressed if receiving MTM counseling has a relationship to medication complexity; the other, if receiving MTM counseling has a relationship to medication adherence. The goal of both questions was to determine an associated relationship between independent and dependent variables. To determine these relationships, participants were followed over time after an intervention has been imposed.

The use of a cohort study design was appropriate for this study because there was preexisting evidence to suggest an association between an intervention and outcome and the interval between the intervention and development of the outcome was relatively short to minimize loss to follow-up, in accordance with the suggestions of Carlson and Morrison (2009) and Issel and Handler (2009). Because cohort designs allow for data collection prior to the intervention, and due to the temporal nature of the design, cohort designs may be able to assess relationships (Carlson & Morrison, 2009; Issel & Handler, 2009).

Cohort studies are increasingly used in research as they combine elements of observation and experimental research methods, but have several distinct disadvantages. One is loss of participants to follow-up and the costs of maintaining contact during the evaluation follow-up (Carlson & Morrison, 2009; Issel & Handler, 2009). Loss due to attrition may have adverse consequences for design validity and the statistical conclusions (Carlson & Morrison, 2009; Issel & Handler, 2009). Another disadvantage is that there may be alternative explanations for the study results. It is important, therefore, to consider confounding factors when evaluating study results (Carlson & Morrison, 2009; Issel & Handler, 2009).

This research study used secondary data from health care claim records at a single PBM. There are several advantages to using secondary archival data. Doing so offers an economic approach and access to a larger data pool, and it may establish observations that may not have been present at the time of the original data collection (McKenzie, Neiger, & Thackeray, 2009). The secondary analysis of archival data also provides researchers with increased opportunities to develop new knowledge (McKenzie, Neiger, & Thackeray, 2009). Another advantage of using secondary data is that such data are more readily available than primary data. In contrast, a major disadvantage is that there is less control over data collection and data entry and one cannot determine firsthand the reliability and validity of the data (Issel & Handler, 2009). Another disadvantage is that secondary data may be several years old (Issel & Handler, 2009).

Methodology

Population

This secondary data analysis reused data from a study conducted by a PBM company in 2013 (Moore et al., 2013). Moore et al. (2013) used data from 4,500 high-risk members of a large employer group to examine the effectiveness of MTM on therapy adherence and clinical outcomes. All member participants in Moore et al.'s study had a diagnosis of asthma, depression, T2DM, hypertension, and/or hyperlipidemia. The current study used a subset of Moore et al.'s (2013) population, consisting of high-risk plan members 65 years and older who were recorded as having T2DM. The PBM study database used by Moore et al. provided eligibility information, pharmacy claims, and medical claims for the T2DM subset (n = 1,157), who were identified using the ICD-9 code of 250.x.

Power analysis. Statistical power depends on three classes of parameters: (a) the significance level (α), (b) the size of the sample used for the intervention, and (c) the effect size (f^2), the expected differences in the means between the control and interventional groups expressed in standard deviation units (Creswell, 2009).

Conventional set values for these three factors are usually set as $\alpha = 0.05$, power $(1-\beta) = 0.80$, and medium effect size $(f^2) = 0.15$. The power $(1-\beta)$ of a study, typically presented as high, medium, or low, denotes the beta error probability of falsely retaining an incorrect null hypothesis.

I conducted a post hoc power analysis because this was a secondary analysis of an already published study (Cohen, 1988; Faul, Erdfelder, Land, & Buchner, 2007). Post hoc power analysis was obtained using G*Power 3.1.2 (Faul et al., 2007). In a post hoc analysis, power is computed as a function of alpha, the population effect size, and the sample size used in the study. For this post hoc analysis, I used a small effect size ($f^2 = 0.02$, alpha = 0.05), and a sample size of 1,157. The post hoc analysis using multiple regression revealed that a sample size of 1,157 with two predictors and four predictors both achieved a power of 99%, a good threshold for power to avoid type II error (Faul et al., 2007).

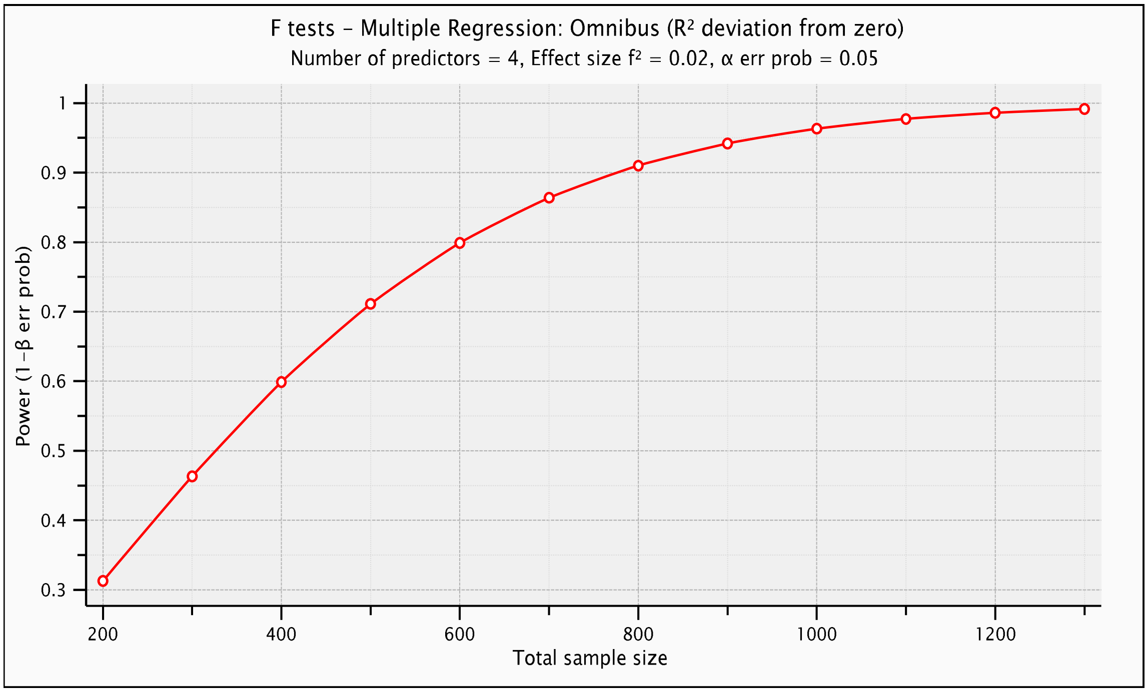

Figure 1. A graph showing the post hoc analysis distribution.

Sampling and Sampling Procedures

The target population for the original study was comprised of high-risk plan members, from a large nationally diverse managed care health (Moore et al., 2013). Plan members were considered high-risk if they

- were 18 years of age or older;
- were heavy prescription users (14 or more claims in a 3-month period); and
- had a pharmacy profile that showed the absence of a recommended treatment therapy or the presence of a conflicting treatment therapy in the treatment of conditions such as asthma, T2DM, hypertension, dyslipidemia, and/or depression.

Pharmacy benefit management MTM pharmacists identified a total 13,092 high-risk plan members between October 1, 2007, and November 12, 2008 (Moore et al., 2013). Plan members were excluded if they had dual coverage of Medicare and Medicaid or lacked medical plan payments *(n* = 8,723). After completing three pharmacy consultations with clinical pharmacists, 2,250 plan members enrolled in the program and 6,463 plan members declined. Plan members that declined during this period became part of a control group *(n* = 2,250). The original study consisted of 4,500 plan members. Propensity scoring was used to match the control group to the intervention group. The T2DM subgroup consisted of 1,157 plan members, 546 were in the intervention group, and 611 were in the control group.

Procedures for Data Collection

The collection of primary data using the high-risk plan members was performed prior to this study (Moore et al., 2013), and PBM pharmacy personnel handled all data entry. The PBMs pharmacy systems were responsible for quality assurance including checking data entry for errors. The original data are stored and saved on a directory in this PBM data environment. The data was not archived but saved as a data set.

I obtained the diabetes data set from this PBM after approval of my proposal by Walden University Institutional Review Board (IRB). All data requested from this PBM was required go through the mandatory Confidential Information Access Request (CIAR) process, the formal proposal in writing outlining the need for proprietary study data. After approval of my CIAR, I gained access to the data files from J. Moore, a member of the enterprise analytics department of this PBM and author of the pilot study (Moore et al., 2013). Prior to releasing the electronic files to me, Moore de-identified the data, removing all personal identifying markers (i.e., names, addresses, Social Security numbers, and plan member identification numbers). The CIAR document approval is located Appendix B.

Instrumentation and Operationalization of Constructs

Treatment complexity. All patients in the diabetes cohort were assigned a complexity score based upon an algorithm developed by George et al. (2004). The Medication Regimen Complexity Index (MRCI) is an instrument composed of 65-items used to quantify complexity of medication regimens and has been used in adherence studies (Libby et al., 2013; McDonald et al., 2013; Pollack et al., 2010). The MRCI was found to be valid with an inter-rater and test-retest reliability of ≥ 0.9 (George et al., 2004) and valid tool for quantifying the complexity of medication regimens (Libby et al., 2013; McDonald et al., 2013; Pollack et al., 2010). The instrument consists of three sections: (a) route of drug administration, (b) dosing frequency, and (c) additional directions. Additional directions are recommendations by the manufacturer product insert (Facts & Comparisons eAnswers, 2013) or physician, which a patient may need to follow in adhering to a prescribed regimen (e.g., at a specific time). The sum of the three sections contributes to the complexity index. This study used only those items in the MRCI that were applicable to oral and topical prescription medications. The MRCI was calculated from the drug database at baseline and then after the intervention. The significance of using the MRCI score was that it could be a useful tool in facilitating

MTM pharmacists in identifying patients who may have been at a higher risk medication nonadherence.

Calculating MRCI score. The original index includes the summation of weighted components of (a) dosage form, (b) dosing frequency, and (c) additional administration instructions (see Appendix A). For a patient taking medications, the minimum MRCI index score would be 1.5. This score represents a single tablet or capsule taken once daily as needed; the number increases with the number of medications.

Component A: Dosage form/route. Component A incorporates a weighting scheme for dosage forms (tablet/capsule vs. spray vs. drop vs. ampoule), and route of administration. Nasal sprays, oral or ophthalmic drops, and subcutaneous ampoules are considered more complex than tablets or capsules and are given a heavier weight. The MRCI developers provided weights for 32 different combinations. For this study, I only used items in the MRCI that were applicable to oral medications and topical patches pertinent to diabetes and associated comorbidities. Representative combinations are presented in Table 1 (alignment of PBM data to MRCI components). To tabulate Section A, a given form/route combination is counted only once within a regimen. For example if a patient takes two capsules and two tablets, the subset score for Section A is 1. However, if a patient takes two tablets and uses a nasal spray, then the patients' subset score for A is 3.

Component B: Dosing frequency. George et al. (2004) included 23 weights ranging from 0.5 for a once daily as needed up to 12.5 for medications that need to be taken or used every2 hrs. For this study, only dosing frequencies applicable to oral maintenance medications was used (see Table 1). Dosing frequency is tabulated to account for all medications. For example if the patient is taking two tablets and two capsules and all four medications are taken once a day, the Component B subset would be scored as 4. If a patient were taking two tablets each once a day and uses a nasal spray on alternate days, the Component B subset score would be 4.

While it may be helpful to identify a given medication and possible dosing frequency, this information does not provide specific dosing information for a specific individual. Frequency is not in automatic property linked with a manufacturer's identification number. For this study, drug dosing was calculated per the manufacturer’s suggested dosing and days’ supply of medication.

Component C: Additional directions. George et al. (2004) provided for 10 additional directions a patient may need to follow for a patient to be fully medication adherent (George et al., 2004). Special instructions were obtained from the patient message code that was linked to the drug identification number. Table 1 Component C represents examples and their assigned weights. A weight is given per each instruction per medication. For example, if a patient needs to take two capsules needed before breakfast and two tablets at bedtime, then Component C subset score is 4. The MRCI score for this patient would be the sum of section A (1) + B (4) + C (4) = 9. The higher the MRCI score of the medication regimen, the more complex the regimen becomes (Libby et al., 2013). For this study, the MRCI score was calculated at baseline than after the intervention.

Table 1

Alignment of PBM Data to MRCI Components

MRCI component A: form/route- weight			MRCI component B: dosing frequency- weight		MRCI component C: special instructions - weight	
Tablet/capsule	oral	1	Once a day	1	Break or Crush tablet or Do not break or crush	1
Liquids	oral	2	Twice a day	2	Multiple units at one time	1
Sublingual	oral	2	Three times a day	3	Take at specific times	1
			Four times a day	4	Take in relation to food	1
			On alternate days or less frequently	2	Variable dose	1
					Tapering or increasing the dose.	2
					Alternating the dose	2
					Take as directed	2

Note. Adapted from George, J., Phun, Y., Bailey, M. J., Kong, D., & Stewart, K.(2004). Development and validation of the medication regimen complexity index. *The Annals of Pharmacotherapy, 38*(24)1369-1376. doi:10.1345/aph.1D479
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Treatment adherence. The MPR, a measure of adherence, was calculated for each patient in the study for each oral medication that the patient used. Medication possession ratios were calculated from claims data as the sum of days during the year when the patient had the medication divided by the number of days in the year. The MPRs for each oral medication were then weighted by the percentage of time. An average composite score was computed for each patient. The value of the MPR ranges from 0 to 1. Patients were considered adherent if they obtained MPR score was ≥ 0.8

(80%) (Choudhry et al., 2009; Osterberg & Blaschke, 2005; Zhang et al., 2010). Medication possession ratios for this study were calculated at baseline and then after the intervention.

Study Variables and Covariates

Dependent Variable

The dependent variables were medication adherence and medication complexity. The medication possession ratio measures medication adherence, and changes in this ratio indicate whether individuals are more or less adherent to their medication regimens. Increased adherence with medication regimens lessens adverse events. The Medication Regimen Complexity Index (MRCI) measures medication complexity. Medication Regimen Complexity Index is a composite number that represents the complexity of an individual's medication regimen. Reducing the MRCI score represents a less complex medication regimen. Simplifying medication regimens increases medication adherence. Both the MRCI score and MPR ratios are measured before the intervention and then after the intervention. Medication adherence and medication complexity, their source, potential responses, and level of measurement are presented in Table 2.

Independent Variable

The MTM program is the intervention and the independent variable for this research. Medication therapy management programs essentially are to resolve and prevent drug therapy problems and increase medication adherence. The primary focus was the changes in MRCI scores and MPR ratios. Medication therapy management program source, potential response, and level of measurement are presented in Table 2.

Covariates

The covariate in this study included age, gender, and comorbidities. Studies (Doggrell, 2010; Lehane & McCarthy, 2006) have shown that age itself not necessarily influences medication nonadherence; however, poor disease management may represent a greater risk for older adults due to multiple co-morbidities and multiple medication use, leading to medication complexity. Polypharmacy correlates with increased ADEs, medication nonadherence, health-care costs, hospitalization, and mortality (Budnitz et al., 2011; Mansur et al., 2012).

Table 2

Study Variables

Variable Type	Variable Name	Level of Measurement	Potential Response	Source of data
Dependent	MPR±	Continuous	percentage	Calculated†
Dependent	MRCI*	Continuous	Range from 3-60	Calculated†
Independent	MTM** counseling program	Nominal	Yes/No	PBM claims database
Covariates	Age	Continuous	Age in years	PBM claims database
Covariates	Gender	Nominal	Male/Female	PBM claims database

† See discussion of calculations in instrumentation and operationalization
± Medication Possession Ratio, * Medication Regimen Complexity Index, **Medication Therapy Management

Data Analysis Plan

This was a quantitative secondary analysis of a cohort study on MTM pharmacist counseling program from a large PBM company on medication adherence and clinical outcomes on high-risk individuals (Moore et al., 2013). The primary study identified the target population from a national plan sponsor that covers employees, retirees, and dependents. Medication therapy management (MTM) pharmacists from the PBM stratified the target population into two groups, intervention, and control.

Descriptive statistics using SPSS v.21 described the patient characteristics. Each patient's age, number of medical conditions, number of medications and medication complexity were described as the means. Medication adherence was labeled as a percentage. I used a two-sided tail in all analysis and a *p*-value of less than or equal to 0.05 was considered statistically significant.

Analysis Plan for Research Question 1

I used correlation and multiple regression analysis to see if there was an association between receiving MTM pharmacist counseling (independent variable) and medication complexity (dependent variable) and to measure the strength of the relationships between both variables while controlling for age, gender, and comorbidities. The hypothesis was expressed as a *p*-value, the correlation coefficient r^2 described the strength of the relationship, and the regression line illustrated the relationship of the variables. The coefficient correlation can fall anywhere between -1 to 1. The closer the value of r^2 is to 1, the stronger the linear correlation. A value of 0 denotes little or no linear correlation. To test for the hypothesis, tstat = r/SEr, where SEr = $\sqrt{}$ 1- r^2/n - 2 degrees of freedom. Squaring r derives a statistic called the coefficient of determination (r^2), which quantifies the proportion of the variance in the dependent variable (medication complexity) explained by the independent variable (MTM pharmacist counseling). The *t*-stat is converted to a *p*-value. The hypothesis would rejected if $p <$ 0.05.

Analysis Plan for Research Question 2

I used correlation and multiple regression analysis to see if there was an association between receiving MTM pharmacist counseling (independent variable) and medication adherence (dependent variable) and to measure the strength of the relationships between the both variables while controlling for MRCI scores. The hypothesis was expressed as a *p*-value, the correlation coefficient r^2 described the strength of the relationship, and the regression line illustrates the relationship of the variables. The coefficient correlation can fall anywhere between -1 to 1. The closer the value of *r* is to 1, the stronger the linear correlation. A value of 0 denotes little or no linear correlation. To test for the hypothesis, tstat = r/SEr, where SEr= $\sqrt{}$ 1- r^2/n - 2 degrees of freedom. Squaring *r* derives a statistic called the coefficient of determination (r^2), which quantifies the proportion of the variance in the dependent variable (medication adherence) explained by the independent variable (MTM pharmacist counseling). The *t*-stat is converted to a *p*-value. The hypothesis would be rejected if $p < 0.05$.

Correlation and multiple regression are appropriate tests when there are continuous and a nominal variables, and to check if two variables are associated, without necessarily inferring a cause-and-effect relationship (McDonald, 2009). Assumptions using correlation and multiple regression are that there is normal distribution, equal variance (homoscedasticity), data will fit a straight line, and data points are independent of each other. I used the standard deviation as a measure of spread to test for homoscedasticity and a scatter plot to test for linearity. All analysis was done using SPSS v.21.

Threats to Validity

Internal Validity

The internal validity is the degree to which the study design accurately reflects whether the change that was measured can be attributed to the program. An important question of internal validity is whether the observed changes can be attributed to the intervention and not to other possible causes or alternative explanations (Trochim & Donnelly, 2008). A randomized experiment is the strongest in of designs in establishing relationships. Using a randomized control experiment was not feasible for this PBM. Quasi-experimental design studies do not possess the strength of randomized experiments for establishing evidence of program effect; however, quasi-experiments can provide moderate strength of program effect (Austin, 2011). Because of the lack of random assignment, extraneous confounding variables may negatively influence program effect. In quasi-experimental design studies, participant characteristics (e.g., age, gender, SES, industry, etc.) can influence selection bias (Austin, 2011). Propensity scoring allows for the mimicking of some of the characteristics (reduction or elimination of confounding effects) of a randomized controlled trial so that the effect of treatment on outcomes can be estimated directly between intervention and control groups (Austin, 2011).

In the original study by Moore et al. (2013), authors address the potential self-selected control group bias; Moore et al. used propensity score matching to match the control group to the intervention group. The pilot study focused on the impact on MTM on plan-paid health care costs, utilization of medical services, overall day's supply of targeted medications, and MPRs. The following characteristics were used: age, gender, baseline day's supply of medications, baseline plan-paid pharmacy costs and medical costs, physician and inpatient visits, and number of pharmacy-derived chronic disease states. Individuals for this study were not matched on specific disease states, such as depression or diabetes (Moore et al., 2013).

External Validity

Medication therapy management was created to be different from all other counseling program, as fully explained in Chapter 2. More specific, to be eligible, recipients must have multiple chronic diseases, must be on prescription medication covered under Medicare Part D drugs, and must be age 65 years and older. External validity is the extent to which the program can be expected to produce similar effects in other populations (McKenzie, Neiger, & Thackeray, 2009). The more tailored a program is to a particular population, the less likely the program can be generalized to other population and the greater the external validity. The present study focused on the Medicare eligible recipients who have T2DM only. To improve the validity of the study, the sample included participants from across the United Sates who were insured with this large employer prescription benefit plan.

Ethical Procedure Information

This study did not involve experimentation on human participants, and it was limited to retrospective review of secondary data collected during a previous study done by Moore et al. (2013). The PBMs analytic department coded each subject's information and removed names, Social Security numbers, insurance identification numbers, and other personal information from the electronic data file. With the approval of Walden's IRB, permission to access information, data review, and analysis, a formal Confidential Information Access Request (CIAR) was filed with the chief privacy officer of the PBM. All electronic information remains the property of the PBM. No personal information was used in describing the study and its results.

Summary

In this study, I used a quantitative approach of a secondary data source to examine the role of MTM pharmacists on medication complexity and adherence. I aimed to identify the relationship of receiving MTM pharmacist counseling on medication adherence and complexity in the older adult population. The study follow-up cohort was limited to participants who had been identified as high-risk members 65 years and older, had T2DM, and had belonged to a large employer group.

Chapter 3 provided the detailed methodology for this quantitative secondary data analysis. Using a cohort design, I used multiple regression and correlation to test the hypotheses that there may be a relationship in receiving MTM pharmacist counseling on medication adherence and complexity in older adults. Chapter 4 reports the summary of the results of this quantitative secondary data analysis that either supports or does not support the research hypothesis presented.

Chapter 4: Results

Introduction

The purpose of this quantitative study was to examine the relationship of a pharmacy benefit management (PBM) company's Medication Therapy Management (MTM) telephonic pharmacist-consulting program to medication adherence and medication complexity. It specifically examined this relationship with a group of Medicare Part D recipients serviced by a single PBM, using a secondary data set from a previously published study. As described in Chapter 3, multiple regression was used as the primary statistical analysis.

The results of my study revealed that there was not a statistically significant relationship between receiving MTM pharmacist support and medication complexity, and MTM pharmacist support and medication adherence. However, small in magnitude, there was a statistically significant association between comorbidities and medication complexity.

This chapter describes the analysis and results conducted to address the study's two research questions. The research questions and associated null hypothesis for this study were:

Research Question 1: Is there an association between receiving medication therapy management pharmacist telephonic support and medication complexity in Medicare Part D beneficiaries having T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities?

$H_{01:}$ There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

H_{A1}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

Research Question 2: Is there an association between receiving MTM pharmacist telephonic support and medication adherence in Medicare Part D beneficiaries having T2DM as measured by a change in MPR percentages after controlling for MRCI scores?

H_{02}: There is not a statistically significant association receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

H_{A2}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

Data Collection

This study used secondary archival data exclusively. After receiving approval from Walden's IRB (09-26-14-0088140) and obtaining approval through the PBM's

Confidential Information Access Request (CIAR) process, I acquired four datasets in Microsoft Excel format: PCare, GPI drug data, Pre-intervention GPI, and Post-intervention GPI. The four Excel datasets were downloaded by me from the PBM's secure transport system, converted to an SPSS format, and stored on an external hard drive.

The datasets contained the following information:

1. The PCare dataset contained the demographic information on the T2DM study population and the independent variable MPR.
2. The GPI Drug dataset contained the medications that the T2DM population were receiving or had received during the study period. Each medication record included the medication dosage form (tablet, ointment, creams, patches, intravenous and/or subcutaneous route), strength of each medication and any pertinent special instructions by the manufacturer. Not all medications have special instructions from manufacturers (see Appendix A).
3. The Preintervention GPI dataset contained the random ID numbers of the population, associated medications for each random ID, and days' supply of each medication prior to the intervention.
4. The Postintervention GPI dataset contained the same information as the Preintervention GPI database, but only for the period after the intervention.

Creation of New Variables, Total MRCI and Total Medication Count

The GPI Drug data set required the creation of two additional independent variables., which were labeled TMRCI and TMeds. These variables were created to explain medication complexity. In creating the TMRCI variable, as one of two of additional variables to the GPI Drug dataset, I deleted all the records that represented medications that were in liquid form, intravenous and subcutaneous route, creams, or ointments. From this modified version, I created a new variable TMRCI. In order to do this, I first created individual MRCI scores for each drug (Appendix A). Each MRCI score is the sum of three components (Component A + Component B + Component C).

- Component A (drug dosage form, tablet, capsule or patch) was weighted either as 1 or 2.
- Component B (drug dosing frequency) was weighted from 0.5 to 4 depending upon the manufacturer's recommended dosing.
- Component C (special instructions) was weighted from 0 to 3 depending upon the drug manufacturer's warnings and precautions. Some medications had more than one precaution leading to a higher score.

This modified data set was coded as Drug Data with MRCI. The individual MRCI scores were added to the pre- and postintervention GPI data set and the two new databases were coded as Preintervention MRCI and as Postintervention MRCI. From both of these datasets, I then computed a total MRCI (TMRCI) score and total medication count for each random ID record. The variables TMRCI and total medication count (TMeds) were created by summing up all the individual MRCI's and medications for each random ID record in the Preintervention MRCI and Postintervention MRCI datasets. These two new variables were added to the Pcare dataset.

Results

Descriptive Statistics of Participants

The study population consisted of the T2DM subset of a group of high-risk plan members aged 60 years and older and enrolled at a single PBM Company that provided data. All source data consisted of a secondary dataset from a previous study conducted by this PBM Company in 2013 (Moore et al., 2013). The extracted dataset used in the current study consisted of data that represented 1,158 participants. These data sets were first scrubbed for missing responses and extreme scores (outliers) that might affect the results of the statistical analyses. Three records were removed due to missing data (diabetic MPR change scores). In addition to identify outliers, the raw scores were converted to z scores where 0 was the mean and the standard deviation was 1. Scores that were higher or lower than 99% of the other scores (z = 3.29+/-) were considered extreme, resulting in the removal of the associated records. Six scores met this criterion. After screening, complete and nonoutlying data were available on 1,148 records (Intervention n = 543, Control n = 605).

For the T2DM study population, the ages ranged from a minimum of 60 years to a maximum of 97 years, with a mean age of 75 years and a median of 76 years. There were 301(49.8%) men and 304 (50.2%) women in the control group, and 258 (47.5 %) males and 285(52.5%) in the intervention group, which equaled 1,148 participants (Table 3). Table 4 illustrates comorbidity count between groups and genders. There were no statistical differences between gender with (p = 0.809). There was a statistical difference between the groups in comorbidity count of two or less (p = 0.028). The total number of medications per participant at baseline, ranged from 1–20, with a mean and median of eight. The differences between the groups were not statistically different (p = 0.33). Gender differences were not statistically different (p = 0.556).

Table 3

Demographic Characteristics of Study Participants

	Gender		
Study Group	Males	Females	Total
Control	*n* = 301	*n* = 304	*n* = 605
% within Study Group	49.8 %	50.2%	100%
Intervention	*n* = 258	*n* = 285	*n* = 543
% within Study Group	47.5%	52.5%	100%
Total	*n* = 589	*n* = 559	*n* = 1148
% within Study Group	48.7%	51.3%	100%

Table 4

Gender and Comorbidity Count Study Group Cross-tabulation

	Gender		Study Group		
Comorbidities	Male	Female	Control	Intervention	Total
2 or less Count	70	71	99	42	141
% within Comorbidities	49.6%	50.4%	70.2%	29.8%	100%
Group	12.5%	12.1%	16.4%	7.7%	12.3%
3 or more Count	489	518	506	501	1007
% within Comorbidities	48.6%	51.4%	50.2%	49.8%	100%
% within Gender	87.5%	87.9%	83.6%	92.3%	87.7%
Total	559	589	605	543	1148
% within Comorbidities	48.7%	51.3%	52.7%	47.3%	100%
% within Gender	100%	100%	100%	100%	100%

Analysis

Research Question 1: Is there an association between receiving medication therapy management pharmacist telephonic support and medication complexity in Medicare Part D beneficiaries having T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities?

$H_{01:}$ There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

H_{A1}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication complexity in the Medicare Part D beneficiaries with T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities.

The means and standard deviations for the MRCI raw scores are shown in Table 5. As observed, there was no statistical difference between the pre and post raw scores for the two groups. Further, for each participant, a change score was obtained which was the difference between pre- and postintervention. This difference could show no change in complexity, a decrease, or an increase in complexity. Here again, the two groups were not statistically different.

Table 5

*Descriptive Statistics for MRCI Raw Scores and Percent's for Direction of Change Scores for the Intervention Group (*n *= 543) and the Control Group (*n *= 605)*

					MRCI Complexity		
Group	Pre-MRCI		Post-MRCI		No Change	Decreased	Increased
	M	*SD*	*M*	*SD*	%	%	%
Intervention	23.03	8.42	22.84	7.98	16.2	41.5	42.3
Control	22.84	9.56	22.56	9.51	12.3	43.3	44.4

As described in Chapter 3, multiple regression was employed to examine the association between the MTM program and medication complexity after controlling for age, gender, and comorbidities. The descriptive statistics for these variables are provided in Table 6. For purposes of the regression analysis, the MRCI change score was designated as the dependent variable. Comorbidities, age, and gender were the independent variables and considered as covariates in the regression analysis. The differences between the mean change scores for the two groups as well as the covariates for the two groups were small and similar to Table 5. The change scores ranged from -24 to 36. Minus or negative scores reflected greater complexity on the post MRCI while positive change reflected less complexity. As such, the means for MRCI change indicate that, on average, both groups showed slightly less complexity on the MRCI post-intervention while their standard deviations indicate that there was wide variability within each group. Observation of the covariates also indicates that the groups were quite similar.

Table 6

*Descriptive Statistics for MRCI Change and Covariates for the Intervention Group (*n = *543) and Control Group (*n = *605)*

	MRCI change		Covariates							
			Comorbidities		Age		Male		Female	
Group	*M*	*SD*	*M*	*SD*	*M*	*SD*	*n*	%	*n*	%
Intervention	0.28	6.94	3.37	0.74	74.6	8.14	258	47.5	285	52.5
Control	0.20	6.36	3.25	0.82	75.7	8.08	301	49.8	304	50.2

Table 7 further describes the variables through their bivariate correlations with each other. Correlation and regression require the measures on each participant to be numerical. To meet this requirement group membership was coded as 0 (control group) and 1 (intervention group). Likewise, gender was coded as 0 (male) and 1(female).

Row 1 of the matrix is of most interest and informative. It shows that the dependent variable (MRCI Change) had near zero correlation with the primary independent variable of group (r = 0.01). Reading further across the row indicates zero and near zero correlations between MRCI Change for age and gender. While the correlation with comorbidities was statistically significant it was small in magnitude (r = 0.10, $p < 0.05$). The correlations thus support the previous descriptive statistics in Tables 5 and 6, which suggest that the association between group membership and MRCI Change would be small.

Table 7

Intercorrelations between MRCI Change, Group, and Covariates

Variable	MRCI Change	Group	Age	Gender	Comorbidities
MRCI Change	__	0.01	0.00	-0.02	0.10**
Group		__	-0.07**	0.02	0.08**
Covariates					
Age			__	-0.01	-0.06*
Gender				__	0.10**
Comorbidities					__

*p < 0.05, **p < 0.01.

Based on the descriptive statistics and correlations provided above, the expectation was that the regression analysis would not reveal additional information about the association between group membership and MRCI Change. However, it was felt that it would be useful to include it as part of this analysis. Hierarchical multiple regression was the procedure employed. In this approach, the variables were entered in steps where the primary independent variable is entered as the first step followed by the variables that are considered as covariates. As part of the procedure, the data were first examined for the assumptions underlying regression and no violations were found. Assumptions using correlation and linear regression are that there is normal distribution, equal variance (homoscedasticity), data will fit a straight line, and data points are independent of each other (McDonald, 2009). The 0.05 level of probability was used as the criterion for statistical significance.

Provided in the table are the standardized beta weights (β), the t-ratios, statistical probabilities (*p*), the multiple correlation (*R*). Whereas Table 7 provides the bivariate correlation (*r*) between each set of two variables, multiple correlation is the correlation when variables are combined together. Of interest in hierarchical regression is the change in the multiple correlation (*R*) as the variables are combined as the analysis proceeds from step-to-step.

For these data, there were four steps. The first step was the primary independent variable (group) and its association with the dependent variable, medication complexity (MRCI Change). Because it is the first step and just two variables (MRCI Change and Group), the multiple correlation ($R = 0.01$) is the same as the bivariate correlation in Table 7 ($r = 0.01$). Age was entered as Step 2 and contributed no change to R. This coincides with Table 7, which shows that there was no correlation between age and MRCI Change ($r = 0.00$). When gender is added in Step 3, the multiple correlation increased slightly ($R = 0.02$) since it is the combined relationship between MRCI, group, age, and gender. Comorbidities were entered as the final step and the multiple correlation increased from 0.02 to 0.10. The *t* and *p* columns indicated the statistical significance of

R. To be statistically significant *p* had to be 0.05 or less. The *p* value for $t = 3.44$ was 0.01 thus showing statistically significance beyond the 0.05 criterion.

The standardized beta weight (β) is useful in that from a prediction perspective the weights may be compared directly. Observation of the weights indicates that comorbidities would contribute nearly 10 times more weight in predicting medication complexity (MRCI Change) than any of the other variables.

In summary, for research question 1, no support was found for an association between MTM telephonic support and medication complexity as measured by a change in MRCI scores. Thus, the null hypothesis (H_{01}) was not rejected. The only association found was between comorbidities and medication complexity as measured by change in MRCI scores. While the relationship was statistically significant, it was small in magnitude.

Table 8

Hierarchical Regression Analysis Summary for Group and Covariates Predicting MRCI Change

Step and Variable	β	*t*	*p*	*R*
Step 1				
Group	0.01	0 .20	0.84	0.01
Covariates				
Step 2				
Age	0.00	0.11	0.92	0.00
Step 3				
Gender	-0.02	-0.50	0.62	0.02
Step 4				
Comorbidities	0.10	3.44	0.01	0.10

Research Question 2: Is there an association between receiving medication therapy management pharmacist telephonic support and medication adherence in Medicare Part D beneficiaries having T2DM as measured by a change in MPR percentages after controlling for MRCI scores?

H_{02}: There is not a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

H_{A2}: There is a statistically significant association between receiving medication therapy management pharmacist telephonic support and medication adherence in the Medicare Part D beneficiaries with T2DM as measured by a change in MPR percentages after controlling for MRCI scores.

The means and standard deviations for the variables used for this research question are shown in Table 9. The pre and postintervention means and standard deviations indicate small differences between the two groups for MPR. The Percent Change values indicate that there was some difference between the means with much greater variation within the intervention group as shown by the standard deviations. The MRCI means and standard deviations are the same as those in the previous research question. They are shown again here because the MRCI is used as the covariate.

Table 9

*Descriptive Statistics for Pre and Post-MPR, MPR Percent Chang, and the MRCI Covariate for the Intervention Group (*n *= 543) and Control Group (*n *= 605)*

	Pre-MPR		Post-MPR		% Change		Pre-MRCI	
Group	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Intervention	.77 *	.25	.78*	.27	.64	8.95	23.03	8.42
Control	.74*	.25	.73*	.29	.22	1.93	22.84	9.56

* Multiply ratio by 100 to equal percentage. 80% is considered adherent.

The correlations observed in Table 10 indicate small relationships between the three variables with the correlation between the medication adherence (MPR percent change) and group being near zero ($r = 0.03$). Although the correlation between medication complexity (Pre-MRCI) and medication adherence (MPR Percent Change) is statistically significant, it is small in size.

Table 10

Intercorrelations between MPR Percent Change, Group, and Covariate

Variable	MPR % Change	Group	Pre-MRCI
MPR Percent Change	__	0.03	0.05*
Group		__	0.01
Covariate Pre-MRCI			__

*$p < 0.05$.

Hierarchical regression was also used to examine research question 2. The results shown in Table 11 indicate no statistical support for an association between the MTM pharmacist telephonic support program and medication adherence as represented by the percentage change scores.

Table 11

Hierarchical Regression Analysis Summary for Group and Covariate Predicting MPR Percentage Change

Step and Variable	β	*t*	*p*	*R*
Step 1				
Group	0.03	1.11	0.27	0.03
Covariates				
Step 2	0.05	1.82	0.07	0.06

Summary

The study examined an MTM pharmacist telephonic consulting program and its relationship to medication complexity and adherence to medications. Regression analyses on post program complexity and adherence change scores showed no correlation between MTM telephonic pharmacist support and the reduction in complexity or an increase in adherence. However, regression analysis did show that comorbidities were influential in predicting medication complexity (MRCI Change) than any of the other variables.

In Chapter 5, I discuss the results presented in this chapter and interpret them in light of current theory and literature. I present the importance of these finding to this population, and MTM pharmacists and propose further research to validate these results and explore using MRCI score as a tool in greater depth as well recommend PBM MTM interventions to reduce medication complexity and increase medication adherence in the older adult with T2DM.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this quantitative study was to examine the relationship of a pharmacy benefit management (PBM) company's Medication Therapy Management (MTM) telephonic pharmacist-consulting program to medication adherence and medication complexity. It specifically examined this relationship with a group of Medicare Part D recipients serviced by a single PBM, using a secondary data set from a previously published study. The study controlled for age, gender, and comorbidities, and was designed to answer two primary research questions:

1) Is there an association between receiving medication therapy management pharmacist telephonic support and medication complexity in Medicare -D beneficiaries having T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities?
2) Is there an association between receiving medication therapy management pharmacist telephonic support and medication adherence in Medicare -D beneficiaries having T2DM as measured by a change in MPR percentages after controlling for MRCI scores?

This retrospective study used quantitative archival data from a PBM located in the Midwest region of the United States. Regression analysis tested whether there were changes in postprogram complexity and adherence by the MTM's pharmacist telephonic support; the overall findings showed no statistical correlation between MTM telephonic pharmacist support and the reduction in complexity or an increase in adherence.

However, regression analysis did show that after controlling for the covariates comorbidities, age, and gender, comorbidities significantly (p=0.01) predicted medication regimen complexity than age or gender. These findings suggested that in complex disease states such as Type 2 Diabetes Mellitus (T2DM), there is no statistical correlation between MTM pharmacist telephonic support and medication adherence.

Interpretation of the Findings

Type 2 Diabetes Mellitus is often considered a complex disease and is the seventh-leading cause of death and morbidity in the United States (ADA, 2013; Qaseem et al., 2012). Type 2 Diabetes Mellitus is the most common form of diabetes and its prevalence increases with age; at the time of the study, nearly 25% of the United States population older than 65 years had T2DM (Qaseem et al., 2012). If left untreated or poorly treated, the disease leads to microvascular (retinopathy, nephropathy, and neuropathy), and/or macrovascular (coronary artery disease, heart failure, cerebrovascular and peripheral vascular disease) complications (ADA, 2013; Qaseem et al., 2012).

Adherence is a key link in obtaining positive outcomes for medical care. Medication Possession Ratio percentages (ratios) in this study were used to represent medication adherence. This study used stages of change (SOC) theory as its theoretical foundation, which describes the stages of readiness, the decisional balances, and self-efficacy used by individuals in making a behavior change. These changes usually occur in stages, and are not always linear (Prochaska & DiClemente, 1983). Pharmacists are important in assisting patients with needed behavioral and medication regimen changes to maintain adherence to pharmacological treatment for improving the prognosis of T2DM (Rodriguez de Bittner & Zaghab, 2011; Viswanathan, 2012).

The study results showed that there was neither increase nor statistical decrease in medication adherence in the T2DM population. The treatment guidelines for treating T2DM are annually updated to promote better management of this population, and as such, treatment may becomes more complicated. T2DM treatment not only includes the medication for the disease itself, but also includes medications for preventative use for downstream complications and medications for the associated comorbidities that may be present (ADA, 2013). Many consultations with the patients and pharmacists end with new medications added to patients' already complex regimens due to the standard treatment guidelines for T2DM. For successful MTM consultations, pharmacists need to use combinations of skills that will assist patients with taking their medication and any new life-style changes into a patient's life. Adherence to prescribed medication is crucial to therapeutic success.

MTM Pharmacist Telephonic Support and Medication Complexity

Research Question 1: Is there an association between receiving medication therapy management pharmacist telephonic support and medication complexity in Medicare Part D beneficiaries having T2DM as measured by a change in MRCI scores after controlling for age, gender, and comorbidities?

Quantifying regimen complexity is a concept that was introduced in 2004 by George et al. (2004). Medication complexity is more than the amount of tablets that a patient takes; it is the summation of dosage forms, frequency of dosing, and additional usage instructions and varies from one medication to another (George et al., 2004, Libby et al., 2013). For example, Choudhry et al. (2011) showed that patients' making multiple pharmacy trips is a significant factor in therapeutic complexity. Medication complexity is strongly correlated with medication nonadherence (Choudhry et al., 2011; Corsonello et al., 2009; Libbey et al., 2013; Moore, Shartle, Faudskar, Matlin, & Brennan, 2013; Pollack et al., 2010). MRCI scores in this study represented medication complexity.

This research study used a standard protocol of evaluating patients medication regimens (see MTM services in Chapter 2); the results showed that there was no association between receiving MTM pharmacist telephonic support on reducing medication complexity (p= 0.84). The patient's medication regimens were not, however, simplified as a result of the MTM pharmacist consultation. This finding is consistent with other studies (George et al., 2004; Libby et al., 2013; Mansur et al., 2012) that found that it is very difficult for the pharmacist to quantify regimen complexity without using a reliable tool such as the MRCI index. When comparing two medication regimens with the same medication counts side by side, both regimens may look very similar, when in fact, they are not (Libby et al., 2013). The common practice of using a simple medication count ignores medication regimen complexity. This was evident in this study and its conclusion that complexity was not reduced as a result of the consultation by the pharmacist.

Comorbidities and Complexity

When controlling for covariates (age, gender, and comorbidities), age and gender were not statistically correlated (r=0.00, p=0.92; and r=0.02, p=0.62, respectively) with medication complexity. This finding is consistent with other studies (Corsonello et al., 2009; Mansur, Weiss, & Beloosesky, 2012). However, in the current study, results found that comorbidities were statistically correlated with medication complexity (r=0.10, p=0.01), although the strength of this correlation was weak. This finding adds to the earlier findings by Libby et al. (2011) that disease states such as T2DM, Geriatric Depression, and HIV are more complex in treatment. More than 45% of patients in the three cohort disease states in the present study were on more than 11 different medications, compared to 28% in the hypertension cohort. This group's mean MRCI scores ranged from 23–26, versus 18 in the hypertension cohort. Medications that were prescribed outside of the cohort-defining disease medications also contributed the most to the MRCI patient scores. The complexity of treating T2DM is that the treatment consists of the medications for the disease itself, plus treatment medications for the comorbidities that present due to the complications of the disease (ADA, 2012; Qaseem et al., 2012). These treatment regimens are often complex, intrusive, and inconvenient for the patient often-influencing medication adherence, as noted by Qaseem et al. (2012).

Intensive diabetes control includes using medications to control the diabetes itself, but also preventative medications to prevent diabetes-related complications (ADA, 2013). Nonadherence affects not only a patient's T2DM itself, but also any diabetes-related complications such as hypertension, heart disease, and kidney disease that they may also have (ADA, 2013). Treatment of diabetes thus presents clinical challenges to MTM pharmacists related to polypharmacy, prevalent symptoms, and complexity of care.

MTM Pharmacist Telephonic Support and Medication Adherence

Research Question 2: Is there an association between receiving medication therapy management pharmacist telephonic support and medication adherence in Medicare Part D beneficiaries having T2DM as measured by a change in MPR percentages after controlling for MRCI scores?

Medication adherence has been defined as the degree to which patients take their medications that have been prescribed to them by their health care providers (Osterberg & Blaschke, 2005). Adherence can vary across the different chronic illnesses, from minimal to very significant (Ingersoll & Cohen, 2008). Adherence was significant with less complex disease conditions such as hypertension or dyslipidemia as compared to more complex disease conditions such as T2DM, Geriatric depression or Asthma (Moore et al., 2013). Consequences of nonadherence or limited adherence to T2DM medical regimens may result in lack of glycemic control, with downstream increases seen in increased associated medical costs (Moore et al., 2013; Pollack, Chastek, Williams, & Moran, 2010).

There are two preferred methods used for measuring medications adherence, Medication Possession Ratio (MPR) and Proportion of Days Covered (PDC). For this study, I focused on the MPR. The MPR is a ratio that reflects the proportion of days during a defined period that a patient had possession of any of the drugs used to treat an illness (Choudhry et al., 2009; Karve et al., 2008; Karve et al., 2009; Nau, 2012).

When using MPR, the ratios are always between 0 and 1 and may be represented by a percentage (ratio multiplied by 100) and a ratio of ≥ 0.80 (80%) is the industry standard acceptance for adherence (Osterberg & Blaschke, 2005). The reported adherence rate reflects the percent of patients who achieved a high level of adherence to the target class of drugs. Adherence to a complex disease such as T2DM is difficult for older adults as the medication regimen is complex.

In my study, the base adherence (pre-treatment) mean ratios for the T2DM intervention group were 0.77 (77%), and T2DM control group were 0.74 (74%). The post-treatment mean ratio of the T2DM intervention group was 0.78 (78%) and control was 0.73 (73%). Results of my study showed that both the intervention and control group remained below the industry standard of acceptable adherence rate of 0.80 or 80% (Osterberg & Blaschke, 2005). Medication Therapy Management pharmacists may have improved patient outcomes in other arenas in patient care (problem solving, medication costs, etc.). However, patients remained vulnerable to possible adverse events of being non-adherent leading to increased risks for all cause hospitalization and mortality (Ho et al., 2006; Lau & Nau, 2004; Yang, 2009). Insurers, self-insured employers, and government agencies primarily will shoulder the increased medical costs and medications (Shrank, Porter, Jain, & Choudhry, 2009). The low adherence rates of the T2DM cohort in my study are consistent with existing literature representing complexity with this chronic disease (Choudhry et al., 2011; Corsonello et al., 2009; Pollack, Chastek, Williams, & Moran, 2010). The under recognition of medication nonadherence in older adults with T2DM can have adverse consequences and it is important that MTM pharmacists strive to improve adherence.

My study results found there was no significant difference between receiving MTM pharmacist counseling and medication adherence (*p*=0.36) even after controlling for medication complexity (*p*=0.07). This finding correlates with other studies that have compared regimen complexity with medication adherence (Moore et al., 2013; Pollack, Chastek, Williams & Moran, 2010). However, study results did identify a significant difference between medication adherence and medication complexity (*p*=0.034). Results of this study showed that with older adults T2DM, complex medication regimens influenced medication adherence. This result is important to PBM's and MTM pharmacists, when evaluating medication regimens. Complexity is an important factor to consider when trying to increase medication adherence. Multiple day dosing, complex instructions and multiple trips to the pharmacy have been implicated for the failure of completion of first fill or refills of prescriptions (Choudhry et al., 2011; Karter, et al., 2009; Ho et al., 2006). This study results highlight an essential aspect of the therapeutic cascade that may be burdensome to the patient. These results add to current literature in support of the importance of considering medication complexity on medication adherence especially in the T2DM population (Choudhry et al., 2011; Corsonello et al., 2009; Ingersoll & Cohen, 2008; Mansur, Weiss, & Beloosesky, 2012; Nam et al., 2011).

Current literature supports patient factors such as depressed economic status, and cognitive/physical impairment, are difficult modifiable correlates of nonadherence (Corsonello et al., 2009; Ingersoll & Cohen, 2008; Mansur, Weiss, & Beloosesky, 2012; Nam et al., 2011). However, polypharmacy, reducing adverse drug events and regimen complexity are to some extent modifiable correlate of the outcome (Choudhry et al., 2011; Corsonello et al., 2009; Ingersoll & Cohen, 2008; Mansur, Weiss, & Beloosesky, 2012; Nam et al., 2011). Despite the numerous studies that exist around medication nonadherence, some grey areas still exist in the understanding of all the factors involved in nonadherence in older adults. Medication Therapy Management pharmacists have the opportunity to work collectively with the physician and patient to offer solutions that will help increase medication adherence in this complex patient population.

Limitations of the Study

There were several limitations to this study:

- I used archival data from a previous study of health care in a large PBM. The selection, quality, included variables, and the method of data collection were not under my control and validation was not possible.
- Since the MRCI index score was used retrospectively and not prospectively, the MTM pharmacists did not use this tool when evaluating patient profiles for medication complexity. This may have influenced outcomes regarding reducing medication complexity and increasing medication adherence.
- Only records of oral maintenance medications pertinent to the disease itself, or to existing comorbidities, and preventive maintenance medications were considered for my study. I did not consider the use of other medications such as anti anxiety, sleep aids, and or as needed pain medications. Libby et al. (2013) tracked all the over the counter medications (OTCs) taken by the patients in this study. The addition of

OTCs, added another 12% to the total MRCI scores in the Diabetes Mellitus patient cohot.

Recommendations

This study represents a first step towards filling the information gap on research involving PBM MTM pharmacists in telephonic consulting roles on medication complexity and nonadherence. Although no statistically significant results were identified between the independent variable MTM pharmacist counseling program and the dependant variables medication adherence (MPR) and medication complexity (MRCI), a causational link between comorbidities and medication complexity could not be ruled out.

The results from research questions 1 and 2 contribute to existing knowledge of comorbidities adding to disease state complexity, and medication complexity, and their effects on medication adherence. Based on these results, it is important that PBM MTM pharmacists consider medication complexity and using a validated tool such as the MRCI index when evaluating complex medication regimens to increase medication adherence. Further studies are needed to evaluate the use of the MRCI index prospectively by PBM MTM pharmacists on medication adherence and medication complexity.

Implications

Implications for Social Change

The number of medications taken by older adult's increases with age and disease-related comorbidities carry a high risk of polypharmacy (Budnitz, Lovegrove, Shehab, & Richards, 2011; Corsenello, Pedone, Corica, & Incalzi; Mansur, Weiss, & Beloosesky, 2012). Polypharmacy among older adults with T2DM has been associated with poor adherence, increased risk of adverse events, leading to hospitalizations, emergency department visits, and all cause mortality (Chisholm-Burns et al., 2010; Congressional Budget, 2010; Doggrell, 2010; Moore et al., 2013; Roebuck et al., 2011; Yang et al., 2009). Medication complexity and nonadherence have negative effects on medication adherence and therepeutic outcomes which could undermine effective treatments in complex chronic diseases such as T2DM (Choudhry et al., 2011; Libby et al., 2013; Pollack, Chastek, Williams, & Moran, 2010).

Pharmacy Benefit Management MTM telephonic programs provide a unique opportunity to promote health by assisting patients to receive the appropriate medication and to adhere to their medication regimens. The MRCI index is a proven method of identifying medication complexity and would provide PBM MTM pharmacists a more efficient approach to identifying high-risk patients. This would allow for targeted interventions to improve adherence and achieve optimum outcomes in diabetes management, potentially reducing morbidity and mortality. Using medication complexity as an indicator to identify medication nonadherence may be a useful strategy for PBMs to reduce long-term costs and decrease downstream costs to insurance companies and patients (Congressional Budget, 2010; Lawrence et al., 2012; Shrank, Porter, Jain, & Choudhry, 2009).

Implications for Stages of Theory Change

This study strengthens the overall concept of the theory, as it relates to patient behavior. To improve medication adherence, the causes of nonadherence must be understood followed by different strategies by pharmacists in consulting patients on their medications. As the individual builds self-efficacy, the individual's decisional balance has a positive shift forward propelling the individual to the next stage (Prochaska et al., 2008). Increasing self-efficacy is important to maintaining a new behavior, such as being medication adherent. Pharmacists are instrumental in factors influencing adherence, including patient's comprehension of medication regimen and its benefits, potential side effects, and costs (Moczygemba, Barner, Gabrillo, & Godley, 2008; Moore et al., 2013; Patwardhan, Duncan, Murphy, & Pegus, 2012; Rodriguez de Bittner & Zaghab, 2011; Schnipper et al., 2006).

Recommendations for Practice

The results of my study, while not confirming statistically significance, suggest that there may be some merit in pursuing the use of the MRCI index as a valid tool for evaluating medication complexity as a means to increase medication adherence. The lack of statistical significance should not be interpreted to mean that MTM pharmacists were not effective in increasing medication adherence. This study showed that it was not demonstrable in this study. As was pointed out in Chapter 2, it is important to evaluate all the factors that influence medication nonadherence, including medication complexity (Ingersoll & Cohen, 2008; Libby et al., 2013; Mansur, Weiss, & Beloosesky, 2012; Pollack et al., 2010). When evaluating medication complexity, it is important to use a validated tool such as the MRCI index rather that medication count (George et al., 2004). These results should be presented to PBMs in hopes the it will spawn additional inquiry into using the MRCI index as a tool to assist MTM pharmacists when evaluating medication profiles for medication complexity.

Conclusion

For older adults, treatment of T2DM will require continuous medical care and patient self-management including using preventative strategies beyond glycemic control (ADA, 2013). Preventive strategies include cardiovascular disease risk management. Type 2 Diabetes Mellitus has been shown to be major risk factor for cardiovascular disease, increasing the risk for morbidity and mortality for these individuals (ADA, 2013). Treatment strategies include high blood pressure management, dyslipidemia/ lipid management and coronary heart disease prevention (ADA, 2013). The care of older adults with T2DM is complicated by their comorbidities and poly pharmacy. Pharmacists are integral in the ongoing patient self-management education. Pharmacists' support is critical to preventing acute and long-term complications.

Baseline data from this study indicate that the T2DM cohort were not medication adherent and are vulnerable to possible long-term complications. Pharmacy benefit managers and MTM pharmacists must consider not only the complications of the nonadherence to the individual but the increased downstream costs to the insurers, self-insured employers, and government agencies. There are many factors that influence medication nonadherence, medication complexity is a modifiable factor in medication nonadherence.

Healthcare plans and providers continue looking into ways to measure quality care that is being provided by healthcare delivery. Healthcare plans are now incorporating measures of quality in an effort to evalute themselves, how employers choose plans and consumers decide who provides their care (Seabury, Lakdawalla, Dougherty, Sullivan & Goldman, 2015). Medication adherence is an excellent entrant for quality measurement, for as medication adherence increases, regimen complexity and medical costs decrease, and clinical outcomes increase (Cutler & Everett, 2010; Seabury, Lakdawalla, Dougherty, Sullivan & Goldman, 2015; Viswanathan et al., 2012).

Concerted efforts need to be made to increase awareness to PBM's and MTM pharmacists involved with evaluating medication profiles the importance for evaluating medication complexity especially in complicated disease states such as T2DM. More prospective studies are needed using the MRCI index as a means to evaluate regimen complexity. Exploring this using a mixed study approach would be valuable for getting phamacists' perceptions about the use of the MRCI index when evaluating patient profiles.

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Appendix A: Medication Regimen Complexity Index Section

Dosage forms (A)		Weighting	Dosing Frequency (B)	Weighting
Oral	Capsules/Tablets	1	Once daily	1
	Gargles/Mouthwashes	2	Once daily as needed (prn)	0.5
	Gums/Lozenges	2	Twice daily	2
	Liquids	2	Twice daily prn	1
	Powders/ Granules	2	Three times daily	3
	Sublingual sprays/ tabs	2	Three times daily prn	1.5
Topical	Creams/ Gels/Ointments	2	Four times daily	4
	Dressings	3	Four times daily prn	2
	Patches	2	Every 12 hrs	2.5
	Sprays	1	Every 12 hrs prn	1.5
Ear, Eye & Nose	Ear drops/ creams/ ointments	3	Every 8 hrs	3.5
	Eye drops/gels/ointments	3	Every 8 hrs prn	2
	Nasal drops/ cream/ointment	3	Every 6 hrs	4.5
	Nasal spray	3	Every 6 hrs prn	2.5
Inhalation	Accuhalers	3	Every 4 hrs	6.5
	Metered dose inhalers	4	Every 4 hrs prn	3.5
	Nebulizer	5	Every 2 hrs	12.5
	Dry powder inhaler	3	Every 2 hrs prn	6.5
Others	Enemas	2		
	Injections: Prefilled	3	On alternate days or less frequently	2
	Injections: Vials	4		
	Suppositories/ Vaginal creams	2		
			Additional Directions (C)	Weighting
			Break/ crush/ dissolve	1
			Multiple units at one time (e.g. 2 tablets, 2 inhalations)	1
			Variable dose (e.g. 1 to 2 tablets, 2 or 3 inhalations	1
			Take at specific time/s (e.g. at bedtime, at noon)	1
			Relation to food (e.g. before or after meals, with a snack)	1
			Take as directed	2
			Tapering/increasing dose or alternating dose (1 tablet in the morning and 2 tablets at bedtime)	2

Note. Adapted from George et al., 2004.

Appendix B: Confidential Information Access Request

From: Kemper, DiAnne M.
To: Swift, Katherine
Subject: FW: CIAR# 4149665 Status Update - Request Approved
Date: Wednesday, January 07, 2015 2:18:48 PM
DiAnne Kemper | CVS Caremark | Advisor, Information Governance & Privacy, Legal | 480-391-4649 | 480-314-6905 | 9501 E Shea
Blvd, MC016, Scottsdale, AZ 85260 | dianne.kemper@cvscaremark.com

From: Information.Governance@CVSCaremark.com
[mailto:Information.Governance@CVSCaremark.com]
Sent: Tuesday, November 04, 2014 3:33 PM
To: Kemper, Dianne M.
Subject: CIAR# 4149665 Status Update - Request Approved
Information Governance and Privacy Operations
CIAR Team
A Confidential Information Access Request (CIAR) has been reviewed by the CIAR Team.
CIAR Record: 4149665
Project Name: Dissertation: Analysis of telephonic pharmacist counseling
This CIAR is now APPROVED.
Click on the hyperlink provided above to access the CIAR record.
Please contact Information.Governance@CVSCaremark.com if you have any questions.
This notification has been sent to:
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