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ASSESSEMENT OF HEALTH LITERACY AS A PART OF A UNIVERSITY MEDICATION THERAPY MANAGEMENT PROGRAM FOR PATIENTS WITH CHRONIC CONDITIONS

by

JASON T. RANGE

DISSERTATION

Submitted to the Graduate School

of Wayne State University

Detroit, Michigan

in partial fulfillment of the requirements

for the degree of

DOCTOR OF PHILOSOPHY

2011

MAJOR: CURRICULUM AND INSTRUCTION

Approved by:

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Advisor Date

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DEDICATION

To my husband Gary D. Butkus and
to the ever-present Carroll B. and
Katherene M. Range.

ACKNOWLEDGEMENTS

I remain deeply grateful to my dissertation committee for all of their individual and collective contributions. Many years ago, it was Dr. Marc Rosa who helped me identify what I wanted to do with the next chapter of my life; he lent a hand in guiding the way, offering opportunities to explore, providing a forum for hours of discussion. When it was evident that I wished to go into higher education, Dr. Sharon Elliot kindly took me under her wing. With her many years of experience in teaching, administration and grant making, Dr. Elliot asked at one point if I cared to share an office with her. It was one of the best things that I ever did. The time spent with Dr. Elliot provided me with an immeasurable opportunity to observe firsthand the many nuances of higher education. With her deep commitment to my success, it was Dr. Elliot who helped lay the foundation for my new career.

In finally deciding on health literacy as the topic for my dissertation, Dr. Feleta Wilson most graciously offered guidance on how to approach the study and the selection of the appropriate assessment instrument. Equally important, Dr. Wilson offered me a few life lessons along the way, and for that, I am most thankful. During this entire journey, it was my committee chair, Dr. Karen Tonso who offered unwavering support and guidance. Instinctively, she seemed to know what I needed at any given time. I extend to Dr. Tonso my heartfelt appreciation for all of her work in seeing me through.

I would also like to thank my colleagues at Butler University for their assistance in completing this study. Thank you to Dr. Carrie Maffeo, Dr. Priscilla Ryder, Susan MacLaren, John Mulvaney and Jason Humphrey. Finally, I would like to acknowledge the support of the Barry-Bashur Foundation of Michigan for its support of the MTM Health Literacy Project.

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CHAPTER 1: THE STUDY PROBLEM

Introduction

In 1993, the National Adult Literacy Survey reported that more than 40 million Americans were functionally illiterate, meaning that they could not perform the basic reading tasks necessary to function fully in society (Kirsch, Jungeblut, Jenkins, & Kolstad 1993). Although this survey did not include health-related items, these findings suggested that many Americans—approximately 43%—were unable to read and comprehend essential information they would likely encounter when seeking health care (Baker et al., 2002).

The 2003 National Adult Literacy Survey indicated that literacy rates in the United States remained much the same (Kutner, Greenberg, & Baer, 2006). Nearly 90 million adults—almost half of all adults in the country—lack the literacy skills needed to effectively function in the present U.S. health system (Nielsen-Bohlman, Panzer, & Kindig, 2004).

In its report entitled *Health Literacy: A Prescription to End Confusion*, the Institute of Medicine (Nielsen-Bohlman, et al., 2004) adopted Ratzan and Parkers' (2000) definition of health literacy as being "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health care decisions" (p. 2). In discussing health literacy, the Institute of Medicine emphasized that little attention is given to whether patients are able to comprehend their condition and treatment, to make the best decision for their care, and to take the correct medication in the right dose and at the right time. Increasingly, the healthcare system in the U.S. imposes complex demands on adults whereby they are asked to assume new roles in seeking out health information, understanding rights and responsibilities, and making healthcare decisions for

themselves and others. Underpinning these demands are assumptions about patients' abilities and skills (Nielsen-Bohlman, et al., 2004).

Today, many patients are living with chronic conditions that require ongoing proper use of medications. In fact, more than one in four Americans have multiple (two or more) concurrent chronic conditions, including asthma, diabetes mellitus, heart disease and hypertension (Anderson, 2010). To properly manage their chronic conditions, patients need to know why they need to take their medications, how their medications work and how to properly use or administer their medications. Studies have shown that patients with limited literacy have a poorer understanding of prescription medication names, indications for use, and instructions (Davis, Wolf, Bass, Tilson, et al., 2006; Kalichman, Ramachandran, & Catz, 1999; Wolf et al., 2005). Limited literacy also been associated with drug therapy problems (e.g. duplicate medications, adverse effects) and poor adherence by the patient to a particular drug therapy (Knapp-Dlugosz, 2008).

At the core of the pharmacy profession is the improvement of health outcomes through the proper use of medications (Brown, 2006). Pharmacists remain among the most accessible healthcare providers and can be one of the first healthcare providers to recognize that a patient has lower literacy (Youmans & Schillinger, 2003). As such, knowing the health literacy level of patients and the association of lower levels of literacy to health outcomes have become increasingly important to pharmacists. To adequately prepare future pharmacists, colleges of pharmacy should include training with regard to patient-centered approaches to health care, which include the relationships between literacy and health (Youmans & Schillinger, 2003).

Problem Statement

This study was undertaken as a step in furthering understanding the relationships between health literacy and specific variables in a population of persons taking medication for the chronic diseases of asthma, cardiovascular disease/hypertension, depression/anxiety and diabetes mellitus so that educational materials may be developed for pharmacy education.

In particular, this study was guided by the research question: Do the subject characteristics health literacy, gender, race, age, and levels of education influence clinical outcomes of patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety?

Purpose of the Study

The purpose of this study was to examine the extent to which health literacy is associated with different demographic factors (e.g. gender, race, educational level) and the extent to which health literacy is associated with clinical outcomes for patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety in a well-defined, self-insured university population.

The primary aim of this study was to test the hypothesis that limited health literacy, alone or in combination with other factors is associated with certain clinical outcomes of patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety. The findings of this study will be used in the development of educational materials for pharmacy education.

Aims and Hypotheses

As described more fully in Chapter 3, the research question was explored using the following aims and hypotheses:

1. To evaluate the association of health literacy with the following demographic factors: gender, race, age, and level of education.

   H_{1a}: Limited health literacy is associated with higher age and lower levels of education.

   H_{1b}: Limited health literacy is not associated with gender or race.

2. To evaluate the association of health literacy with clinical outcomes of patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety.

   H_{2a}: Limited health literacy is associated with clinical outcomes of asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety.

   H_{2b}: Limited health literacy is associated with higher body mass index (BMI), higher blood pressure, higher fasting blood glucose levels, and dyslipidemia.

   H_{2c}: Limited health literacy is associated with lower medication adherence.

   H_{2d}: Limited health literacy is associated with the need for patient education.

   H_{2e}: Limited health literacy is associated with sub-optimal medication regimens.

3. To construct a logistical regression model to determine independent predictors of health literacy from among the variables considered in research questions 1 and 2, above.

   H_3: Each of the following will independently predict health literacy: gender, race, age, level of education, health outcomes of asthma, diabetes mellitus, cardiovascular disease, and depression/anxiety, lower medication adherence, increased need for patient education, and sub-optimal medication regimens.

Data Sources

Relationships between the study variables: health literacy, and health outcomes of patients with asthma, diabetes mellitus, cardiovascular disease and depression, as well as potential co-variates of age, gender, race, and education level, will be tested using data

previously collected as a part of a university heath wellness Medication Therapy Management program.

Definition of Terms

To ensure consistency in the implementation and analysis of the study, key terms and study variables were defined as follows:

- *Adherence* is the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice (Meichenbaum & Turk, 1987). For this study, medication adherence was measured by patient interviews and the use of the Modified Morisky Scale (Morisky, Green, & Levine, 1986).
- *Asthma* is an inflammatory lung disease (Poureslami et al., 2007). Asthma is considered a common chronic disorder of the airways which is characterized by, among other things, recurring airflow obstruction (National Heart, 2007). For purposes of this study, asthma was determined by participants' self-report of being diagnosed with asthma. The level of asthma control was measured by the administration of the Asthma Control Test (QualityMetric Incorporated, 2002).
- *Body Mass Index* (BMI) is a ratio used to describe patient's weight based on patient's height. It is calculated by dividing a patient's weight by the patient's body surface area (height in meters squared). A BMI of 25.0-29.9 is considered overweight and a BMI of 30.0 or above suggests obesity and risk factor for diabetes mellitus and cardiovascular disease.

- *Cardiovascular disease* affects the heart and blood vessels. Cardiovascular disease includes hypertension and is associated with dyslipidemia. Control of cardiovascular disease was measured by measuring participants' blood pressure, BMI, and blood glucose levels.
- *Chronic illnesses* (or chronic diseases) are conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living (Warshaw, 2006).
- *Depression* is a mental state characterized by a pessimistic sense of inadequacy and a despondent lack of activity. Depression/ anxiety is often associated with chronic diseases including asthma, diabetes and cardiovascular disease. For purposes of this study, depression/anxiety was determined by participants' self-report of being diagnosed with depression or anxiety. The level of a patient's depression was measured by the Zung Self-Rating Depression Scale (Zung, 1965).
- *Dyslipidemia* is a condition marked by abnormal concentrations of lipids or lipoproteins in the blood. For purposes of this study, dyslipidemia was determined by participants' self-report of being diagnosed with dyslipidemia. The level of a patient's dyslipidemia was measured by the administration of a blood test measuring, in milligrams per deciliter (mg/dl): triglycerides, total cholesterol (TC), high density lipoprotein (HDL), and low density lipoprotein (LDL) cholesterol. Dyslipidemia is associated with diabetes mellitus and can lead to cardiovascular disease.

- *Diabetes mellitus* is a polygenic disease characterized by abnormally high glucose levels in the blood. For purposes of this study, diabetes mellitus was determined by participants' self-report of being diagnosed with type 1 or type 2 diabetes and/or the administration of a blood glucose test after the patient fasts for at least eight hours (a fasting blood glucose test). There are three levels of blood glucose: normal, pre-diabetic and diabetic. Patients with diabetes mellitus often also have cardiovascular diseases.
- *Functional health literacy* is a measure of a person's ability to perform basic reading and numeric tasks in the healthcare context, such as reading medication labels and insurance forms and performing mathematical tasks associated with taking medications (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999).
- *Health literacy* is the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions (Ratzan & Parker, 2000). For purposes of this study, health literacy was determined by the participants' score on The Newest Vital Sign (Weiss et al., 2005) and will be categorized as having adequate health literacy or limited health literacy.
- *Health outcomes* are changes in a patient's health status resulting from healthcare service. These include mortality (death), morbidity (increased or additional illness), functional status, and quality of life (Donabedian, 1978). Health outcomes also

include relief of symptoms, adverse drug interaction, medication adherence and the need for patient education (Mullins, Baldwin, & Perfetto, 1996).

- *Hypertension* is high blood pressure measured in systolic over diastolic blood pressure. For purposes of this study, hypertension was determined by participants' self-report of being diagnosed with hypertension and/or having abnormally high blood pressure. Hypertension is considered a cardiovascular disease and is often associated with diabetes mellitus.
- *Literacy level* is the assessment of grade level reading ability. It can be measured by instruments such as the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis et al., 1993). Ninth-grade reading ability and higher is considered standard literacy and eighth-grade reading ability and lower is considered low literacy.
- *Medication Education* for purposes of this study included the need for patient to receive guidance and/or training from a pharmacist on the following: proper use of medication, patient self-care, medication adherence, use of monitoring devices, disease state management and lifestyle changes.
- *Medication Therapy Management* (or MTM) describes the services provided by pharmacists to patients under which optimization of medication is used for the improvement of health outcomes. For purposes of this study, the *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model (version 2.0)* (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008) served as the basis of MTM discussions.

- *Sub-Optimal Medication Regimen* for purposes of this study included sub-optimal medication regimen included patients: needing additional drug information; having been prescribed medication(s) that were insufficient *or* excessive in dose or duration; having been prescribed medication(s) that are ineffective; needing more cost effective drug option(s); under using medication(s); receiving unnecessary drug therapy; having poor drug administration technique; using drugs excessively; requiring additional laboratory monitoring; for whom additional drug therapy is needed; and that have had adverse drug event(s).

Assumptions

The following assumptions were made for this study:

1. The Asthma Control Test is a valid and reliable instrument that measures a patient's control of asthma.

2. The Modified Morisky Scale is a valid and reliable instrument that accurately measures a patient's medication adherence.

3. The Newest Vital Sign is a valid and reliable instrument that accurately measures an individual's health literacy level.

4. The Zung Self-Rating Depression Scale is a valid and reliable instrument that accurately measures a patient's level of depression/anxiety.

5. The self-report items of age, years of education and race are accurate.

6. The self-report of being diagnosed with a particular disease(s) state is accurate.

Significance

This study sought to gain additional information on the complex relationships between the health literacy of patients with asthma, diabetes mellitus, cardiovascular disease and depression/anxiety, and patient variables including age, gender, race, and levels of education. Hundreds of studies have explored how patients' ability to read and comprehend healthcare information is associated with poor health outcomes (Wallace, 2010) and there have been pharmacist-led studies which have examined these same issues. However, there have been few pharmacist-led MTM studies that have included the assessment of the health literacy of patients. This study explores the relationship between the health literacy and the health outcomes of those patients with chronic diseases who took part in a MTM program administered as part of a university health wellness program.

CHAPTER 2: CONCEPTUAL FRAMEWORK AND LITERATURE REVIEW

Introduction

This chapter introduces the conceptual framework that was used to guide the construction of the study, including the Health Literacy Model and the Medication Therapy Management Service Model. After the discussion of these models, relevant research literature is presented on each of the study variables: health literacy, asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety. For the literature review, a comprehensive search of the literature was conducted using electronic search engines, electronic databases, reviews of bibliographies of published research and manual searches of journals and other publications. A graphic representation of the models used in this study will be presented.

Conceptual Framework

Although the significance of low functional literacy on health outcomes had been studied since the 1980s, it was not until 1995 that a landmark case highlighted the magnitude of this issue. The case showed that up to two-thirds of patients seen in public hospitals in the United States were unable to comprehend key health information on how to take medication or how to schedule a follow-up appointment (Wallace, 2010; Williams, Parker, Baker, & al, 1995). As a result of this study and those that followed, in 2004, the Institute of Medicine sought to document the problem of health literacy in the United States and to describe its origins, consequences, and solutions. As a result, *Health Literacy: A Prescription to End Confusion* was published (*Health literacy: A prescription to end confusion*, 2004). This

publication contained "Health Literacy Framework" and "Potential Intervention Points" (Figures 1 and 2, respectively).

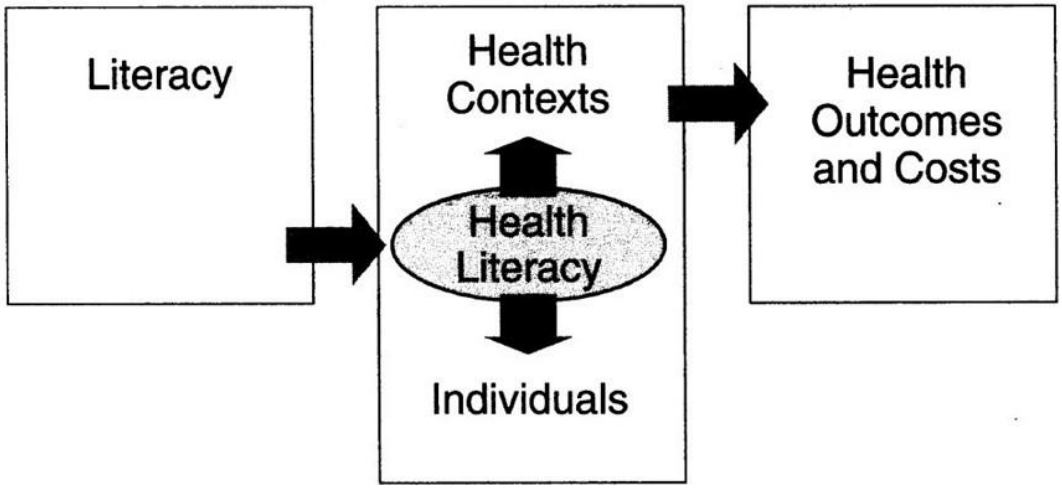

Figure 1. Health Literacy Framework
(*Health literacy: A prescription to end confusion*, 2004)

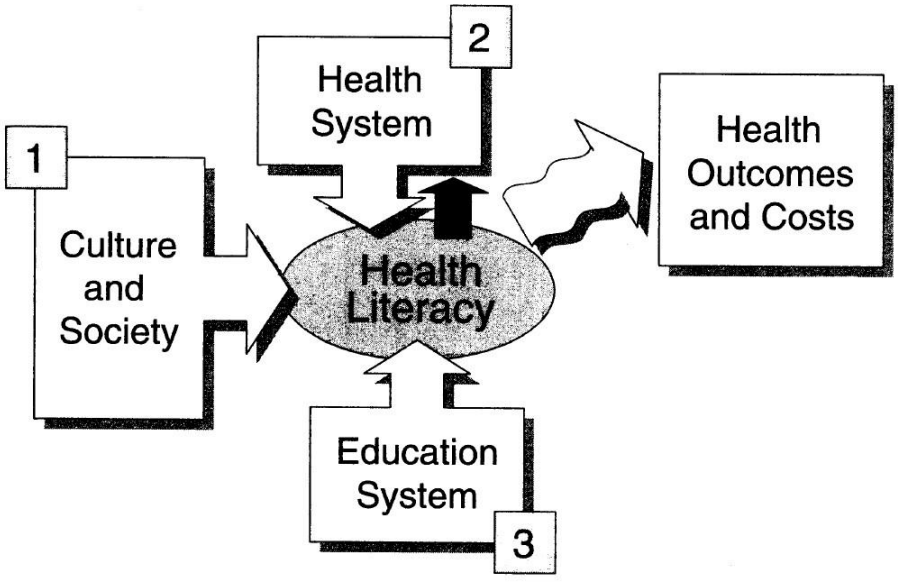

Figure 2. Potential Intervention Points
(*Health literacy: A prescription to end confusion*, 2004)

Figure 2 shows literacy as the foundation of health literacy and health literacy as the active mediator between individuals and health contexts (p. 32). Figure 2 illustrates the

potential influence on health literacy as individuals interact with educational systems, health systems, and cultural and social factors, and suggests that these factors could ultimately contribute to health outcomes and costs (p.4). Figure 2 also indentifies three major areas of potential intervention in effecting health literacy, namely culture and society, the health system and the educational system.

The Institute of Medicine suggests that the U.S. educational system offers a primary point of intervention in the improvement of literacy and health literacy (p. 142). In this section of the report, the committee includes recommendations for K−12 education, the adult education system, and education for health professionals. With regard to healthcare professionals, the committee recommends that professional schools in health fields, including schools of pharmacy, incorporate health literacy into their curricula and areas of competence (Recommendation 5-6, 2004, p. 161).

It is upon this basis that this study was undertaken; the results of this study will be used to formulate educational materials for pharmacy education in the areas of health literacy and the improvement of health outcomes for patients with chronic diseases.

Before discussing the literature related to health literacy and chronic conditions that are addressed in this study (i.e. asthma, diabetes mellitus, cardiovascular disease, and depression), a brief history of pharmacy education and Medication Therapy Management (MTM) is presented, along with a review of selected laws involving pharmacists and MTM.

Pharmacy Education in the United States

Historically, students in the United States wishing to become licensed pharmacists pursued baccalaureate degrees in pharmacy, generally through five-year programs. A student

could (and can) attend a stand-alone college of pharmacy or a school of pharmacy housed within a university. After decades of debate within the pharmacy community, in 1997, the educational requirements of pharmacy programs increased (Accreditation Council for Pharmacy Education, 2011). Beginning with 2005, those wishing to become licensed pharmacists must now complete a Doctor of Pharmacy (Pharm.D.) professional degree. Today, all pharmacy programs in the United States are professional doctorate programs.

Graduates who complete a Doctor of Pharmacy degree and wish to practice pharmacy in the United States must become licensed. They must sit for and pass the North American Pharmacist Licensure Examination (NAPLEX). State boards of pharmacy require licensure applicants from the United States to have graduated from an accredited Doctor of Pharmacy program to be eligible to sit for the NAPLEX.

In the United States, Pharm.D. programs are accredited through the Accreditation Council for Pharmacy Education (ACPE), founded in 1932 as the American Council on Pharmaceutical Education. ACPE is an autonomous and independent agency whose board of directors is appointed by the American Association of Colleges of Pharmacy, the American Pharmacists Association, the National Association of Boards of Pharmacy and the American Council on Education. ACPE's mission is "to assure and advance excellence in education for the profession of pharmacy"(preamble) (Accreditation Council for Pharmacy Education, 2011) in the United States, which it accomplishes, in great part, through its accreditation of U.S. schools of pharmacy.

In 2006, the ACPE revised its accreditation standards to include provisions mandating that schools of pharmacy include training in the patient-centered pharmaceutical care model

(Accreditation Council for Pharmacy Education, 2011). This was the result of a paradigm shift that had taken place in the profession as pharmacists sought to expand their roles past the "mundane counting and pouring, licking and sticking" (Higby, 2010) (p. 112). Pharmacy students are now trained to be drug information specialists and medication counselors. At the heart of being an effective medication counselor is the concept of patient-centered pharmaceutical care.

Pharmaceutical Care

According to the American Pharmacists Association, the definition of pharmaceutical care is:

> a patient-centered, outcomes oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient's other health care providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective.

Under this definition, pharmaceutical care is a form of pharmacy practice that is patient-centered rather than medication-centered. Pharmacists are required to accept responsibility as direct patient-care providers and enter into a more formalized relationship with their patients for the explicit purpose of improving patient outcomes (Cipolle, Strand, & Morley, 2004). This type of patient-centered pharmaceutical care often includes Medication Therapy Management services.

Medication Therapy Management

Academy of Managed Care Pharmacy (AMCP) has indicated that, for Medication Therapy Management (MTM) to be effective, several things must occur, including: the medication must be prescribed at the correct dose and the proper duration; the patient must get the prescription filled and must be adherent to the therapy; patients must be monitored to

ensure that the best health outcomes are achieved, that the objectives of the therapy are being met, and that adverse events are minimized; and patients must be properly educated and counseled.

This is especially true for patients who are at high risk as a result of chronic conditions and/or complex medication regimens. MTM services greatly enhance patient care, leading to improved overall health, while at the same time decreasing healthcare costs by reducing improper medication use, preventing adverse drug events and supporting therapeutic goals (Academy of Managed Care Pharmacy, 2006).

Pharmacist-led medication therapy reviews have shown to reduce the healthcare costs for diabetic patients, including the reduction in physician visits and emergency department visits (Cranor, Bunting, & Christensen, 2003; Garrett & Bulmi, 2005). Medication therapy reviews have also shown to reduce asthma-related emergency room/hospital visits and changes in asthma-related costs over time (Bunting & Cranor, 2006).

In 2004, eleven pharmacy organizations including the American Pharmacists Association (APhA), the American Association of Colleges of Pharmacy, and the National Association of Boards of Pharmacy achieved a consensus definition of MTM services as a distinct service or group of services that optimize therapeutic outcomes for individual patients (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2005). Building on this consensus definition, the APhA and the National Association of Chain Drug Stores Foundation developed a model framework for implementing effective MTM services in a community pharmacy setting. This service model was later revised and memorialized in *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service*

Model Version 2.0. (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008).

The MTM service model in pharmacy practice 2.0 includes these five core elements:

- Medication therapy review
- Personal medication record
- Medication-related action plan
- Intervention and/or referral
- Documentation and follow-up

A diagram of the MTM Service Model is presented in Figure 3 below. The "Medication Therapy Review" element of the model has been highlighted as this is the area of inquiry of this study.

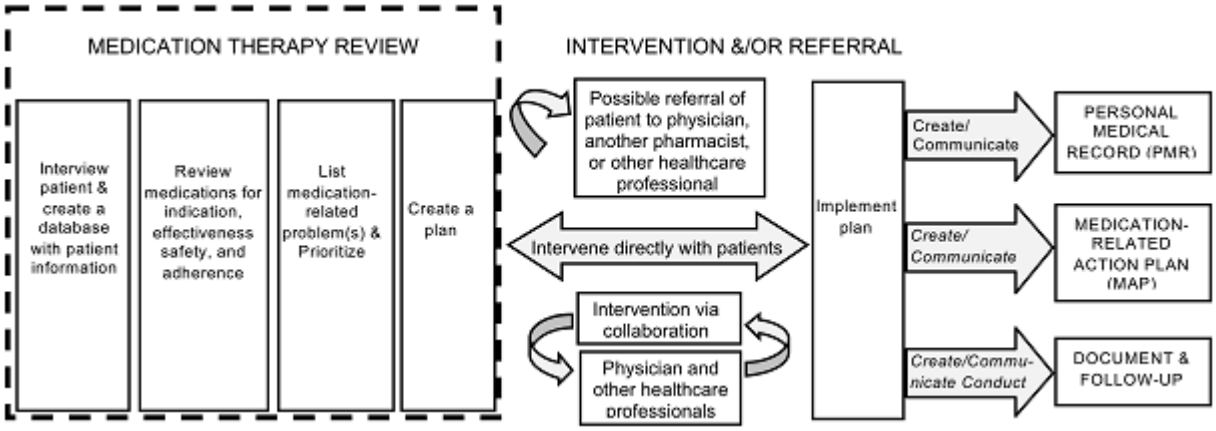

Figure 3. The Medication Therapy Management Core Elements Service Model (American Pharmacists Association and The National Chain of Drug Stores Foundation, 2008)

A "Medication Therapy Review" includes a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve

them (p.344). The APhA and the National Association of Chain Drug Stores Foundation suggest that medication therapy reviews include interviewing the patient to gather data including demographic information, general health and activity status, medication history, and patient's thoughts or feelings about his or her conditions and medication use (including medication adherence) (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008).

Additionally, as part of a medication therapy review, assessing a patient's health literacy level (Brown, 2006)—the education level of the patient, language differences, and other characteristics of patient's communication ability that could affect health outcomes—proves important. This is especially true for patients with chronic diseases such as asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety which were the subjects of this inquiry.

Laws associated with MTM services

An impetus for these organizations to develop a recognized model of MTM services was the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This act, among other things, established Medicare Part D, which provides prescription drug coverage for Medicare beneficiaries (seniors and persons receiving Social Security Disability Insurance) through prescription drug plans. According to this law, all Part D plans must have a MTM program (section 1860-4[c][1][2]). MTM programs target Medicare beneficiaries who have multiple chronic diseases, are taking multiple drugs covered under Part D, and are likely to incur annual drug cost exceeding a certain level (differs by year). The Centers for Medicare and Medicaid Services (CMS) now require that all such MTM programs include an annual

medication review, a person-to-person consultation (face-to-face or by telephone) and a written summary ("Pharmacy educators utilize key partnerships to provide patient care," 2010).

This act also created unprecedented opportunity for pharmacists as the first federal law specifically authorizing direct payment of pharmacists for MTM services, without being "incident to" the services of a physician. In other words, pharmacist can now directly bill for MTM services under their own set of billing codes (Hogue & Bluml, 2009). This recognizes the valuable role that pharmacists play in improving the health outcomes of patients, especially when it comes to MTM services.

MTM and pharmacy education

These same opportunities provide challenges for pharmacy education. MTM requires the development of problem-solving skills and improved communication capabilities on the part of pharmacy students. To be effective, pharmacy students must be taught how to anticipate, prevent, and solve drug-related problems; identify which problems must be attended to first (in cooperation with the patient); develop action plans that include non-drug therapies; and be able to explain and justify these alternatives to patients, physicians, and third parties (e.g. insurance companies). This requires a different skill set from those needed to dispense medications (Berger, 2005, p.8).

To provide the requisite training for pharmacy students, educational materials about MTM services need to be developed for pharmacy education. These materials should include the demonstration of the relationships between health literacy, MTM services and health outcomes of patients with chronic conditions.

The following section presents relevant literature on health literacy and the relationships of health literacy on the health outcomes for patients with asthma, diabetes mellitus, cardiovascular disease, and depression.

Health Literacy

> A two-year old is diagnosed with an inner ear infection and prescribed an antibiotic. Her mother understands that her daughter should take the prescribed medication twice per day. After carefully studying the label on the bottle and deciding that it doesn't tell her how to take the medication, she fills a teaspoon and pours the antibiotic into her daughter's painful ear (Parker, Ratzan, & Lurie, 2003).

While this may be an extreme case, it highlights the importance of health literacy to ensure appropriate health outcomes. Health literacy can be defined as the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions (Ratzan & Parker, 2000). According to the World Health Organization, "health literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health"(World Health Organization, 1998). Health literacy includes the ability to perform basic reading and mathematical tasks to comprehend and act on health information such as prescription labels, appointment cards, and hospital forms (Andrus & Roth, 2002).

Health literacy differs from general literacy, which refers to the basic ability to read, write, and compute, without regard to context in which the reading or writing occurs (Mayer & Villaire, 2007, p.17). Health literacy refers to how well a person applies a broad range of literacy skills *in the context of health care* (Mayer & Villaire, 2007)(p.3). Many people with otherwise acceptable general literacy may find it difficult to understand and act upon the concepts and

vocabulary used in health-related contexts; therein lies the difference, especially in patient populations with higher levels of education.

Presented with the issue of differing levels of health literacy among their patients, pharmacists need to be in the position to educate and counsel patients in a comprehensive way, identifying patients' level of understanding, and selecting appropriate educational materials (Rantucci, 2007, p.7).

Health Literacy and Health Outcomes for Patients with Asthma

Asthma is a chronic inflammatory disease of the airways that affects more than 22 million people in the United States. According to the National Heart, Lung, and Blood Institute, in spite of recent advances in the detection and prevention of asthma, asthma accounts for 2 million emergency visits per year and approximately 500,000 hospitalizations annually (National Heart, 2007). In 2002, direct costs were estimated at $9.4 billion, with additional costs of $4.6 billion in indirect costs related to loss of work, loss of school days, and mortality (American Lung Association Epidemiology and Statistics Unit Research and Scientific Affairs, 2004).

One of the hypotheses of the proposed study is that inadequate health literacy is associated with clinical outcomes for patients with asthma, including the extent to which patients know how to appropriately administer their medication. In order to effectively manage their asthma, patients must be knowledgeable about their disease and must be able to use metered-dose inhalers (MDIs) correctly. In a study examining the relationship of health literacy to asthma knowledge and the ability to use metered-dosed inhaler, Williams, et al. (1998) surveyed 483 patients presenting themselves either to an emergency room department or routine care in a specialized asthma clinic. In accessing the patients' health literacy, they

used the Rapid Estimate of Adult Literacy in Medicine (REALM). To assess the patients' knowledge of asthma, they administered a 20-item oral questionnaire used in previous studies. Proficiency in the use of an MDI was measured by requesting patients to demonstrate their usual MDI technique of "taking two puffs" in the event of an asthma attack.

In this study, they found that only 27% of patients read at the high-school level, although two-thirds reported being high school graduates; 33% read at the seventh-to-eighth grade level, 27% at the fourth-to-sixth-grade level, and 13% at or below the third-grade level. They found that reading level was the strongest predictor of asthma knowledge in a multivariate analysis; in a multivariate regression analysis, reading level was the strongest predictor of MDI technique. In sum, inadequate literacy was common and strongly correlated with poorer knowledge of asthma and improper MDI use.

In 2006, Mancuso and colleagues explored the association between health literacy and longitudinal outcomes in a cohort of asthma patients. They assessed the extent to which health literacy and other variables were independently related to health outcomes, including physical activity which is of interest in the proposed study. Patients within an urban setting were eligible for participation in the study if they required daily asthma medications, such as inhaled corticosteroids and were enrolled when they came in for scheduled office visits with their primary care physician. Health literacy was measured with the Test of Functional Health Literacy in Adults (TOFHLA) and overall asthma-related quality of life was measured with the Asthma Quality of Life Questionnaire, a well-established scale measuring symptoms, activity limitations, and the effects of emotions on asthma. Resource utilization for asthma was measured by self-report of emergency room visits during three- month intervals.

Of those who participated in this study, 82% had adequate health literacy, 8% had marginal health literacy, and 10% had inadequate health literacy. In subsequent analyses, the subjects were dichotomized into those with adequate health literacy (82%) and those with marginal/inadequate health literacy. Although inadequate health literacy was associated with worse quality of life, worse physical function, and more emergency department utilization, in multivariable analysis, health literacy did not remain statistically significant with any of the measured outcomes.

In 1991 the National Asthma Education and Prevention Program, coordinated by the National Heart, Lung, and Blood Institute (NHLBI) published the *Expert Panel Report: Guidelines for the Diagnosis and Management of* Asthma, which it updated in 1997, 2002 and 2007 (National Heart, 2007). Contained in these guidelines was the recommendation that patients receive education to help improve the physician-patient partnership in managing patients' asthma. Noting that no studies to date had evaluated the extent to which inadequate health literacy served as a barrier to learn and retain asthma self-management skills (Berkman et al., 2004), in 2005 Paasche-Orlow, et al. sought to examine the relationship between inadequate health literacy and difficulties learning and retaining instructions about discharge medications and appropriate MDI technique. The extent to which inadequate health literacy is associated with the need for patient education is also the subject of this proposed study.

In exploring these variables, Paasche-Orlow, et al. recruited 73 adults who were hospitalized for severe asthma at two inner-city academic medical centers. At hospital discharge, participants received intensive one-on-one, guideline-based written and oral

instruction about their asthma discharge regimen as well as appropriate MDI technique. Health literacy was measured with the Short Test of Functional Health Literacy in Adults (S-TOFHLA) and participants were classified as having or not having inadequate health literacy. In accessing patients' understanding of asthma medications (including inhaled corticosteroids), the researchers developed an asthma knowledge scale. MDI technique was measured by demonstration of the use of an MDI inhaler. In follow-up visits, these same items were re-assessed. Additionally, asthma symptom control was measured using the Asthma Control Questionnaire.

Of the 73 participants, 22% had inadequate health literacy. Before instruction, inadequate health literacy was associated with lower asthma medication knowledge and worse MDI technique (a form of medication adherence). However, inadequate health literacy was not associated with difficulty in learning or retaining instructions about discharge regimen nor was inadequate health literacy associated with difficulty in learning or retaining appropriate MDI technique. The results of this study suggest that tailored patient education may reduce disparities in asthma self-management.

MTM and health outcomes for patients with asthma

Exploring the theme of patient education and health outcomes for patients with asthma, in their 2006 study, Bunting & Cranor assessed the clinical, humanistic, and economic impact of a MTM program on adult patients with asthma living in and around Asheville, N.C. This study was modeled after an earlier well-documented program entitled the *Asheville Project* which examined a community-based pharmacist-driven diabetes care model. (The *Asheville*

Project will be discussed under *Health Literacy and Health Outcomes for Patients with Diabetes Mellitus*, below.)

In their quasi-experimental, longitudinal pre-post study, these researchers recruited 207 adult patients with asthma covered by two self-insured health plans—similar to the proposed study site. They examined the impact of asthma education and regular long-term follow-up by pharmacists, using scheduled consultations, monitoring, and recommendations to physicians. Asthma education was provided by specially trained community pharmacists in one or two individual one-on-one sessions, lasting 60-90 minutes each.

Patients were eligible to participate if they were covered by participating employers' health plans and had a diagnosis of asthma, regardless of baseline control or severity of disease. This study was unique as patients were not specifically targeted because of history of emergency department visits, hospitalizations, or high utilization of health plan dollars.

Measured clinical outcomes included asthma severity, humanistic measures (i.e. how asthma was affecting their lives), direct medical care costs (e.g. emergency room visits and prescriptions), and indirect costs (i.e. cost to employer of lost work hours due to absenteeism) over a period as long as five years. However, it is important to note that the patients' health literacy level was *not* examined in this study.

The findings of the study were significant: All objective and subjective measures of asthma control improved and were sustained for as long as five years. Asthma severity lessened significantly, and emergency visits and hospitalizations significantly decreased. Spending on asthma medications increased; however overall asthma-related medical claims decreased. This

study is important as it shows the value of pharmacy-provided MTM services, including patient education as the same relates to health outcomes for those patients with asthma.

The above cited study emphasizes the integral role that MTM services can play in reducing overall healthcare costs and improving health outcomes of patients with asthma. What makes this study unique is that *health literacy levels* of MTM patient participants were measured to examine to what extent health literacy plays a role in predicting the health outcomes of patients with asthma.

Health Literacy and Health Outcomes for Patients with Diabetes Mellitus

Societal changes in recent years have led to a dramatic increase in the prevalence of obesity among adults and children in the United States. These changes include increased food intake, nonhealthful foods, and physical inactivity. In 2007, 25.6% of the adults in the United States were obese by self-report (Centers for Disease Control and Prevention). Obesity is a major risk factor for cardiovascular disease, certain types of cancer, and type 2 diabetes (Centers for Disease Control and Prevention). It is estimated that in 2010, diabetes affected 25.8 million people in the United States or 8.3% of the U.S. population; medical expenses for those who have diabetes mellitus are more than two times higher than for people without the disease (Centers for Disease Control and Prevention, 2011).

Given the complexity of managing diabetes mellitus, health outcomes for adults with diabetes mellitus are better for those who can optimally incorporate self-management of their diseases into their daily lives (Sigurdardottir, 2005). Diabetes care requires an informed individual who can seek, obtain, and comprehend information to engage in the management of his/her health (Morris, MacLean, & Littenberg, 2006).

This study included patients with diabetes mellitus and helps determine if health literacy is a factor in the management of their chronic condition. Along with levels of physical activity, measurements of diabetes management included blood pressure, body mass index (BMI), hemoglobin A1c (as an indication of glycemic control), triglycerides, and cholesterol levels. The need for patient education in this population was also assessed.

Studies on health literacy and diabetes mellitus

To date, results of studies examining the relationship of health literacy and health outcomes for patients with diabetes mellitus have been inconsistent. In an early study, Williams (1998), examined the relationship between literacy and knowledge of chronic disease focusing on patients with diabetes mellitus and hypertension. Drawing subjects from two urban hospitals, the study enrolled 402 patients with hypertension and 114 patients with diabetes mellitus. The patients' literacy level were tested using the TOFHLA; their knowledge of their illness was assessed using 21 hypertension and 10 diabetes questions based on key elements in educational materials used in their clinics. Other health outcomes measured in the study were patients' levels of blood pressure and hemoglobin A1c.

These researchers found that 48% of the patients had inadequate functional health literacy, and these patients had significantly less knowledge of their disease, important lifestyle modifications, and essential self-management skills. For the diabetes patients in the study, this finding was especially important because patients had attended formal educational classes on diabetes; researchers realized that their educational strategies were not optimal with the large number of patients with lower literacy. However, the researchers did not find a significant relationship between literacy and levels of blood pressure or hemoglobin A1c.

In 2002, Schillinger et. al. investigated the association between health literacy and diabetes outcomes in a cross-sectional study of 408 patients at two primary care clinics at a university- affiliated hospital in San Francisco, Calif. The patients' health literacy level was assessed using the short-form Test of Functional Health Literacy in Adults (s-TOFHLA). Health outcomes measured in the study included patients' hemoglobin A1c level (as an indication of glycemic control), self-report rates of retinopathy (diabetic eye disease), depression (as measured by the Center for Epidemiologic Studies Depression Scale-10) and levels of social support (as measured by questions from the Diabetes Care Profile). These researchers found inadequate health literacy was independently associated with worse glycemic control and higher rates of retinopathy, but did not find a significant relationship between health literacy and the other health outcomes.

A recent study also reported conflicting results when studying health literacy and health outcomes for those with diabetes mellitus. Osborn, Bains and Egede (2010) examined the relationships between health literacy, determinates of health care, and glycemic control in 125 adults with type 2 diabetes. In this study, information collected included the patients' level of health literacy (utilizing the Revised Rapid Estimate of Adult Literacy in Medicine), diabetes knowledge and diabetes self-care (e.g. medication adherence, blood sugar testing, foot care). Hemoglobin A1c levels came from patients' medical records. These researchers found no direct relationship between health literacy and diabetes self-care or glycemic control. In a subsequent analysis of the data, only diabetes knowledge was found to be significantly associated with lower health literacy (Bains & Egede, 2011).

Studies on MTM programs and health outcomes for patients with diabetes mellitus

MTM services have shown to improve health outcomes for patients with diabetes mellitus. The most notable study is the *Asheville Project* (Cranor, et al., 2003). In that study, investigators assessed the persistence of certain health outcomes for up to five years following the initiation of community-based pharmaceutical care services for patients with diabetes. Although health literacy levels of patients were not assessed, this study demonstrated the benefit of pharmacy-led diabetes care program for its participants. Again, health literacy levels will be established in the proposed study, adding an additional element in the evaluation of MTM programs for patients with chronic conditions.

In their quasi-experimental, longitudinal pre-post study, Cranor and colleagues studied the effects of patient education provided by certified diabetes educators, ongoing pharmacist consultations, clinical assessments, and collaborative drug therapy management with physicians. The main measured outcomes were changes in hemoglobin A1c and serum lipid concentrations, as well as total medical utilization costs over time for 157 patients. As a result of these interventions, the researchers found that mean A1c levels decreased at all follow-up visits, with more than 50% of patients demonstrating improved levels each time. Additionally, more than 50% showed improvements in lipid levels. Finally, total mean direct medical costs decreased by $1,200 to $1,872 per patient per year compared to baseline expenditures.

Health Literacy and Health Outcomes for Patients with Cardiovascular Disease

In its 2010 publication Defining and Setting National Goals for Cardiovascular Health Promotion and Disease Reduction: The American Heart Association's Strategic Impact Goal Through 2020 and Beyond (Lloyd-Jones et al., 2010), the American Heart Association (AHA) set

forth a new definition of cardiovascular health and outlined metrics needed to monitor health over time.

In this document, the AHA indicated that ideal cardiovascular health should be defined by the presence of both ideal health *behaviors* and ideal health *factors*. Included in ideal health behaviors are nonsmoking, a low body mass index (BMI), certain levels of physical activity, and a diet within prescribed guidelines. Although not included in the definition of ideal health behaviors, the AHA also recognized the importance of lipid-lowering medications and antihypertensive medications in reducing risks in patients with cardiovascular disease. These medications can allow a patient to go from "poor cardiovascular health" to "intermediate cardiovascular health" (as defined in the report and discussed below). The AHA also acknowledged the importance of monitoring medication adherence in those patients taking medications as better adherence has shown to improve health outcomes.

In outlining ideal health factors, the AHA indicated that adults should have untreated total cholesterol of less than 200 mg/dL, untreated blood pressure of diastolic less than 120 over less than 80 mm Hg., and fasting blood glucose less than 100 mg/dL. Taking into consideration both ideal health behaviors and ideal health factors, under these guidelines patients can be categorized as having poor, intermediate or ideal cardiovascular health.

Both ideal health behaviors and ideal health factors were measured in this study. Measurements of health behaviors for patients with cardiovascular disease included BMI (as an indicator of proper nutrition) and the levels of physical activity. Adherence to medication regimen was also assessed as a health behavior using the Modified Morisky Scale (Morisky, et

al., 1986). Health factors included measurements of cholesterol, blood pressure, and fasting blood glucose levels.

Studies on health literacy, cardiovascular disease, and health behaviors

Perhaps the largest and most documented study dealing with health literacy and chronic conditions, including cardiovascular disease, has become known as the *Prudential Study.* As of 2010, eight articles using the *Prudential* data have been published by various authors including, Baker, Gazmararian, Howard, and Wolf (Berkman et al., 2011). All of these articles utilize information obtained from approximately 3,000 members in the Prudential Medicare plan with enrollees in Cleveland, Ohio; Houston, Texas; and Tampa, Fla., and south Florida.

Participants in the *Prudential Study* completed a one-hour in-person interview in their home. Survey items included demographics, current and past smoking behaviors, BMI measurement, chronic conditions (e.g. hypertension, diabetes mellitus, heart failure, and asthma), and self-rated physical and mental health functioning. Patients were excluded from the study if it was determined they were not comfortable speaking English or Spanish, were blind, or had limited cognitive functioning (e.g. they did not know their address, year they were born or the current year or month) (Wolf, Gazmararian, & Baker, 2005). In assessing health literacy, the researchers used the short version of the Test of Functional Health Literacy in Adults (s-TOFHLA)(Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Using the Prudential data, Wolf, et al. (2005) found that enrollees with inadequate health literacy were significantly more likely to report having heart failure and/or diabetes; were more likely to have limitations in instrumental activities of daily living; and had lower

mental health. However, in a subsequent study, they found no significant difference in the BMI of those patients with inadequate health literacy (Wolf, Gazmararian, & Baker, 2007).

With regard to adherence to cardiovascular medication within this same group, Gazmararian et al. (2006) found no significant association between health literacy levels and medication refills. Although, those with inadequate health literacy skills had increased odds of low refill adherence compared with those with adequate health literacy skills.

In order to have a diet within the suggested AHA guidelines, patients need to be able to read and interpret food nutrition labels. This involves not only reading skills, but basic numeracy skills (e.g. ability to perform basic math). In a cross-sectional study of 200 adult patients in an academic primary-care clinic, Rothman et al. (2006) examined the relationship of health literacy and the understanding of food labels. These researchers used the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis, et al., 1993) to measure literacy and the Wide Range Achievement Test (3rd ed.) (Wilkinson, 1993) to measure numeracy. The ability to understand food labels was assessed using a Nutrition Label Survey which the researchers developed for the study.

These researchers found that lower literacy and numeracy levels were highly correlated with poorer performance on the Nutrition Label Survey. In fact, even patients with higher literacy could have difficulties interpreting labels. In analyzing the results of their study, common reasons for incorrect answers included misapplication of serving size, confusion due to extraneous material on the label, and incorrect mathematical calculations.

In examining patients' ability to manage their medications, including the ability to identify, open, describe the dose, and describe the timing of their cardiovascular medications,

Kripalani, et al. (2006) found those with inadequate health literacy significantly less likely to identify all of their medications, compared with those with adequate health literacy. No significant difference was found between inadequate health literacy and other components (e.g. being able to open container, indicate dose, and report timing).

One notable study examined a pharmacist-led intervention designed to increase medication adherence in patients with heart failure. In a randomized control trial, Murray, et al. (2007) measured adherence to those medications commonly used by such patients including ACE inhibitors, beta-blockers, and diuretics by patients in a university-affiliated, inner-city ambulatory care practice. Medication adherence was measured several ways including self-reported adherence (through the use of Morisky Medication Adherence Scale), refill adherence (using prescription records), and the use of electronic prescription container lids (devices that record the time and date of each opening and closing of a prescription container). Health literacy, however, was not measured.

As was the case in this study, the pharmacists-led intervention included a medication history of all prescription and over-the-counter medications and dietary supplements taken by the patients. Additionally, the pharmacists provide patient-centered verbal instructions, written instructions, and medication containers containing medication category icons (e.g., a red ace of hearts for ACE inhibitors). The same icon appeared in the written directions and container labels and lids to improve medication identification.

These researchers found that taking and refill adherence were greater in the intervention group during the nine-month intervention period, but adherence dissipated with

subsequent follow-up visits. However, emergency department visits and hospital admissions lessened and annual direct healthcare costs were lower in the intervention group.

Studies on health literacy, cardiovascular disease, and health indicators

As mentioned above, *health indicators* for those with cardiovascular disease include the measurement of levels of cholesterol, blood pressure, and blood glucose. Studies examining the relationship of health literacy and these indicators are also inconsistent. (As studies exploring these health indictors in diabetic patients have already been outlined in *Studies on health literacy and diabetes mellitus*, above, this section will focus on studies examining patients with hypertension, a form of cardiovascular disease.)

A 2009 cross-sectional study explored the association between health literacy levels, hypertension control (measured by blood pressure) and knowledge (Pandit et al., 2009). In this study, 330 patients with hypertension were recruited from six primary care safety net clinics in Grand Rapids, Mich.; Chicago, Ill.; and Shreveport, La. Participants were given the s-TOFHLA to access their health literacy; hypertension knowledge was measured by asking patients a series of questions about the characteristics and symptoms of high blood pressure. Blood pressure was taken from the medical records and considered controlled if it was below 140 mmHg for diastolic and below 90 mmHg for systolic (or <130 mmHg/<80 mmHg for patients with diabetes mellitus). These researchers found lower health literacy was significantly associated with a lower probability of having controlled blood pressure.

Powers, et al. conducted a similar study with different results (2008). For their study, these researchers pooled data from patient interviews performed at the time of enrollment for two separate randomized controlled trials to improve blood pressure control. The first

underlying study was the *Veteran Study to Improve the Control of Hypertension*, conducted at three VA medical primary care clinics in Durham, Va. The other participants were enrolled in Duke University Health Care System's *Take Control of Your Blood Pressure* study. To assess literacy, the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis, et al., 1993) was given to all participants and blood pressure readings were abstracted from the individuals' medical record. Additionally, self-reported medication adherence was assessed using the Morisky scale (Morisky, et al., 1986). When looking at both groups of patients, these researchers found no significant difference in blood pressure control among those with lower literacy compared to those with higher literacy.

One study sought to determine if a nurse-administered, patient-tailored intervention could improve blood pressure control in a group of 294 veterans taking hypertension medication (Bosworth et al., 2005). As a part of this study, the health literacy of the patients was measured using the REALM (Davis, et al., 1993). If patients had lower levels of health literacy, their hypertension medication regimen was explained to them verbally, in effort to increase patients' knowledge and medication adherence. After the first six months of the study, of those patients receiving the nurse-led intervention, there was no significant increase in patients' knowledge of hypertension or medication adherence.

Next, empirical literature about health literacy and patients with depression and anxiety will be presented.

Health Literacy and Health Outcomes for Patients with Depression/Anxiety

Compared with the literature examining the relationships between health literacy and asthma, diabetes, and cardiovascular disease, there are fewer studies that examine health

literacy, depression and anxiety. Of those studies that have explored these variables, many of them involve patients with HIV/AIDS (Kalichman et al., 2008; Murphy et al., 2010; Nokes et al., 2007) or Latinos with limited English skills (Bennett, Culhane, McCollum, & Mathew, 2007; Coffman & Norton, 2010). However, for purposes of this study, they have limited applicability.

However, there are two studies relevant to the proposed study. Sudore, et al. (2006) assessed the prevalence of limited health literacy and comorbid conditions associated with limited health literacy, including depression. As a part of the *Health, Aging and Body Composition (Health ABC) Study*, these researchers administered the Center for Epidemiologic Study Depression Scale (Radloff, 1977) to 2,512 well-functioning black and white Medicare-eligible men and women. Drawing participants from Pittsburgh, Pa., and Memphis, Tenn., the health literacy level of the patients was measured using the REALM (Davis, et al., 1993). Information on the health status of the patients, including certain comorbid diseases such as cardiac disease, stroke, hypertension, and diabetes mellitus was obtained using a variety of data sources including clinical data obtained at yearly study examinations. These researchers found that patients with lower health literacy had significantly worse health status, including hypertension, diabetes, obesity, and depression.

Conversely, as a part of the Prudential Study described earlier, Howard, Gazmararian & Parker (2005) explored the relationship of health literacy and self-reported depression. In their analysis of 3,260 managed care patients, they found no significant relationship between inadequate health literacy and depression.

Conclusion

The role of pharmacists in the United States is changing. No longer are pharmacists only responsible for dispensing medication; now, pharmacists are required to accept responsibility as direct patient-care providers and enter into a more formalized relationship with their patients for the explicit purpose of improving patient outcomes (Cipolle, et al., 2004). This type of patient-centered pharmaceutical care often includes Medication Therapy Management (MTM) services. Going forward, through providing MTM services, pharmacists will be in the position to help improve the health outcome of patients with chronic diseases such as asthma, diabetes mellitus, cardiovascular disease, and depression. However, in order to do this most effectively, pharmacists must be aware of the health literacy level of their patients and be aware of the relationships between health literacy and health outcomes of those patients with chronic conditions.

To provide the requisite training for pharmacy students, educational materials about MTM services must be developed for pharmacy education. These materials need to include the demonstration of the relationships between health literacy, MTM services and health outcomes of patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety. As will become clear in Chapter 3 below, this study's methodology was designed to build on existing knowledge in these areas to assist in the development of such materials.

CHAPTER 3: METHODS

Introduction

This study is a secondary analysis of data previously collected as a part of an investigation entitled *Medication Therapy Management and Health Literacy Assessment through Health Horizons: Manage My Medications* (hereinafter, *Manage My Medications*). Started in 2008, the *Manage My Medications* study was part of Healthy Horizons, a health wellness program at Butler University in Indianapolis, Ind. Butler University's Institutional Review Board approved the *Manage My Medications* study on August 28, 2008 (Appendix B) and its continuance (Appendix C). Data from *Manage My Medications* was supplied to this investigator in the form of a de-identified dataset whereby the subjects were not identified either directly or through identifiers linked to the subjects. The proposed investigation was submitted to Wayne State University's Human Investigation Committee for approval as "Exempt" (Appendix A).

Study Site

In 2004, in collaboration with Butler University's College of Pharmacy and Health Sciences (COPHS) and Butler's Department of Human Resources, Healthy Horizons was established with the mission of improving the health and well-being of Butler's faculty and staff. As of part its mission, Healthy Horizons provides comprehensive, confidential health screening and patient education aimed at improving patient outcomes. In an effort to decrease the overall financial impact of rising healthcare costs (including medication), in 2007, Butler University became self-insured. Along with this change came an imperative to contain medication costs, especially for faculty and staff with chronic conditions.

Armed with de-identified prescription medication claims data of Butler employees from the previous year, in 2008, Healthy Horizons identified the medications most frequently prescribed for covered employees. Based on this data, Healthy Horizons began an MTM program aimed at those Butler employees taking medications for chronic conditions including asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety. The *Manage My Medications* study was based on this MTM program.

Subject Recruitment

Criteria for admission into *Manage My Medications* included: (a) being enrolled in Butler University's health insurance plan [including spouses and domestic partners]; (b) ability to sign the consent form; (c) ability to complete the study instruments with a minimum of assistance; and (d) taking at least one monthly prescription medication(s) for the treatment of asthma, diabetes, hypertension, depression/anxiety, hyperlipidemia, heartburn/GERD, hypothyroidism, *or* taking four or more chronic prescription medications. Additionally, subjects had to be at least 18 years of age. Exclusion criteria included: (a) pregnancy; (b) having utilized Health Horizon's services in the past twelve months; and (c) unwillingness to make the required visits, which included baseline and one follow-up visit after six months.

Persons who met the inclusion criteria were invited to participate in the study. If they were interested, they were provided with study details, which include information on an incentive gas card valued at $50. Those who agreed to participate signed an informed consent form and were enrolled in the study.

Data Collection

Approximately 90 subjects were enrolled in *Manage My Medications*. Data were collected on demographic, psychosocial, and physical functioning using instruments designed by Healthy Horizons for the program and standard assessment instruments. Additionally, certain clinical tests were performed to assess and gain an understanding of the control of patients' disease state(s). These data were collected at the date of enrollment in the study. Data collection points were baseline upon entry into the study and at six months. This study only examined baseline data.

Study Design

The study was a cross-sectional study to investigate associations of levels of health literacy and various demographic and health-related outcomes. The research question was operationalized as two specific aims and corresponding research hypotheses which were presented in Chapter I.

After assessing base-line differences among health literacy levels, univariate analyses were conducted to determine associations between study variables utilizing the chi-squared test of association for categorical variables and t-tests for continuous variables. Significance was set at the 5% level for a two-sided test. All testing was conducted using commercially available statistical software (e.g. SAS). Finally, a logistical regression model was constructed to predict inadequate health literacy, using variables assessed in the previous step. The logistical regression model allowed for determination to what extent any particular variable is an independent predictor of inadequate health literacy, controlling for other variables in the study.

Operationalization of the Study Variables

As discussed in Chapter II, the variables of interest for this study were conceptually derived from *Health Literacy Framework* (*Health literacy: A prescription to end confusion*, 2004) and *The Medication Therapy Management Core Elements Service Model (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008)*. Within this framework, health literacy is identified as the study variable. This investigation examined the associations of health literacy and the following factors: (a) age, gender, race, and levels of education; (b) clinical outcomes of asthma, diabetes mellitus, cardiovascular disease/hypertension and depression/anxiety, (c) medication adherence, (d) the need for patient education and (e) sub-optimal medication regimens. The operationalization of the concepts and their associated measures are presented in Table 1. A discussion of the instruments measuring these variables follows.

Table 1. Operationalization of Study Variables

Operationalization of Study Variables

Concept	Variable	Measure
Health Literacy	Health Literacy	The Newest Vital Sign
Patient Variables	Age	Age at entry into Manage My Medications
	Gender	Self-report of gender
	Race	Self-report of race/ethnicity
	Education	Self-report of years of formal education
Health Outcomes	Asthma Control	Self-Report with Asthma Control Test
	Diabetes Mellitus	1. Self-Report 2. Blood pressure 3. Fasting blood glucose test 4. Test for the following: triglycerides, Total cholesterol (TC), high density lipoprotein (HDL), and low density lipoprotein (LDL). 5. Body Mass Index (BMI)
	Cardiovascular Disease	1. Self-Report 2. Blood Pressure 3. Body Mass Index (BMI) 4. Fasting blood glucose test
	Depression	Self-report with Zung Depression Scale
	Medication Adherence	Patient Interviews and Self-Report with Modified Morisky Medication Scale
	Patient Education	Patient interviews
	Optimal Medication Regimen	Patient interviews

Health Literacy

Health literacy, as previously defined, is the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions (Ratzan & Parker, 2000). There are multiple instruments that can measure health literacy. As previously mentioned, these tests include the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA) (Baker, et al., 1999; Davis, et al., 1993). Newer tests have been developed to assess health literacy, including The Newest Vital Sign (Weiss, et al., 2005).

For the *Manage My Medications* investigation, The Newest Vital Sign was used to measure health literacy. One of the strengths of The Newest Vital Sign is that it tests both reading comprehension and the ability to make calculations (numeracy) (Mayer & Villaire, 2007). Additionally, when compared to other tests, The Newest Vital Sign is very quick to administer; it takes only 3 minutes to assess health literacy. Finally, The Newest Vital Sign is available in both English and Spanish.

The Newest Vital Sign uses the nutrition label from the back of a carton of ice cream as the testing vehicle. Patients are given a copy of the nutrition label and asked six questions, several of which require them to make mathematical calculations. For example, one of the questions asks, "If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?" To answer the question correctly, the patient must refer to the label, note that there are 250 calories in each serving, and divide this 250 (calories in one serving) by 2,500 (usual calories in a day) to come up with the correct answer of 10 percent. The total number of correct answers is the patient's health literacy score, with a

total possible score being 6 points. A score of 0-1 suggests high likelihood of limited literacy, a score of 2-3 indicates the possibility of limited literacy, and a score of 4-6 almost always indicates adequate literacy. The Newest Vital Sign is presented in Appendix D. For purposes of this study, scores were broken down into two groups: those having *limited* health literacy (scores 0-3) and those having *adequate* health literacy (scores 4-6)

Patient Variables

Patient variables such as age, gender, race, and levels of education were assessed by questions posed to the patients by the interviewer/pharmacist and answers were recorded on a multi-page Data Collection form, which was developed by Healthy Horizons for the study. Existing medical conditions (e.g. asthma, diabetes, cardiovascular disease/hypertension, depression/anxiety) were recorded, along with the number of prescriptions per month and amounts spent each month on prescription medications. Patients' health literacy score on The Newest Vital Sign were also recorded on the Data Collection form. The Data Collection form is presented in Appendix E.

Asthma Control

As mentioned earlier, asthma is an inflammatory lung disease (Poureslami, et al., 2007) and is considered a common chronic disorder of the airways which is characterized by, among other things, recurring airflow obstruction (National Heart, 2007). According to the National Heart, Lung and Blood Institute, effective asthma management includes the development of an individual treatment plan aimed at minimizing symptoms, proper use of medications, preventing limitations in work and other physical activity, and preventing acute attacks (National Heart, 2007). However, level of asthma control is often overstated by both patients

and physicians, resulting in missed work or school and increased use in healthcare services (Nathan, 2004). Therefore, the American Lung Association recommends everyone 12 years of age or older with asthma be assessed for asthma control (QualityMetric Incorporated, 2002).

In the Manage My Medications study, for those patients reporting being diagnosed with asthma, control over their condition was measured using the Asthma Control Test (QualityMetric Incorporated, 2002). The Asthma Control Test (ACT) consists of a series of five questions, each worth 5 points, with a total possible score of 25. The questions presented in the ACT not only measure how often patients use asthma medications (e.g. metered-dose inhalers), but also assesses the functional impact of asthma on patients' daily lives. For example, question number one on the ACT asks, "In the past **4 weeks**, how much of the time did your **asthma** keep you from getting as much done at work, school or at home?" (emphasis supplied). A score of 19 points or less on the ACT indicates that a patient's asthma may not be controlled as well as it could be. The Asthma Control Test is presented in Appendix F.

Depression

As noted earlier, those patients with chronic conditions such as diabetes and cardiovascular disease may also suffer from depression. In order to assess the rate of depression in those patients participating in the Manage My Medication study who reported being diagnosed with depression or anxiety, the researchers administered the Zung Self-Rating Depression Scale (Zung, 1965). The Zung Self-Rating Depression Scale consists of 20 statements with a value of 1-4 correlating to each response. Statements include: "I feel down-hearted and blue," "I get tired for no reason," "I feel hopeful about the future," and "I feel I am still useful and needed." In response to each statement, patients indicate: "a little of the time" (1 point),

"some of the time" (2 points), "good part of the time" (3 points), or "most of the time" (4 points). Most people with depression score between 50 and 69; the highest possible score is 80. The Zung Self-Rating Depression Scale is presented in Appendix G.

Medication Adherence

Adherence is the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice (Meichenbaum & Turk, 1987). Measuring medication adherence (e.g. taking correct medication in the correct amount at the correct time) is an integral part of the *The Medication Therapy Management Core Elements Service Model* (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008). As such, patients' medication adherence was measured as a part of the Manage My Medications study.

For the study, medication adherence was measured of all participants using the Modified Morisky Scale (Morisky, et al., 1986). Based on an earlier version, the Modified Morisky Scale measures a patient's motivation to take their medication and their knowledge about their medications. Both of these factors help explain the intention of the patient to adhere to their medication regimen. For those patients with chronic diseases, medication adherence is of particular importance.

The Modified Morisky Scale consists of six questions, with three questions measuring motivation and three questions measuring knowledge. For the motivation domain, each "no" answer (questions 1, 2 and 6) receives a score of 1 and each "yes" answer receives a score of 0. This provides a range of motivation scores of 0 to 3. A score of 0 to 1 in this domain indicates low motivation; a score greater than 1 indicates high motivation. For knowledge (questions 3, 4

and 5) a score of 0 to 1 indicates low knowledge and a score greater than 1 indicates high knowledge. Motivation scores and knowledge scores are combined to determine the patient's overall adherence level (total possible of six points). The Modified Morisky Scale is presented in Appendix H.

Optimal Medication Regimen and Need for Patient Education

A significant part of any medication therapy management (MTM) program is the review of all of the patient's medications (both prescriptions and over-the-counter) and a pharmacist/patient consultation. This is the hallmark of the patient-centered pharmaceutical care model. As stated earlier, MTM's are designed to improve collaboration among pharmacists, physicians, and other healthcare providers; enhance communication between patients and their healthcare team; and optimize medication use for improved patient outcomes (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008).

As part of the Manage My Medications MTM program, patients were asked to bring in all of their prescription and over-the-counter medications when they came in for their scheduled interview. A series of health screenings, including blood pressure, body mass index (BMI), cholesterol, and fasting blood glucose were performed on each patient.

During their consultation, all of the patient's medications were reviewed for the following potential problems: additional therapy needed, unnecessary therapy, drug interactions, adverse effects, insufficient dose/duration, excessive dose/duration, ineffective drug, administration/technique, more cost effective options, excessive use, and under use.

Based on the consultation, the need for health education and/or medical education was

also identified and patient specific education was proffered when needed. All of this information was recorded on the Data Collection form and kept as a part of the patient's confidential medical record. All medical records were/are stored in compliance with all federal (e.g. HIPPA) and state laws.

Based on the above, a personalized health wellness plan was then developed for each patient, including recommendations on disease management. Patients were given the option to have the results of their MTM consultation (including health screenings) sent to their physician(s). Recommended changes in medication were also sent to physicians when requested by the patient. Finally, a six-month follow-up appointment was scheduled for each patient.

Summary

This chapter has presented an overview of the *Medication Therapy Management and Health Literacy Assessment through Healthy Horizons: Manage My Medications* investigation from which data will be used to answer the specific aims of the proposed study. Information on the study site, subject recruitment, data collection, study design, study variables and their measures has been presented. Results of the analysis and discussion of the findings will be presented in following chapters.

CHAPTER 4: RESULTS

Introduction

In this chapter, the results of the *Medication Therapy Management and Health Literacy Assessment through Healthy Horizons: Manage My Medications* investigation are presented. Following a description of the participants (including the health outcomes measured in this study), the results of the regression analyses are reported.

Description of the Participants

Socio-Demographics

A total of 90 participants took part in the MTM study. Slightly more women (N=52; 57.78%) than men (N=38, 42.22%) participated. With regard to race, seventy-nine of the participants self-identified as Caucasian (87.78%), nine participants (10.0%) self-identified as African-American, and two participants (2.22%) self-identified as being Hispanic.

The participants ranged in age from 27 to 71, with a mean age of 50.4 years (SD= $\pm$ 11.58). Participants in the study were grouped into ten-year categories. Four (4.44%) were 20-29 years of age, ten (11.11%) were 30-39, 27 (30.0%) were 40-49 years old, 25 participants (27.78%) were between 50 and 59, 18 (20.0%) were 60-69, and two (2.22%) were 70 years of age or older. (Age was missing for four of the participants.)

When considering the years of formal education, the data revealed that eight (8.89%) completed high school, ten (11.11%) attended some college, 28 (31.11%) completed bachelors degrees, 23 (25.56%) had a master's degree, and 21 (23.33%) had received a doctoral degree.

The socio-demographics of the study population can be found in Table 2 below.

Table 2. Socio-Demographics of the Study Population (N=90)

Socio-Demographics of the Study Population (N=90)		
Characteristic	**N**	**%**
Gender		
Female	52	57.78
Male	38	42.22
Race		
African American	9	10.00
Caucasian	79	87.78
Hispanic	2	2.22
Age at time of entry of study (years)		
20-29	4	4.44
30-39	10	11.11
40-49	27	30.00
50-59	25	27.78
60-69	18	20.00
70+	2	2.22
(missing ages for four participants)		
Highest education level completed at entry of study		
High school	8	8.89
Some college	10	11.11
Bachelors degree	28	31.11
Masters degree	23	25.56
Doctorate degree	21	23.33
Health Literacy Score		
Limited (0-3)	10	11.11
Adequate (4-6)	80	88.12

Health Outcomes of Participants

As a part of the MTM program, various health outcomes of the participants were measured. These assessments included:

(a) Participants' self-report of being diagnosed with a specific condition(s) (e.g. asthma, diabetes, hypertension);

(b) Physiologic outcomes (e.g. blood pressure, total cholesterol, fasting blood glucose, body mass index);

(c) Results of standardized self-report measures (e.g. Asthma Control Test, Zung Depression Scale, Morisky Medication Adherence Scale);

(d) Patient interviews assessing the need for patient education (e.g. proper use of medication, medication adherence, use of monitoring devices); and

(e) Patient interviews identifying sub-optimal drug regimens (e.g. unnecessary drug therapy, excessive dose/duration, additional drug therapy needed).

The results of these assessments are discussed below by specific health outcome.

Asthma

Of the 90 participants, twelve (13.3%) patients reported having being diagnosed with asthma. When these twelve patients were administered the previously described Asthma Control Test, nine of these patients (or 75%) scored $\leq$19 points, indicating that their asthma may not be controlled as well at it could be.

Diabetes mellitus

Of the 90 participants in the study, 11 (12.22%) reported having been diagnosed having pre-diabetes and nine (10.0 %) reported having being diagnosed as having either type 1 or type 2 diabetes mellitus. Of those who had type 1 or type 2 diabetes mellitus, 55.6% (N=5) had both fasting blood glucose levels that were not in optimal range (>70 and <130 mg/dL) and low density lipoprotein (LDL) levels not within optimal range (>70 and 100mg/dL).

Cardiovascular disease/hypertension

Over a third of the participants (N=33; 36.67%) reported having being diagnosed with hypertension. Blood pressure readings were taken of these 33 patients; it was found that 27 (81.82%) did not have their blood pressure under control (>140/90 mm Hg). Of those patients *not* reporting having being diagnosed with hypertension, blood pressure readings indicated that three participants (3.33%) had pre-hypertension ($\geq$ 120/90 mm Hg).

Body mass index

A body mass index or BMI (as described in Chapter 1) was calculated for all participants in the study. A BMI <25 is considered normal, $\geq$ 25 is considered overweight, and $\geq$ 30 suggests obesity, a risk factor for diabetes mellitus and cardiovascular disease. In this study, 38.89% (N=35) of the participants had BMI's indicating that they were overweight and 35.56% (N=32) had BMI's indicating obesity.

Fasting blood glucose levels for those patients NOT self-reporting diagnosis of pre-diabetes or type 1 or 2 diabetes

Similar to the BMI test, all participants were administered a fasting blood glucose test, including those patients who did not report being diagnosed with pre-diabetes or type 1 or 2 diabetes mellitus. For non-diabetes patients, fasting blood glucose levels of 100-125 mg/dL

indicate pre-diabetes, and fasting blood glucose levels of ≥ 125 suggests diabetes. For those participants that did not report being diagnosed with either pre-diabetes or diabetes, 20 (28.57%) had fasting blood glucose levels indicating pre-diabetes and 1 patient (1.43%) had a blood glucose level indicating diabetes mellitus.

Dyslipidemia

Dyslipidemia (or abnormal cholesterol levels) is associated with diabetes mellitus and heart disease. Ideally, a patient's total cholesterol level should be <200 mg/dL, their high density lipoprotein (HDL or "good" cholesterol) should be >40 mg/dL, and their triglycerides should be <150 mg/dL. With regard to low density lipoprotein (LDL or "bad" cholesterol), LDL levels of >130 mg/dL indicate moderate risk for cardiovascular disease and LDL levels of <100 mg/dL indicate high risk.

In this study, 47 participants (52.22%) reported having been diagnosed with dyslipidemia (or abnormal cholesterol levels). Of these 47 patients, 13 (27.66%) had higher than normal total cholesterol levels; 16 (34.0%) had both sub-optimal HDL levels and higher than normal triglycerides. Twenty-one participants (44.68%) had LDL levels indicating having moderate risk and nine participants (19.15%) had LDL levels indicating a high risk of cardiovascular disease.

Depression/anxiety

Of the 90 participants, 27.8% (N=25) reported having being diagnosed with depression or anxiety. These patients (reporting a diagnosis of depression or anxiety) completed the Zung Self-Rating Depression Scale. Of these 25 participants, five patients (20%) scored ≥ 50 points on the Zung Self-Rating Depression Scale indicating the presence of depression.

Adherence

As mentioned in Chapter 1, adherence concerns the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice (Meichenbaum & Turk, 1987). Measuring medication adherence (e.g. taking correct medication in the correct amount at the correct time) is an integral part of *The Medication Therapy Management Core Elements Service Model* (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008). Similar to other tests already mentioned, all participants in the study were administered Modified Morisky Adherence Scale to help determine how adherent they were with their medication regimen. Of the 90 participants in the study—all of whom were taking at least one medication—19 (21.11%) had scores indicating sub-optimal adherence to their medication regimen.

Need for patient education

As a part of this medication therapy management (MTM) study, patient interviews were conducted to help identify specific areas in which patients needed education regarding their medication and lifestyle. All participants (N=90; 100%) needed some form of patient education and these needs were stratified into six different categories: education about medication, additional information, help with disease management, help with monitoring devices, education about self-care, and life-style counseling. In particular, of these 90 participants, 85 (94.44%) needed education on the proper use of their medication, while 58 patients (64.44%) needed additional information on adherence to their medication regimen. Seventy-one (78.89%) needed help with the management of their disease(s), and 15 (16.67%) needed help with monitoring devices (e.g. blood glucose testing, blood pressure monitoring). Fifty-one

patients (56.67%) needed education regarding self-care, while 80 (88.89%) needed counseling on lifestyle changes.

Identification of sub-optimal drug regimens

Patient interviews done as a part of the MTM program helped identify specific problems with patients' medication regimens, these problems being broadly defined as "sub-optimal drug regimens." Patients were asked to bring with them to the interview all medications that they had been prescribed along with any over-the-counter medications they were taking. Patient interviews revealed that 75 study participants (83.33%) had some type of sub-optimal drug regimen issue. Sub-optimal drug regimens were broken down into 12 categories.

Of the 75 patients found having sub-optimal drug regimens, three participants (4.0%) had unnecessary medications and two (2.67%) were taking ineffective drugs. With regard to dose and duration of drug therapy, five participants (6.67%) had *excessive* dose/duration, while 13 (17.33%) had *insufficient* dose/duration. Two of the patients (2.67%) were found taking excessive amounts of their medication(s) and nine (12.0%) were under utilizing their medication. Four patients (5.33%) reported adverse events relating to their drug regimens, two patients (2.67%) needed additional information on their medications, and five patients (6.67%) needed additional or follow-up laboratory monitoring. Further, of the 75 patients with sub-optimal drug regimens, 25.33% (N=19) were found to have exhibited ineffective administration of their medication and 28.0% (N=21) needed additional medications. Finally, 46.67% (N=35) were prescribed medication(s) for which there was a more cost effective (cheaper) option.

A summary of the health outcome measures of the patient population is set forth in Table 3 below.

Table 3. Health Outcomes Measures of Patient Population (N=90)

Health Outcomes Measures of Patient Population (N=90)		
Characteristic	**N**	**%**
Asthma		
Self-reporting having asthma: Yes	12	13.33
Asthma *not* controlled (≤ 19 Asthma Control score): Yes	9	75.0
Diabetes Mellitus		
Self-report having pre-diabetes: Yes	11	12.22
Self-report having type 1 or type 2 diabetes: Yes	9	10.0
Blood glucose level *not* within optimal range (>70 - <130 mg/dL): Yes	5	55.56
Low density lipoprotein *not* within optimal range(LDL) (>70 mg/dL - < 100mg/dL): Yes	5	55.56
Cardiovascular Disease/Hypertension		
Self-report having hypertension: Yes	33	36.67
Blood pressure *not* controlled (>140/90 mm Hg): Yes	27	81.82
Blood Pressure (for those *not* reporting having hypertension)		
Pre-hypertension (≥ 120/90 mm Hg.): Yes	3	5.3
Body Mass Index (BMI)		
Overweight (BMI ≥ 25 - <30 kg/m^2): Yes	35	38.89
Obese (BMI ≥ 30 kg/m^2): Yes	32	35.56
Fasting Blood Glucose (for those *not* reporting being diagnosed with pre-diabetes or diabetes)		
Pre-diabetes (100-125 mg/dL): Yes	20	28.57
Diabetes (>125 mg/dL): Yes	1	1.43
Dyslipidemia (abnormal cholesterol level)		
Self-report having dyslipidemia: Yes	47	52.22
Total cholesterol (> 200mg/dL): Yes	13	27.66
High density lipoprotein (HDL) (< 40mg/dL): Yes	16	34.0
Triglycerides (> 150mg/dL): Yes	16	34.0
Low density lipoprotein (LDL)		
Moderate risk (<130 mg/dL): Yes	21	44.68
High risk (<100 mg/dL): Yes	9	19.15

Table 3 *Health Outcomes Measures of Patient Population (N=90), cont.*

Characteristic	**N**	**%**
Depression/Anxiety		
Self-report having depression/anxiety: Yes	25	27.78
Evidence of depression (≥ 50 Zung score): Yes	5	20.0
Less adherence to medication regimen (≤3 Morisky score)	19	21.11
Need for patient education (assessed by interview)	90	100.0
Proper use of medication	85	94.44
Medication adherence	58	64.44
Disease state management	71	78.89
Use of monitoring devices	15	16.67
Patient self-care	51	56.67
Lifestyle changes	80	88.89
Sub-optimal medication regimen (assessed by interview)	75	83.33
Unnecessary therapy: Yes	3	4.0
Ineffective drug: Yes	2	2.67
Excessive dose/duration: Yes	5	6.67
Insufficient dose/duration: Yes	13	17.33
Excessive use of drug: Yes	2	2.67
Under use of drug: Yes	9	12.0
Adverse events: Yes	4	5.33
Need for drug information: Yes	2	2.67
Requires additional lab monitoring: Yes	5	6.67
Ineffective administration technique: Yes	19	25.33
Additional therapy needed: Yes	21	28.0
Ineffective drug option (cost): Yes	35	46.67

Analysis of Research Questions by Specific Aims

As presented in Chapter 1, this study was guided by one research question, which was operationalized as three specific aims with corresponding hypotheses. The following section will present the analysis for each of these three specific aims.

Specific Aim Number One

1. To evaluate the association of health literacy with the following demographic factors: gender, race, age, and level of education.

H_{1a}: Limited health literacy is associated with higher age and lower levels of education.

H_{1b}: Limited health literacy is not associated with gender or race.

The health literacy level of the participants was measured using the previously described instrument, The Newest Vital Sign. For this study, patients were categorized by having *limited* health literacy (scoring 0-3 on The Newest Vital Sign) or having *adequate* health literacy (scoring 4-6). Looking at the population as a whole, 11.11% (N=10) had limited health literacy, with the remaining 88.89 % (N=80) demonstrating scores of adequate health literacy.

Of the women in the study (N=52), three (5.76%) had limited health literacy, while 49 (94.24%) had adequate health literacy. For the males in the study (N=38), seven (18.42%) had limited health literacy, while 31 (81.58%) had adequate health literacy. The difference in proportions in the two groups was significant at the $p<0.05$ level ($p=0.049$).

When analyzed by race, of the nine participants who self-identified as African Americans, 33.33% had limited health literacy, while six (66.77%) had adequate health literacy. Caucasians represented 87.77% (N=79) of the study population; of this group, 8.86% (N=7) had

limited health literacy, while 91.14% (N=72) had adequate health literacy. (Because of the potential for loss of confidentiality when N<6, Hispanic participants were excluded from this analysis.) Limited health literacy among African Americans and Caucasians was not found to be statistically significant.

When analyzed by age, those between the ages of 20-29 years (N=4), and 30-39 (N=10), all (100%) had adequate health literacy. For the group 40-49 years of age (N=27), 3.70% had limited health literacy; 96.30% had scores indicating adequate health literacy. For those 50-59 years of age (N=25), 12.0% had limited health literacy, while 88.0% had adequate health literacy. For participants between the ages of 60-69 years (N=18), 22.22% had limited health literacy and 77.78% had adequate health literacy. Because of the potential for loss of confidentiality when n<6, those 70 and older were excluded. When analyzed by groups of ten years, age was not found to be statistically significant.

When considering the years of formal education, for those who had completed high school (N=8; 8.9%), 50% had limited health literacy and 50% had scores indicating adequate health literacy. For those with some college (N=10; 11.1%), all (100%) had adequate health literacy. Participants with a bachelors degree (N=28; 31.1%) were divided between 10.71% having limited health literacy and 89.29% having adequate health literacy. Of those with a masters degree (N=23; 25.6%) 4.34% had limited and 95.56% had adequate health literacy. For those having a doctoral degree (the highest education level of the group), 9.52% had scores indicating limited health literacy, while 90.48% had adequate health literacy. Among these groups, there was a significant association between education level and limited health literacy (p=0.024). A summary of these findings can be found in Table 4 below.

Table 4. Characteristics of Study Population by Health Literacy Level (N = 90)

Characteristics of Study Population by Health Literacy Level (N = 90)

Characteristic	Limited Health Literacy Score 0- 3 (N)	Adequate Health Literacy Score 4- 6 (N)	N (Total)	**%** Having Limited Health Literacy	Test Statistic*	Significance**
Total Population	10	80	90	11.11	Not Applicable	
Gender						
Female	3	49	52	5.76	X^2 (7.00)	0.049
Male	7	31	38	18.42		
Race						
African American	3	6	9	33.33	LR (4.04)	0.133
Caucasian	7	72	79	8.86		
Hispanic	***	***	***	***		
Age entering study (years)						
20 - 29	0	4	4	0	LR (8.91)	0.113
30 - 39	0	10	10	0		
40 - 49	1	26	27	3.70		
50 -59	3	22	25	12.0		
60 -69	4	14	18	22.22		
70+	***	***	***	***		

Table 4 *Characteristics of Study Population by Health Literacy Level (N = 90), cont.*

Characteristic	Limited Health Literacy Score 0 – 3 (N)	Adequate Health Literacy Score 4 – 6 (N)	N (Total)	**%** Having Limited Health Literacy	Test Statistic *	Significance**
Highest education level completed at entry of study						
High School	4	4	8	50.0	LR (11.20)	0.024
Some College	0	10	10	0		
Bachelor Degree	3	25	28	10.71		
Masters Degree	1	22	23	4.34		
Doctoral Degree	2	21	21	9.52		

Note(s): *Test statistic is either the X^2 (Chi-squared Test of Association) or the LR (Likelihood Ratio); Fisher's Exact Test (2-sided) used when assumptions for Chi-squared Test were violated.

** Tested at the 95% level (p-value <0.05)

*** Results suppressed due to having fewer than 6 individuals in a socio-demographic cell.

A separate analysis was done to understand the relationship between limited health literacy and age. Participants were stratified by age into two groups: those who <50 years of age (N=43) and those ≥50 years of age (N=43) (with ages for four participants were missing from the data). For those who were <50, only 2.3% had limited health literacy. For those who were ≥ 50 years, 18.6 % had limited health literacy. With these two groups, there was a significant association between age and limited health literacy (X^2 =6.08; p-value= 0.02). Figure 4 illustrates health literacy scores by those <50 and those ≥ 50 years of age.

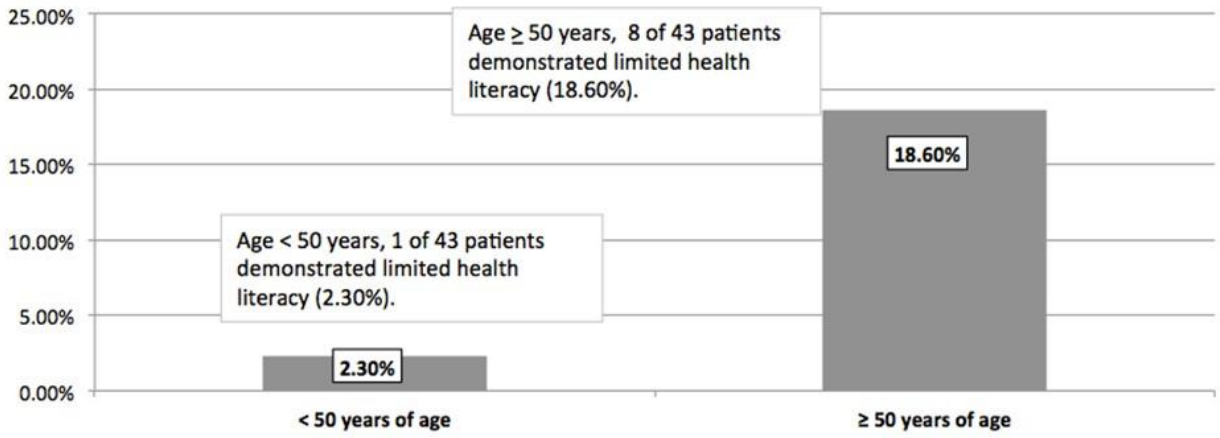

Figure 4. Limited Health Literacy by Age Group

Specific Aim Number Two

2. To evaluate the association of health literacy with clinical outcomes of patients with asthma, diabetes mellitus, cardiovascular disease, and depression.

H_{2a}: Limited health literacy is associated with clinical outcomes of asthma, diabetes mellitus, cardiovascular disease, and depression/anxiety.

H_{2b}: Limited health literacy is associated with higher body mass index (BMI), higher blood pressure, higher fasting blood glucose levels, and dyslipidemia.

H_{2c}: Limited health literacy is associated with lower medication adherence.

H_{2d}: Limited health literacy is associated with the need for patient education.

H_{2e}: Limited health literacy is associated with sub-optimal medication regimens.

Asthma

Of those participants in the study who reported being diagnosed with asthma (N=12), two (16.67%) had limited health literacy, while ten (83.33%) had adequate health literacy. These same patients were administered the Asthma Control Test. Of the asthma patients who scored ≤19 points on the Asthma Control Test (indicating that their asthma may not be

controlled) (N=9), two (22.22%) had limited health literacy and seven (77.78%) had adequate health literacy. There was no association found among either group with regard to health literacy levels.

Diabetes Mellitus

Of the total population, 11 patients self-reported having been diagnosed with pre-diabetes (12.22%); one person of this group (9.09%) had limited health literacy. Nine participants (10.0%) of the study reported being diagnosed with type 1 or type 2 diabetes. Of those having type 1 or type 2 diabetes 11.11% (N=1) had limited health literacy. There was no association found between limited health literacy and being diagnosed with either pre-diabetes or type 1 or type 2 diabetes mellitus.

Those patients who reported being diagnosed with type 1 or type 2 diabetes were administered blood glucose and LDL cholesterol tests. Of the five patients whose blood glucose was *not* within optimal range (>70 - <130 mg/dL), all (100%) had adequate health literacy. Similarly, of those five patients whose LDL was *not* within optimal range (>70 - < 100 mg/dL), all (100%) had adequate health literacy.

Cardiovascular Disease/Hypertension

As stated above, over a third of the participants (N=33; 36.67%) reported having been diagnosed with hypertension. Of those 33 participants, 18.18% (N=6) had limited health literacy. To help gauge whether their blood pressure was under control, blood pressure readings were taken of these 33 patients; it was found that 27 (81.82%) did not have their blood pressure under control (>140/90 mm Hg). Of this group of 27, the data revealed that 22.22% (N=6) had limited health literacy, while 77.78% had adequate health literacy levels.

Of those patients *not* reporting having being diagnosed with hypertension, blood pressure readings indicated that three participants (3.33%) had pre-hypertension ($\geq$ 120/90 mm Hg). All three of these participants (100%) had adequate health literacy. None of the groups mentioned in this *Cardiovascular Disease/Hypertension* section were statistically associated with limited health literacy.

Body Mass Index

A body mass index (BMI) was calculated for all participants in the study and 38.89% (N=35) of the participants had BMI's indicating that they were overweight (BMI $\geq$25 kg/m^2). Of this group, 14.28% (N=5) had limited health literacy, while the remaining 85.72% (N=30) had adequate health literacy scores. Of those whose BMI's indicated obesity (BMI $\geq$ 30 kg/m^2), 6.25% (N=32) had limited health literacy. Neither group showed a statistical association with health literacy.

Fasting Blood Glucose Levels for Patients NOT Self-Reporting Diagnosis of Pre-Diabetes or Type 1 or 2 Diabetes

All participants were administered a fasting blood glucose test, including those patients who did *not* report being diagnosed with pre-diabetes or type 1 or 2 diabetes mellitus. For patients not being diagnosed with diabetes mellitus, fasting blood glucose levels of 100-125 mg/dL indicate pre-diabetes, and fasting blood glucose levels of $\geq$ 125 suggests diabetes. For those participants that did not report being diagnosed with either pre-diabetes or diabetes, 20 (28.57%) had fasting blood glucose levels indicating pre-diabetes. Of this group 15.0% (N=3) had limited health literacy. One patient (1.43%) had a blood glucose level indicating diabetes mellitus and this person's score on the Newest Vital Sign showed adequate health literacy. No associations were found among these groups and health literacy scores.

Dyslipidemia

In this study, 47 participants (52.22%) reported having been diagnosed with dyslipidemia; 8.51% of these (N=4) had limited health literacy, while 91.49% had adequate health literacy. Of these 47 patients, 13 (27.66%) had higher than normal total cholesterol levels and 15.38% of these patients (N=2) had limited health literacy. Of this same group of 47, 16 (34.0%) had both sub-optimal HDL levels and higher than normal triglycerides. For those with sub-optimal HDL levels and higher than normal triglycerides, 6.25% (N=1) had limited health literacy.

Again, of the same group of 47 participants reporting being diagnosed with dyslipidemia, 21 patients (44.68%) had LDL levels indicating having *moderate* risk for heart disease; 9.52% of those (N=2) had limited health literacy. Finally, those in this group showing *high* risk for cardiovascular disease (LDL <100 mg/dL) (N=9), all had scores indicating adequate health literacy. No associations were found among these groups and health literacy scores.

Depression/Anxiety

Of the 90 participants, 27.8% (N=25) reported having being diagnosed with depression or anxiety. Only one of these patients (4.0%) was found to have limited health literacy. Of these 25 patients, five (20%) scored $\geq$ 50 points on the Zung Self-Rating Depression Scale indicating the presence of depression. All five of these members had adequate health literacy.

Adherence

All participants in the study were administered Modified Morisky Adherence Scale to help determine how adherent they were with their medication regimen. Of the 90 participants in the study—all of whom were taking at least one medication—19 (21.11%) had scores $\leq$ 19

points on the scale, indicating sub-optimal adherence. Of this group, 5.26% (N=1) had limited health literacy, the remaining 94.74% (N=18) had scores $\geq$ 4 on the Newest Vital Sign indicating adequate health literacy.

Need for Patient Education

As mentioned above, patient interviews were conducted to help identify specific areas in which patients needed education, including issues involving their drug regimens and lifestyle. All participants (N=90; 100%) needed some form of patient education. Eighty-five participants (94.44%) needed education on the proper use of their medication; it was found that 9.41% (N=8) of these patients had limited health literacy. Of those patients who could benefit from education on self-care (i.e. non-medication related improvements, like avoiding problematic foods) (N=51), 11.76% (N=6) had limited health literacy scores.

For those needing education on medication adherence (N=58; 64.44%), 12.07% (N=7) had limited health literacy. Of the population who could benefit from education on improved use of health monitoring devices (N=15;16.67%), one person (6.67%) had limited health literacy. Seventy-one (78.89%) of the participants needed education on disease state management (e.g. seeking regular laboratory tests, monitoring blood pressure). Of this group, 11.26% (N=8) had scores indicating limited health literacy.

The last category of the need for education was on lifestyle changes, including need for additional physical exercise and/or weight loss. Eighty-eight participants in the study (88.89%) needed assistance in this area. Of these 88, the data revealed that 12.50% (N=10) of them had limited health literacy, while the remaining 87.50% had scores on the Newest Vital Sign

indicating adequate health literacy. Of all of these sub-groups within *Need for Patient Education*, no statistical significance was found with limited health literacy scores.

Identification of Sub-Optimal Drug Regimens

Patient interviews also conducted as a part of this medication therapy management study helped identify specific problems with patients' medication regimens, with these problems being labeled "sub-optimal drug regimens." Patient interviews revealed that 75 study participants (83.33%) had some type of sub-optimal drug issue. The sub-optimal drug regimen area was broken down into 12 categories.

Of these 75 patients having sub-optimal drug regimens, three participants (4.0%) were taking unnecessary medications, and 33.33% (N=1) of this group had limited health literacy. Two participants (2.67%) were prescribed ineffective medications; both had adequate health literacy. With regard to dose and duration of drug therapy, five participants (6.67%) had drug regimens of *excessive* dose/duration,; all had adequate health literacy. On the other hand, 13 (17.33%) patients had drug regimens involving *insufficient* dose or duration, of which one (7.69%) had limited health literacy.

Two of the patients (2.67%) were found taking excessive amounts of their medication(s); both patients had adequate health literacy scores. Of the nine patients (12.0%) who were under utilizing their medication, 11.11% (N=1) had limited health literacy. Four patients (5.33%) reported adverse events relating to their drug regimens and two patients (N=4; 2.67%) needed additional information on their medications. Of both these groups, 50% had limited health literacy (N=2 and N=1, respectively). The study found that five patients

(6.67%) needed additional or follow-up laboratory monitoring, of which 40% (N=2) had limited health literacy levels.

Further, of the 75 patients with sub-optimal drug regimens, 25.33% (N=19) were found to have exhibited ineffective administration of their medication, with 5.26% (N=1) demonstrating limited health literacy. Twenty-one patients (28.0%) were found to be in need of additional medications; 9.52% (N=2) of this group had limited health literacy. Finally, 46.67% (N=35) were prescribed medication(s) for which there was a more cost effective (cheaper) option. Of these 35 patients, 2.86% (N=1) had scores showing limited health literacy.

Of all of these sub-groups within this *Sub-Optimal Medication Regimen* section, no statistical significance was found with limited health literacy.

Summary of Aim Number Two

Limited health literacy was not found to be associated with any of the variables analyzed in *Aim Number Two*: clinical outcomes of asthma, diabetes, mellitus, cardiovascular disease/hypertension, and depression/anxiety; higher body mass index (BMI), higher blood pressure, higher fasting blood glucose levels, and dyslipidemia; lower medication adherence; the need for patient education; and sub-optimal medication regimens. A summary of these findings can be found in Table 5, below.

Table 5. Health Outcome Measure of Study Sample by Health Literacy Level (N = 90)

Table 5 *Health Outcome Measures of Study Sample by Health Literacy Level (N = 90)*

Characteristic	Limited Health Literacy Score 0-3 (N)	Adequate Health Literacy Score 4-6 (N)	N (Total)	% Having Limited Health Literacy	Test Statistic*	Significance**
Asthma						
Self-reporting having asthma: Yes	2	10	12	16.67	X^2(0.433)	0.617
Asthma not controlled (≤ 19 Asthma Control Score): Yes	2	7	9	22.22	X^2 (1.250)	0.261
Diabetes Mellitus						
Self-report having pre-diabetes	1	10	11	9.09	X^2 (0.052)	1.000
Self-report having type 1 or type 2 diabetes: Yes	1	8	9	11.11	X^2 (0.000)	1.000
Blood glucose level not within optimal range (> 70 and < 130 mg/dL): Yes	0	5	5	0	X^2 (1.406)	0.444
Low density lipoprotein not within optimal range (LDL) (> 70 and < 100 mg/dL): Yes	0	5	5	0	X^2 (1.406)	0.444
Cardiovascular Disease/Hypertension						
Self-report having hypertension: Yes	6	27	33	18.18	X^2 (2.638)	0.162
Blood pressure *not* controlled (>140/90 mm Hg): Yes	6	26	27	22.22	X^2 (2.934)	0.157
Blood Pressure (for those not reporting a diagnosis of hypertension)						
Pre-Hypertension (≥ 120/90 mm Hg): Yes	0	3	3	0	X^2 (0.000)	1.000

Table 5: *Health Outcome Measures of Study Sample by Health Literacy Level (N = 90), cont.*

Characteristic	Limited Health Literacy Score 0-3 (N)	Adequate Health Literacy Score 4-6 (N)	N (Total)	% Having Limited Health Literacy	Test Statistic*	Significance**
Body Mass Index (BMI)						
Overweight (BMI $\geq$ 25 & < 30 kg/m^2): Yes	5	30	35	14.28	LR (1.307)	0.520
Obese (BMI $\geq$ 30 kg/m^2): Yes	2	30	32	6.25		
Fasting Blood Glucose (for those *not* reporting a diagnosis of pre-diabetes, or diabetes)						
Pre-Diabetes (100 - 125 mg/dL)	3	17	20	15.0	LR (0.523)	0.770
Diabetes (> 125 mg/dL)	0	1	1	0		
Dyslipidemia						
Self-report of dyslipidemia: Yes	4	43	47	8.51	X^2 (0.674)	0.510
Tot Cholesterol (> 200 mg/dL): Yes	2	11	13	15.38	X^2 (1.091)	0.304
HDL (< 40mg/dL): Yes	1	15	16	6.25	X^2 (0.159)	1.000
Triglycerides (> 150 mg/dL): Yes	1	15	16	6.25	X^2 (0.159)	1.000
LDL						
Moderate Risk (<130 mg/dL): Yes	2	19	21	9.52	X^2 (0.050)	1.000
High Risk (<100 mg/dL): Yes	0	9	9	0	X^2 (1.035)	0.574
Depression						
Self-report having depression: Yes	1	24	25	4.0	X^2 (1.772)	0.273
Evidence of depression ($\geq$ 50 Zung Depr'n Scale)	0	5	5	0	X^2 (0.662)	1.000

Table 5: *Health Outcome Measures of Study Sample by Health Literacy Level (N = 90), cont.*

Characteristic	Limited Health Literacy Score 0-3 (N)	Adequate Health Literacy Score 4-6 (N)	N (Total)	% Having Limited Health Literacy	Test Statistic*	Significance**
Less adherence to medication regimen (≤ 3 Mod-Morisky)	1	18	19	5.26	X^2 (0.834)	0.682
Need for patient education	10	80	90	11.11	X^2 (0.000)	1.000
Proper use of medication	8	77	85	9.41	X^2 (4.47)	0.930
Patient self-care	6	45	51	11.76	X^2 (0.051)	1.000
Medication adherence	7	51	58	12.07	X^2 (0.152)	1.000
Use of monitoring devices	1	14	15	6.66	X^2 (0.360)	1.000
Disease state management	8	63	71	11.26	X^2 (0.000)	1.000
Lifestyle changes	10	70	80	12.50	X^2 (1.406)	0.595
Sub-optimal medication regimen	7	68	75	9.33	X^2 (1.440)	0.361
Unnecessary drug therapy: Yes	1	2	3	33.33	X^2 (1.552)	0.301
Ineffective drug: Yes	0	2	2	0	X^2 (0.256)	1.000
Excessive dose/duration: Yes	0	5	5	0	X^2 (0.662)	1.000
Insufficient dose/duration: Yes	1	12	13	7.69	X^2 (0.180)	1.000
Excessive use of drug: Yes	0	2	2	0	X^2 (0.256)	0.613
Under use of drug: Yes	1	8	9	11.11	X^2 (0.000)	1.000
Adverse events: Yes	2	2	4	50.0	X^2 (6.410)	0.059
Need for drug information: Yes	1	1	2	50.0	X^2 (3.132)	0.211
Requires lab monitoring: Yes	2	3	5	40.0	X^2 (4.474)	0.093
Ineffective admin. technique: Yes	1	17	19	5.26	X^2 (0.008)	1.000
Additional drug therapy needed: Yes	2	19	21	9.52	X^2 (0.070)	1.000
Ineffective drug option (cost): Yes	1	34	35	2.86	X^2 (3.951)	0.082

Note(s): ***:** Test statistic is either the X2 (Chi-squared Test of Association) or the LR (Likelihood Ratio). Fisher's Exact Test (2-sided) used when assumptions for Chi-squared Test were violated.
**: Tested at the 95% level (p-value < 0.05).

Specific Aim Number Three

3. To construct a logistical regression model to determine independent predictors of health literacy from among the variables considered in research questions 1 and 2, above.

H_3: Each of the following will independently predict health literacy: gender, age, race, level of education, health outcomes of asthma, diabetes mellitus, cardiovascular disease, and depression/anxiety, lower medication adherence, increased need for patient education, and sub-optimal medication regimens.

A logistic regression model was constructed to assess potential predictors of health literacy. Candidate variables were entered into the regression model, then removed through backwards (conditional) step-wise regression. The variables that remained after the final step were: gender, age, education, self-reported diagnoses of asthma, hypertension and dyslipidemia. This final model was highly significant (-2LL = 28.596; $p < 0.001$) and significant variance explained (Nagelkerke $R^2 = 0.869$). All of these remaining variables were significant.

These findings can be found in Table 6.

Table 6. Logistic Regression

Logistic Regression

Model: Predictors of Limited Literacy (Score 0 - 3)[1,2,3]

Variable	β(SE)	95% CI for Odds Ratio Lower	Odds Ratio	Upper	Significance (p-value)
Gender	4.21(1.60)	2.970	67.628	1,539.77	0.008
Age (≥ 50)	4.43(1.79)	2.501	83.599	2,794.00	0.013
Education[4]	3.298(1.47)	1.515	27.069	483.767	0.025
Asthma	-5.76(1.61)	0.000	0.003	0.374	0.018
Hypertension	-3.48(1.52)	0.002	0.031	0.603	0.022
Dyslipidemia	2.64(0.93)	13.852	1.295	148.152	0.030

Notes:
1. Stepwise, backwards elimination (conditional), logistic regression model was completed. All variables were entered into the model with the remaining variables left after selection criteria were analyzed through 9 steps.
2. Model Assessment: -2LL = 28.596 (p-value < 0.001); Nagelkerke R^2 = 0.869.
3. Overall model correctly classifies limited literacy in 91.9% of cases.
4. Education was recoded to be dichotomous (Graduate Degree/ Less than Graduate Degree).

Summary

In this chapter, the statistical analysis for the study was presented. A description of the participants included socio-demographics of the population and health outcomes. Each of the three specific aims of the study were examined, including a regression analysis model setting forth the predictors of limited health literacy for the population. In the next chapter, these results will be discussed, along with the implications for future research and pharmacy education.

CHAPTER 5: DISCUSSION

Introduction

The purpose of this study was to examine the extent to which health literacy was associated with different demographic factors (e.g. gender, race, educational level) in a well-defined, self-insured population and to examine the extent to which health literacy was associated with clinical outcomes of those patients taking medications for certain chronic conditions. Other patients were identified through this MTM study with conditions that had previously gone undiagnosed.

The primary aim of this study was to test the hypothesis that health literacy, alone or in combination with other factors, was associated with certain clinical outcomes of patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety. Health outcomes were measured using: participants' self-report of diagnosis with a specific condition(s); physiological outcomes (e.g. blood pressure, body mass index, and fasting blood glucose); results of standardized self-reporting measures (e.g. Asthma Control Test, Zung Depression Scale); pharmacist-led patient interviews assessing the need for patient education (e.g. proper use of medication, use of monitoring devices); and pharmacist-led patient interviews identifying sub-optimal drug regimens (e.g. unnecessary drug therapy, additional medications needed).

The findings of this study will be used in the development of case studies for pharmacy education, supporting the inclusion of issues of health literacy into doctor of pharmacy (Pharm.D.) curriculum. To adequately prepare future pharmacists, colleges of pharmacy need to include training on the relationships between literacy and health (Youmans & Schillinger,

2003). Additionally, the findings of this study can help employers address issues associated with limited health literacy and chronic disease state management, thereby reducing healthcare costs and improving the health outcomes of their employees.

In this chapter, the findings of this investigation are discussed using the operationalization of study variables as an organizing framework. Conclusions drawn from the findings are presented, as are the implications for pharmacy education. Finally, the significance and limitations of the study are discussed and recommendations for future research are delineated.

Health Literacy and Socio-Demographics of Participants

Gender

Of the 90 participants in the study, there were slightly more women (57.78%) than men (42.22%). Of the men in the study, 18.42% had limited health literacy, scoring 0-3 on The Newest Vital Sign, while only 5.76% of the women in the study had similar scores. The difference in the proportion of these two groups was found to be statistically significant at the $p<.05$ level ($p=0.049$). When a logistical regression analysis was conducted for all variables in the study, gender was found to be a predictor of limited health literacy. These findings were consistent with at least one other study that showed an association between men and lower literacy levels (Davis, Wolf, Bass, Tilson, et al., 2006)

Though the scope of the study prevents explaining this circumstance fully, two potential explanations come to mind. First, in the U.S. women hold primary responsibility for family healthcare decisions, which might be a contributing factor in women participants' somewhat greater health literacy. Second, differences in limited health literacy scores between males and

females in this study may relate to the test instrument, The Newest Vital Sign. Although found to be a valid and reliable instrument, The Newest Vital Sign tests a participant's health literacy by having each participant answer certain questions while examining a nutrition label of an ice cream. As U.S. women do much of the food shopping, men may not be as accustomed to reading food nutrition labels, which reduces their health literacy scores.

Race

It was not surprising that in this study there were a higher number of Caucasians (87.78%) than any other racial group. This could be attributed to there being few African American or Hispanic faculty members and staff at the study institution.

Of the Caucasian population, 8.86% had scores indicating limited health literacy, while 33.33% of African Americans (N=3) had scores indicating limited heath literacy. (Health literacy scores for Hispanics were suppressed due to having fewer than six individuals in that socio-demographic category.) Race was not found to be statistically associated with limited health literacy. The logistical regression model constructed also supported the hypothesis that race would not be a predictor of health literacy in this study population.

Age

The average age of participants was 50 years, with ages ranging from 27 to 71 years. In the first analysis, participants in the study were grouped into ten-year categories. Within these ten-year categories, age was not found to be associated with limited health literacy. However, when ages were stratified into those who were <50 years of age and those $\geq$50 years of age, there was a significant association between age and limited health literacy (p-value= 0.02). This finding is in keeping with the general understanding that older patients are more likely to have

lower literacy skills (Kutner, et al., 2006) and that limited health literacy is more common in older people with chronic conditions, including hypertension, diabetes mellitus, obesity and depression (Sudore, et al., 2006). This finding also has importance as older Americans comprise an increasingly larger portion of the population and consume 2-3 times more medication than the general public (Davis, Wolf, Bass, Middlebrooks, et al., 2006). Given this, future pharmacists need to be aware of the association of health literacy and older patients, especially with those with chronic conditions.

Education

In looking at the data of this MTM study regarding education, for those patients whose highest level of formal education was high school, 50% had limited health literacy. This finding was in keeping with the general understanding that those patients with lower education attainment often have lower literacy.

For those participants in the study with some college (less than a bachelors degree), none had limited health literacy. For those with a bachelors degree, 10.71% had limited health literacy; of those with a masters degree, 4.34% had limited health literacy. Interestingly, for those having a doctoral degree, the number of patients with limited health literacy scores increased to 9.52%. This increase seems counterintuitive, but it is consistent with other studies showing years of higher education do not equate to literacy skill (Kirsch, Jungeblit, Jenkins, & al, 1993; Sudore, et al., 2006).

As stated earlier, there was a significant association between education level and health literacy. In the logistical regression model, education was found to be predictor of health

literacy in this study. These findings were in support of the pertinent parts of H_{1a} and H_3 stated in Chapter 1.

Health Literacy and Health Outcomes

Asthma

According to one study, the lifetime economic costs for all people born in the year 2000 who develop a diagnosis of asthma will be $7.2 billion, including $3.2 billion in medical costs and $4 billion in work/productivity loss (Corso & Fertig, 2009). Given the economic impact that asthma can have on both the patient and the workplace, asthma was included as one of the chronic conditions examined in this MTM study. Of the 90 participants, 13.33% reported being diagnosed with asthma, and of this group, 16.67% had limited health literacy.

When the Asthma Control Test was administered to patients diagnosed with asthma, 75% had scores indicating that their asthma was not as controlled as it could be. This percentage was higher than expected, perhaps indicating a need for patient education in the management of their disease. Of those with sub-optimal asthma control, 22.22% of patients had limited health literacy.

Although limited health literacy was not found to be associated with either asthma groups, when the logistical regression model was formulated, asthma did become a predictor of limited health literacy. This finding is in keeping with other studies that have shown associations between health literacy levels and asthma outcomes, including asthma control (Gazmararian, Williams, Peel, & Baker, 2003; Mancuso & Rincon, 2006). It is also important to note that ethnic differences in asthma prevalence, morbidity and mortality are highly

correlated with poverty, urban air quality and lack of patient education (Asthma and Allergy Foundation of America, 2011)

To help their patients with asthma better manage their condition, pharmacists are in a position to help with asthma education. Patient education can include helping patients identify those items that can trigger an asthmatic event, and reviewing patient education materials for readability and the inclusion of culturally sensitive content. The latter is especially true for pharmacists serving urban populations, as commonly used educational materials in these settings have been found to be written at higher grade levels and often do not contain ethnically -related information (Wilson, 1996).

Diabetes Mellitus

As stated earlier, given the complexity of managing diabetes mellitus, health outcomes for adults with diabetes mellitus are better for those who can optimally incorporate self-management of their diseases into their daily lives (Sigurdardottir, 2005). Diabetes care requires informed individuals who can seek, obtain, and comprehend information to engage in the management of their health (Morris, et al., 2006).

When entering the study, 12.22% reported having been diagnosed with pre-diabetes, and 10.0% reported having type 1 or type 2 diabetes mellitus. As part of this MTM study, fasting blood glucose tests were administered by pharmacists to all 90 participants. As a result of these fasting blood glucose tests, an additional 20 patients (28.57% of the population) were diagnosed with pre-diabetes, and one patient was newly diagnosed with type 2 diabetes. These results show the value of fasting blood glucose tests as a part of an MTM program in helping in the early detection of diabetes.

In addition, for those nine patients diagnosed with type 1 or type 2 diabetes mellitus, blood glucose and cholesterol tests were performed to determine if blood glucose levels and lipoproteins (LDL) were in optimal range. Of this group, 55.56% had results on both of these tests outside the optimal range. This is an important finding, as patients with diabetes mellitus should maintain proper blood glucose and LDL levels as a part of managing their chronic condition. Herein, too, lies an opportunity for pharmacists to better serve patient needs and improve health outcomes.

Cardiovascular Disease/Hypertension

Hypertension affects approximately 65 million people in the U.S. (Fields et al., 2004) and is a risk factor for congestive heart failure, stroke and renal disease (Neal, MacMahon, & Chapman, 2000). An important element in reducing the incidence of hypertension-related cardiovascular disease is to increase the number of people who maintain adequate blood pressure control (Bosworth, et al., 2005). In spite of effective drug therapies being available, only 37% of hypertensive patients maintain proper blood pressure levels (*Healthy people 2010: Understanding and improving health*, 2000).

In this study, 33 patients (36.66%) reported being diagnosed with hypertension. When these 33 patients had their blood pressure measured by pharmacists, 81.82% of these patients did *not* have adequate blood pressure control. This percentage (81.82%) is over two times higher than the national average. Of those patients *not* reporting being previously diagnosed with hypertension, blood pressure measurements indicated that three participants (3.33%) suffered from pre-hypertension ($\geq$ 120/90 mm Hg).

Regarding the health literacy of the patients in these categories, 18.18% of those reporting being diagnosed with hypertension had limited health literacy, and of the 27 hypertensive patients in the study whose blood pressure was less than optimal, the data revealed that 22.22% had limited health literacy. All three of the participants not previously diagnosed with hypertension had adequate health literacy. Although limited health literacy was not found to be statistically significant in those diagnosed with hypertension or those found to have pre-hypertension, in the logistic regression model, hypertension was found to be a predictor of limited health literacy.

Pharmacists are highly accessible healthcare professionals and as such, pharmacists have a unique opportunity to influence the health outcomes of patients with hypertension by playing a more active role in assisting hypertensive patients in the management of their disease (Santschi, Chiolero, Burnand, Colosimo, & Paradis, 2011). This would include monitoring the blood pressure of their patients, as well as (as we will see below) helping them achieve target cholesterol levels. This study underscores the importance of ensuring future pharmacists receive specific instruction in how to take blood pressure readings, along with administering and interpreting other laboratory tests. It also highlights the importance of the inclusion in pharmacy education of information concerning the relationship of limited health literacy and hypertension.

Dyslipidemia

Dyslipidemia is a condition marked by abnormal concentrations of lipoproteins (or lipids) in the blood. Dyslipidemia is often associated with diabetes mellitus and cardiovascular disease. For purposes of this study, dyslipidemia was determined by participants' self-report of

being diagnosed with dyslipidemia. The level of a patient's dyslipidemia was measured by the administration by pharmacists of a blood test measuring: triglycerides, total cholesterol (TC), high density lipoprotein (HDL), and low density lipoprotein (LDL) cholesterol.

In this study, over half of the participants (52.22%) reported having been diagnosed with, and taking medication for, dyslipidemia. Of these patients, 27.66% had higher than normal total cholesterol levels and 34.0% had both sub-optimal HDL levels and higher than normal triglycerides. 44.68% of this group had LDL levels indicating having *moderate* risk for cardiovascular disease and 19.15% had LDL levels indicating *high* risk for cardiovascular disease. These findings are in keeping with at least one other pharmacy-led study that indicated only a minority of patients with cardiovascular disease factors achieve targeted goals for LDL (Pearson, Laurora, Chu, & Kafonek, 2000).

When examining the prevalence of limited health literacy of these patients, only 8.51% of those patients diagnosed with dyslipidemia had limited health literacy. However, for those same patients in this group who had higher than normal total cholesterol levels, the prevalence of limited health literacy increased to 15.38%. For those among this group with sub-optimal HDL levels and higher than normal triglycerides, the number of those with limited health literacy was 6.25%. Of those having LDL levels showing a *moderate* risk of cardiovascular disease, 9.52% had limited health literacy levels, and interestingly, none of those who showed a *high* risk of cardiovascular disease had limited health literacy.

When taken individually none of these groups showed a statistically significant association with health literacy; however, when the logistical regression model was constructed, dyslipidemia was shown to be a predictor of health literacy.

Anxiety/Depression

Past studies examining the association of health literacy in patients with anxiety and depression have had varying results. Of the 90 participants in this study, 27.8% reported having being diagnosed with depression or anxiety and having been prescribed medication to treat their condition. To help gain an understanding of how effective their medication was in managing their condition, these patients completed the Zung Self-Rating Depression Scale. Of the 25 participants having been diagnosed with depression or anxiety, 20% scored $\geq$ 50 points on the Zung Self-Rating Depression Scale, indicating the presence of depression. This result suggests that, for most of the patients in the study diagnosed with anxiety or depression, their medication regimen seems to have been effective.

Need for Patient Education and Identification of Sub-Optimal Drug Regimens

As mentioned in Chapter 1, the Accreditation Council for Pharmacy Education revised its accreditation standards in 2006 to require that schools of pharmacy include training in the patient-centered pharmaceutical care model. These revisions were the result of a paradigm shift that has taken place in the profession as pharmacists seek to expand their role beyond the person responsible for the distribution of medicine. Although this role remains an important part of the activities of a pharmacist (as seen in this MTM study), increasingly, pharmacists are taking a more active role in the clinical care of their patients.

Today, pharmaceutical care includes working in concert with the patient and the patient's other healthcare providers (e.g. physicians, nurses, physician assistants) to promote better health, prevent disease, and in general, help improve health outcomes. This includes assessing the need for, and the provision of, appropriate patient education. It also involves

pharmacists assessing, monitoring, initiating, and modifying medications to help assure that drug therapy regimens are safe and effective. These activities are most aptly carried out as a part of an MTM program, specifically through pharmacist-lead patient interviews.

Need for Patient Education

As a part of this study, patient interviews were conducted to help identify specific areas in which patients needed education, including issues involving their drug regimens and lifestyle. A full 100% of the participants needed some form of patient education. More particularly, 94.44% needed education on the proper use of their medication and 56.66% could benefit from education on self-care (i.e. non-medication related improvements, like avoiding problematic foods).

Adherence is often described as the extent to which a person's behavior (e.g. taking medications) coincides with medical or health advice (Meichenbaum & Turk, 1987). Patient interviews revealed that 64.44% of all patients required assistance adhering to their medication regimen. As medication adherence is often problematic for patients with chronic conditions, a separate test (e.g. Modified Morisky Scale) was administered to those in the study. On this self-reported test, only 21.11% of the participants had scores indicating less than optimal drug adherence. The reason for these conflicting results is unknown, although it seems reasonable to consider that patient interviews may more accurately reflect patients' adherence rates.

It was also found that 16.67% of the population could benefit from education on improving the use of their health monitoring devices, while 78.89% of the participants needed education on disease state management (e.g. seeking regular laboratory tests, monitoring blood pressure). The last educational category was the need for information on lifestyle

changes, which included suggestions for additional physical exercise and/or weight loss. The data showed that 88.89% of the participants needed additional help in this area. Importantly, many of these recommended changes could be implemented by patients without physician approval.

The above findings were in keeping with Body Mass Index (BMI) calculations, which revealed that 74.45% of the total population was either overweight or obese. Obesity remains an important concern of healthcare professionals as it can lead to chronic diseases such as diabetes mellitus and hypertension.

However, neither the general category of the need for patient education nor any of its sub-groups had a statically significant association with health literacy. BMI calculations also were not associated with health literacy. None of these areas were found to be predictors of health literacy in the logistical regression model.

Identification of Sub-Optimal Drug Regimens

Patient interviews were also conducted as a part of this MTM study to help pharmacists identify specific problems concerning patients' medication regimens. The 1995 landmark study conducted by Johnson and Bootman projected that healthcare costs associated with drug therapy problems was projected to be $76.6 billion (Johnson & Bootman, 1995). In 2001 when the study was updated, projected costs associated with drug therapy problems had increased to $177.6 billion (Ernst & Grizzle, 2001). In this regard, MTM programs have proven to be very helpful, as pharmacists can play a valuable role in identifying drug problems and increasing medication safety, thereby substantially reducing healthcare costs.

In this study, pharmacist-led interviews revealed that 83.33% of patients had sub-optimal drug regimens. For purposes of analysis, the sub-optimal drug regimen category was broken down into 12 different types of drug-related issues. The prevalence of these 12 issues are described below.

Of these 75 patients who had sub-optimal drug regimens, 4.0% were taking unnecessary medications, and 2.67% were prescribed ineffective medications. 6.67% had drug regimens of *excess* dose or duration, while 17.33% of the patients had drug regimens involving *insufficient* dose or duration. 2.67% were found taking excessive amounts of medications, while 12.0% were underutilizing their medications. 5.33% of the patients reported adverse events relating to their drug regimens and 2.67% required additional drug information. The study also found that 6.67% of these patients needed additional or follow-up laboratory monitoring.

Although these issues involved smaller segments of the population, the identification of these problems provided an opportunity to significantly reduce the healthcare costs associated with medication-related complications at this self-insured university.

There were a few other important findings within this group. These include that 25.33% of the patients exhibited ineffective administration of their medication and 28.0% were found to be in need of additional medication therapy to help better manage their chronic condition(s). Finally, 46.67% were prescribed medication(s) for which there was a more cost effective (cheaper) medication option. As a part of this MTM program, patients had the option of having the pharmacist share this information with their physician, providing an opportunity for significant cost savings to both the patient and the institution.

With regard to health literacy, of all of these sub-groups within this sub-optimal medication regimen section, no statistical significance was found with health literacy, nor were the sub-groups found to be a predictor of health literacy in the logistical regression model.

Limitations and Strengths of Study

Several limitations of this study should be considered. First, these data reflect the results of one MTM study, conducted as a part of health wellness program at a small mid-western university. It is possible that different findings could be found from a broader selection of study sites, especially those with more diverse patient populations. The second limitation was the number of the participants. Having only 90 patients taking part in the study limited definitive conclusions. A third limitation was the study's design. As it was a cross-sectional study, it provided information about the associations of limited health literacy and certain chronic diseases, but did not address causality. Therefore, such inferences must be made with caution.

Despite these limitations, this study has significance. Numerous medical studies have examined health literacy as it relates to health outcomes for patients with chronic conditions. Additionally, many pharmacist-led MTM studies have examined the effectiveness of MTM programs aimed at improving the health outcomes of these same patients. However, what makes this study unique is the *inclusion* of health literacy assessment as a part of a MTM study. Despite being delineated as a part of the American Pharmacists Association and National Association of Drug Stores Foundation's MTM model framework, health literacy remains a relatively under-explored area in pharmacist-led MTM studies. This study contributes to our understanding in this important area.

This study also suggests that to be fully effective in their expanding roles, pharmacists need to be aware of the health literacy levels of their patients, especially those pharmacists more actively assisting in health care of patients with chronic conditions. Finally, as future healthcare professionals, pharmacy students should receive instruction on the relationships of health literacy and health outcomes, including the importance of the inclusion of health literacy assessment as part of a comprehensive medication therapy management program.

Implications for Future Research

Based on this study, several recommendations for future research can be made. This MTM study involved only one location which had a homogeneous population. Other MTM studies should be conducted which assess the health literacy of participants, especially those involving more diverse populations. If possible, data from this MTM study site should be aggregated with other MTM studies. Further exploration of the differences in limited health literacy between women and men in these programs would also be beneficial.

As there was a six-month follow-up visit for patients in this study, assessments should be made to determine if the interventions of this pharmacist-led program resulted in improvements in the health outcomes of the participants. Financial savings associated with the recommended changes in drug therapies should also be examined, as it would be difficult to imagine that there would be none following these pharmacist-led interventions.

Calculating both the costs associated in implementing this MTM program and the fair market value of the laboratory tests conducted by the pharmacists would also be useful. These items would help demonstrate the cost effectiveness and value added for MTM programs, especially for self-insured entities. These analyses could then be shared with doctor of

pharmacy students, arming the students with the necessary data to assist them in effectuating changes in the delivery of health care, especially for patients with chronic diseases.

APPENDIX A:

WAYNE STATE UNIVERSITY'S EXCEPTION LETTER

WAYNE STATE UNIVERSITY

IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
http://irb.wayne.edu

CONCURRENCE OF EXEMPTION

To: Jason Range
Teacher Education
350 North Meridian

From: Virginia Delaney-Black, M.D., M.P.H. or designee D. Kusch MSA (RMP)
Chairperson, Medical/Pediatric Institutional Review Board (MP4)

Date: June 17, 2011

RE: IRB #: 055511MP4X

Protocol Title: Assessment of Health Literacy as a Part of a University Medication Therapy Management Program for Patients with Chronic Conditions

Funding Source:

Protocol #: 1105009729

Expiration Date:

The above-referenced protocol has been reviewed and found to qualify for **Exemption** according to paragraph #4 of the Department of Health and Human Services Code of Federal Regulations [45 CFR 46.101(b)].

- Medical Exemption Form (received 05/11/2011)
- Receipt of research protocol (received 05/11/2011)
- Receipt of HIPAA Summary Form (dated 05/08/2011)

This proposal has not been evaluated for scientific merit, except to weight the risk to the human subjects in relation to the potential benefits.

Exempt protocols do not require annual review by the IRB.

All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.

Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (http://irb.wayne.edu/policies-human-research.php).

NOTE:

1. Forms should be downloaded from the IRB Administration Office website at each use.
2. Submit a Closure Form to the IRB Administration Office upon completion of the study.

APPENDIX B:

BUTLER UNIVERSITY'S INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

BUTLER UNIVERSITY

Institute for Research and Scholarship

4600 Sunset Avenue
Indianapolis, Indiana 46208-3485
(317) 940-9766
Fax: (317) 940-9074
E-mail: birs@butler.edu
Web: http://www.butler.edu/birs

INSTITUTIONAL REVIEW BOARD

August 28, 2008

Ms. Lindsay Saum, Ms. Pamela Burcham, Ms. Christy Pelych
3821 Gable Lane Dr. Apt. 435
Indianapolis, IN 46228

RE: IRB Protocol: Medication Therapy management and Health Literacy Assessment through Healthy Horizons the "Manage My Medications" Study

Dear Ms. Saum, Burcham and Pelych:

On behalf of the Institutional Review Board (IRB), I am pleased to announce that your application for research involving human subjects was approved as expedited on August 26, 2008. Your research has been approved for the time frame of October 1, 2008 to June 1, 2009. Federal regulations require that the IRB provide approval of one year (365 days) or less. At the end of this time frame, please send a brief written report to the IRB stating the total number of subjects employed in this study and the date that you completed your data collection. If your time frame covers more than one year, you should submit a request for a continuation of the study and a report at least annually until the research has been completed, after which you will submit a final report.

It is the responsibility of the Primary Investigator (P.I.) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any unusual incidents that occurred in data collection that differed from your expectations and planned protocol should be reported immediately to the Director of The Institute for Research and Scholarship (Director) (317-940-9766), if indicative of increased risk to subjects, and research should be suspended. You should also suspend research and report to the Director unanticipated negative reactions, either physical or emotional, that occur as a direct result of research participation. Other relevant parties and supervisors should be informed, as well.

Please note that your research is only approved for the time frame listed above. Any modifications to your protocol or any extension to the approval period must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project

May I offer my congratulations on your approval and wish you success on your research. Should you desire additional assistance or clarification, please call me at 9766.

Sincerely,

Robert Holm

Robert F. Holm, Ph.D.
Director, Institute for Research and Scholarship

Cc: C. Maffeo, B. Hancock, J. Gervasio

APPENDIX C:

BUTLER UNIVERSITY'S INSTITUTIONAL REVIEW BOARD CONTINUANCE LETTER

BUTLER UNIVERSITY

Institute for Research and Scholarship
4600 Sunset Avenue
Indianapolis, Indiana 46208-3485
(317) 940-9766
Fax: (317) 940-9074
Email: birs@butler.edu
Web: http://www.butler.edu/birs

January 12, 2010

Carrie Maffeo
COPHS

Dear Dr. Maffeo:

On behalf of the Institutional Review Board (IRB), I am pleased to announce that the revisions to your research involving human subjects entitled "Medication Therapy Management and Health Literacy Assessment through Healthy Horizons the "Manage My Medications" have been approved. The revisions are:

- Extending the approval period to December 31, 2010. (Please note that this extension extends the time frame of your study more than one year. As a result you should submit a report at least annually until the research has been completed, after which you should submit a final report.)

- The addition of the following investigators to your study:
  - Mr. Jason Range, COPHS
  - Dr. Iftekhar Kalsekar, COPHS

I offer my congratulations on your approval and wish you success on your research. Should you desire additional assistance or clarification, please call me at 9766.

Sincerely,

Robert Holm

Robert F. Holm, Ph.D.
Director, Institute for Research and Scholarship

IRB: EXPEDITED

APPENDIX D:

THE NEWEST VITAL SIGN

Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

The Newest Vital Sign™
A Health Literacy Assessment Tool

Score Sheet for the Newest Vital Sign Questions and Answers

READ TO SUBJECT: This information is on the back of a container of a pint of ice cream.

1. If you eat the entire container, how many calories will you eat?

   Answer: *1,000 is the only correct answer*

2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?

   Answer: *Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"*

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?

   Answer: *33 is the only correct answer*

4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?

   Answer: *10% is the only correct answer*

READ TO SUBJECT: Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream?

   Answer: *No*

6. (Ask only if the patient responds "no" to question 5): Why not?

   Answer: *Because it has peanut oil.*

ANSWER CORRECT?	
yes	no

Interpretation

Number of correct answers:

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.

Pfizer

January 2007

APPENDIX E:

HEALTH HORIZON'S DATA COLLECTION FORM

DATA COLLECTION

Demographics

Gender: □ Male □ Female DOB:_____ Age in years: _____

Ethnicity: □ Caucasian □ African American □ Asian □ Hispanic/Latino □Other_____

Highest Education level completed:

□ Some High School or less □ Graduated from High School □ Attended some College

□ Two Year Degree □ Four-Year Degree □ Masters Degree □ Doctorate Degree

Primary Language: □ English □ Spanish □ Other_____

Insurance Program: □ Butler Anthem □ Other

□ Butler Faculty/Staff □ Spouse/Domestic Partner

Number of prescriptions per month: Baseline:_____ Follow-Up: _____

Amount spent on prescription medications per month: Baseline_____ Follow-up:_____

Tobacco Use: □ Cigarettes □ Smokeless

Amount per day _____ Duration of use_____

Initial Visit:	**Performed by:**	
Visit Length	_____Minutes	
Medical Conditions	□ Asthma □ Heartburn/GERD □ Hypertension □ Depression □Anxiety □ Diabetes □ Hypothyroidism □ Dyslipidemia □ Other _____	
Assessments Done	□ Clinical (signs/symptoms) □ Drug Utilization (adherence, etc.) □ Lifestyle (Risk Factor Management, goals, health behaviors)	
Patient Education (check all that apply)	□ Medication □ Trigger Management □ Self Care □ Adherence □ Disease □ Use of Self Monitoring Device □ Lifestyle Changes	
Health Screening Results Initial Hours Fasting: _____	Triglycerides _____ Total cholesterol _____ HDL _____ LDL _____ Non-HDL _____ LDL goal _____ Glucose _____ HgbA1C _____ **Diabetes Risk Factors:** □ Over age 45 □ First degree relative with diabetes □ High risk ethnic groups □ History of gestational diabetes or baby weighing more than 9 pounds □ High blood pressure □ BMI>25 □ Physically inactive □ HDL cholesterol less than 35 □ History of pre-diabetes on a previous screening □ Polycystic ovarian syndrome □ Vascular disease Net DM risk factors _____	Your Heart History: □ Myocardial infarction □ Angina □ Angioplasty □ Peripheral Artery Disease □ Abdominal Aortic Aneurysm □ Diabetes □ Carotid Artery Disease **Cardiovascular Risk factors:** □ Cigarette smoker □ Hypertension □ Low HDL □ Family history of heart disease □ Age □ High HDL (>60) (neg one risk factor) Net Cardiovascular RF's _____ Height _____ Weight _____ BMI _____ % Body fat _____ Blood Pressure: _____/_____ Arm: R or L

Clinical Outcomes	□ **Asthma**: Assessment score: Pre:_____ Post:_____
	□ **Heartburn/GERD**: Improvement of Symptoms: Yes /No Pre:_____ Post:_____
	□ **Depression:** Zung Depression Assessment Score: Pre:_____ Post:_____
	□ **Hypothyroidism:** BASELINE: TSH: FOLLOW-UP: TSH

Morisky Scale Score: Pre:_____ Post:_____
Health Literacy Assessment Score: Pre:_____

Physician Follow-up Needed? □ Yes □ No If yes, Obtain Medical Release

Recommended test to be performed at follow up appointment:

	Test	Follow up Results
□	Cholesterol Panel	Hours Fasting:
	Triglycerides	
	Total Cholesterol	
	HDL	
	LDL	
	Non-HDL	
□	Glucose	
□	HgbA1C	
□	Blood Pressure: R or L	/
□	TSH	

Follow up Visit:	**Performed by:**
Visit Length	_____ Minutes

MEDICATIONS AT FOLLOW UP: List all Rx medications, OTC medications, vitamins & herbals

Medication	Dose	How do you take this medication	Monthly Co-Pay Amount

Drug/Medical Problem	Problems—Initial visit only		MD Consult	Result—Follow-Up visit only	
	□ Needs additional therapy	□ Unnecessary therapy	□ Yes	□ Drug added	□ Drug not added
	□ Drug interaction	□ Adverse effects	□ No	□ Drug discontinued	□ Drug changed
	□ Insufficient dose/duration	□ Excessive dose/duration		□ Interval changed	□ Improved Adherence
	□ Ineffective drug	□ Administration/technique		□ Dose changed	□ Administration improved
	□ More cost effective option	□ Excessive use		□ No Change	□ Therapeutic Success
	□ Underuse	□ Requires Medication Education		□ Other _____	
	□ Requires Health Education	□ Other _____		Intervention: _____	
	Recommendation: _____				
	□ Needs additional therapy	□ Unnecessary therapy	□ Yes	□ Drug added	□ Drug not added
	□ Drug interaction	□ Adverse effects	□ No	□ Drug discontinued	□ Drug changed
	□ Insufficient dose/duration	□ Excessive dose/duration		□ Interval changed	□ Improved Adherence
	□ Ineffective drug	□ Administration/technique		□ Dose changed	□ Administration improved
	□ More cost effective option	□ Excessive use		□ No change	□ Therapeutic Success
	□ Underuse	□ Requires Medication Education		□ Other _____	
	□ Requires Health Education	□ Other _____		Intervention: _____	
	Recommendation: _____				
	□ Needs additional therapy	□ Unnecessary therapy	□ Yes	□ Drug added	□ Drug not added
	□ Drug interaction	□ Adverse effects	□ No	□ Drug discontinued	□ Drug changed
	□ Insufficient dose/duration	□ Excessive dose/duration		□ Interval changed	□ Improved Adherence
	□ Ineffective drug	□ Administration/technique		□ Dose changed	□ Administration improved
	□ More cost effective option	□ Excessive use		□ No change	□ Therapeutic Success
	□ Underuse	□ Required Medication Education		□ Other _____	
	□ Requires Health Education	□ Other _____		Intervention: _____	
	Recommendation: _____				
	□ Needs additional therapy	□ Unnecessary therapy	□ Yes	□ Drug added	□ Drug not added
	□ Drug interaction	□ Adverse effects	□ No	□ Drug discontinued	□ Drug changed
	□ Insufficient dose/duration	□ Excessive dose/duration		□ Interval changed	□ Improved Adherence
	□ Ineffective drug	□ Administration/technique		□ Dose changed	□ Administration improved
	□ More cost effective option	□ Excessive use		□ No change	□ Therapeutic Success
	□ Underuse	□ Required Medication Education		□ Other _____	
	□ Requires Health Education	□ Other _____		Intervention: _____	
	Recommendation: _____				
	□ Needs additional therapy	□ Unnecessary therapy	□ Yes	□ Drug added	□ Drug not added
	□ Drug interaction	□ Adverse effects	□ No	□ Drug discontinued	□ Drug changed
	□ Insufficient dose/duration	□ Excessive dose/duration		□ Interval changed	□ Improved Adherence
	□ Ineffective drug	□ Administration/technique		□ Dose changed	□ Administration improved
	□ More cost effective option	□ Excessive use		□ No change	□ Therapeutic Success
	□ Underuse	□ Requires Medication Education		□ Other _____	
	□ Requires Health Education	□ Other _____		Intervention: _____	
	Recommendation: _____				

Pharmacists Notes at Initial Appointment	Pharmacists Notes at Follow-up Appointment

APPENDIX F:
ASTHMA CONTROL TEST

Asthma and Allergy Foundation of America
MICHIGAN CHAPTER

Take the Asthma Control Test™ now to help you better control your asthma

The American Lung Association recommends **everyone 12 years of age or older** with asthma take the Asthma Control Test, no matter how well controlled you think your asthma is.

Your answers to this 5-question quiz will provide you a score that may help you and your doctor discuss your treatment plan.

How to take the Asthma Control Test

Step 1. Write the number of each answer in the score box provided.
Step 2. Add up each score box for your total.
Step 3. Take the test to your doctor to talk about your total score.

1. In the past **4 weeks**, how much of the time did your **asthma** keep you from getting as much done at work, school or at home?

All of the time	Most of the time	Some of the time	A little of the time	None of the time	SCORE
1	2	3	4	5	

2. During the past **4 weeks**, how often have you had shortness of breath?

More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all	
1	2	3	4	5	

3. During the past **4 weeks**, how often did your **asthma** symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?

4 or more nights a week	2 or 3 nights a week	Once a week	Once or twice	Not at all	
1	2	3	4	5	

4. During the past **4 weeks**, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all	
1	2	3	4	5	

5. How would you rate your **asthma** control during the **past 4 weeks**?

Not controlled at all	Poorly controlled	Somewhat controlled	Well controlled	Completely controlled	
1	2	3	4	5	

AMERICAN LUNG ASSOCIATION.

The American Lung Association supports the Asthma Control Test™ and does not endorse products.

TOTAL

Copyright 2002, by QualityMetric Incorporated
Asthma Control Test is a trademark of QualityMetric Incorporated

expect more

When your asthma is controlled, you should expect to be **MORE** active and have **LESS** symptoms

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What does my score mean?

19 or less

- If your score is 19 or less, your asthma may not be controlled as well as it could be.
- Discuss your Asthma Control Test score with your doctor.
- Ask your doctor about daily long-term medications that can help control airway constriction and inflammation, the two main components of asthma. Many people need to treat both of these components of asthma on a daily basis for the best asthma control.

20 or more

- If you scored 20 or more, your asthma may be well controlled. You should still talk to your doctor about your results.
- Asthma is unpredictable. Your asthma symptoms may seem mild or nonexistent, but they can flare up at any time.
- Take the Asthma Control Test periodically no matter how good you feel, and continue to see your doctor on a regular basis to ensure you are taking the necessary steps to keep your asthma in control.

APPENDIX G:

ZUNG SELF – RATING DEPRESSION SCALE

KEY TO SCORING THE ZUNG SELF-RATING DEPRESSION SCALE

Consult this key for the value (1-4) that correlates with patients' responses to each statement. Add up the numbers for a total score. Most people with depression score between 50 and 69. The highest possible score is 80[1].

Make check mark (✓) in appropriate column.	A little of the time	Some of the time	Good part of the time	Most of the time
1. I feel down-hearted and blue	1	2	3	4
2. Morning is when I feel the best	4	3	2	1
3. I have crying spells or feel like it	1	2	3	4
4. I have trouble sleeping at night	1	2	3	4
5. I eat as much as I used to	4	3	2	1
6. I still enjoy sex	4	3	2	1
7. I notice that I am losing weight	1	2	3	4
8. I have trouble with constipation	1	2	3	4
9. My heart beats faster than usual	1	2	3	4
10. I get tired for no reason	1	2	3	4
11. My mind is as clear as it used to be	4	3	2	1
12. I find it easy to do the things I used to	4	3	2	1
13. I am restless and can't keep still	1	2	3	4
14. I feel hopeful about the future	4	3	2	1
15. I am more irritable than usual	1	2	3	4
16. I find it easy to make decisions	4	3	2	1
17. I feel that I am useful and needed	4	3	2	1
18. My life is pretty full	4	3	2	1
19. I feel that others would be better off if I were dead	1	2	3	4
20. I still enjoy the things I used to do	4	3	2	1

Adapted from Zung.[2]

References: 1. Carroll BJ, Fielding JM, Blashki TG. Depression rating scales: a critical review. *Arch Gen Psychiatry.* 1973; 28:361-366.
2. Zung WWK. A self-rating depression scale. *Arch Gen Psychiatry.* 1965;12:63-70.

Presented as a service by

GlaxoWellcome

Glaxo Wellcome Inc.
Research Triangle Park, NC 27709
Web site: www.glaxowellcome.com

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APPENDIX H:

MODIFIED MORISKY SCALE

Modified Morisky Scale

Question	Motivation	Knowledge
1. Do you ever forget to take your Medicine?	Yes(0) No(1)	
2. Are you careless at times about taking your medicine?	Yes(0) No(1)	
3. When you feel better do you sometimes stop taking your medicine?		Yes(0) No(1)
4. Sometimes if you feel worse when you take your medicine, do you stop taking it?		Yes(0) No(1)
5. Do you know the long-term benefit of taking your medicine as told to you by your doctor or pharmacist?		Yes(1) No(0)
6. Sometimes do you forget to refill your prescription medicine on time?	Yes(0) No(1)	
Score:		

REFERENCES

Academy of Managed Care Pharmacy. (2006). Sound medication therapy management programs: A 2006 consensus document. Alexandria, VA: Academy of Managed Care Pharmacy.

Accreditation Council for Pharmacy Education. (2011). Accreditation standards and guidelines for the professional program in pharmacy leading to the doctor of pharmacy degree. Chicago, IL: Accreditation Council for Pharmacy Education.

Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs. (1999). Health literacy: A report of the Council on Scientific Affairs. *Journal of the American Medical Association, 281*, 552-557.

American Lung Association Epidemiology and Statistics Unit Research and Scientific Affairs. (2004). Trends in asthma morbidity and mortality. Retrieved from www.lungusa.org website.

American Pharmacists Association, & National Association of Chain Drug Stores Foundation. (2005). Medication therapy management in community pharmacy practice: Core elements of an MTM service (version 1.0). *Journal of American Pharmacists Association, 45*, 573-579.

American Pharmacists Association, & National Association of Chain Drug Stores Foundation. (2008). Medication therapy management in pharmacy practice: Core elements of an MTM service model (version 2.0). *Journal of American Pharmacists Association, 48*(3), 341-352.

Anderson, G. (2010). Making the case for ongoing care. Retrieved from http://www.rwjf.org/files/research/50968chronic.care.chartbook.pdf.

Andrus, M. R., & Roth, M. T. (2002). Health literacy: A review. *Pharmcotherapy, 22*, 282-302.

Asthma and Allergy Foundation of America. (2011). Asthma facts and figures. Retrieved from http://aafa.org/display.cfm?id=8&sub=42.

Bains, S. S., & Egede, L. E. (2011). Associations between health literacy, diabetes knowledge, self-care behaviors, and glycemic control in a low income population with type 2 diabetes. *Diabetes Technology &Therapeutics, 13*(3), 335-341.

Baker, D. W., Gazmararian, J. A., Wlliams, M. V., Scott, T., Parker, R. M., Green, D., . . . Peel, J. (2002). Functional health literacy and the risk of hospital admission among Medicare managed care enrollees. *American Journal of Public Health, 92*(8), 1278-1283.

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Education Couselor, 38*, 33-42.

Bennett, I. M., Culhane, J. F., McCollum, K. F., & Mathew, M. S. (2007). Literacy and depressive symptomatology among pregnant Latinas with limited English proficiency. *American Journal of Orthopsychiatry, 77*(2), 243-248.

Berkman, N. D., DeWalt, D. A., Pignone, M. P., Sheridan, S. L., Lohr, K. N., Lux, L., . . . Bonito, A. J. (2004). *Literacy and health outcomes. Evidence report/Technology Assessment No. 87* (Vol. January). Rockville, MD: Agency for Healthcare Research and Quality.

Berkman, N. D., Sheridan, S. L., Donahue, K. E., Halpern, D. J., Viera, A., Crotty, K., . . . Viswanathan, M. (2011). Interventions and outcomes: An updated systematic review.

Evidence Report/Technology Assessment No. 199. Rockville, MD: Agency for Healthcare Research and Quality.

Bosworth, H. B., Olsen, M. K., Gentry, P., Orr, M., Dudley, T., McCant, F., & Oddone, E. Z. (2005). Nurse administered telephone intervention for blood pressure control: A patient-tailored multifactorial intervention. *Patient Education and Couseling, 57*(1), 5-14.

Brown, L. (2006). Low health literacy: What pharmacists can do to help. *Journal of American Pharmacists Association, 46*(1), 4-6.

Bunting, B. A., & Cranor, C. W. (2006). The Asheville Project: Long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. *Journal of American Pharmacists Association, 46*(2), 133-147.

Centers for Disease Control and Prevention. U.S. obesity trends 1985-2009. Retrieved from http://www.cdc.gov/obesity/data/trends.html.

Centers for Disease Control and Prevention. (2011). National diabetes fact sheet: National estimates and general information on diabetes and prediabetes in the United States, 2011. Retrieved from www.cdc.gov/diabetes/pubs/factsheet11.htm.

Cipolle, R. J., Strand, L. M., & Morley, P. C. (2004). *Pharmaceutical care practice: The clinician's guide (2nd ed.).* Columbus, OH: The McGraw-Hill Companies, Inc.

Coffman, M. J., & Norton, C. K. (2010). Demands of immigration, health literacy, and depression in recent Latino immigrants. *Home Health Care Management & Practice, 22*(2), 116-122.

Corso, P., & Fertig, A. (2009). The long-term economic costs of asthma. [Issue Paper #13] Partnership for America's Economic Success. Downloaded from http://www.partnershipforsuccess.org.

Cranor, C. W., Bunting, B. A., & Christensen, D. B. (2003). The Asheville Project: Long-term clinical and economic outcomes of a community pharmacy diabetes care program. *Journal of American Pharmacists Association, 43*(2), 173-190.

Davis, T. C., Long, S. W., Jackson, R. H., Mayeaux, E. J., George, R. B., Murphy, P. W., & Crouch, M. A. (1993). Rapid estimate of adult literacy in medicine: A shortened screening instrument. *Family Medicine, 25*(6), 391-395.

Davis, T. C., Wolf, M. S., Bass, P. F., Middlebrooks, M., Kennen, E., Baker, D. W., . . . Parker, R. M. (2006). Low literacy impairs comprehension of prescription drug labels. *Journal of General Internal Medicine, 21*(8), 847-851.

Davis, T. C., Wolf, M. S., Bass, P. F., Tilson, H., Neuberger, M., & Parker, R. M. (2006). Literacy and misunderstanding of prescription labels, *Annals of Internal Medicine, 145*(12), 887-894.

Donabedian, A. (1978). The quality of medical care. *Science, 200*(4344), 856-864.

Ernst, F. R., & Grizzle, A. G. (2001). Drug-related morbidity and mortality: Updating the cost-of-illness model. *Journal of the American Pharmacy Association, 41*, 192-199.

Fields, L. E., Burt, V. L., Cutler, J. A., Hughes, J., Roccella, E. J., & Sorlie, P. (2004). The burden of adult hypertension in the United States 1999-2000. *Hypertension, 44*(4), 398-404.

Garrett, D., & Bulmi, B. (2005). Patient self-management program for diabetes: First-year clinical, humanistic, and economic outcomes. *Journal of American Pharmacists Association, 45*(2), 130-137.

Gazmararian, J. A., Kripalani, S., Miller, M. J., Echt, K. V., Ren, J., & Rask, K. (2006). Factors associated with medication refill adherence in cardiovascular-related diseases. *Journal of General Internal Medicine, 21*(12), 1215-1221.

Gazmararian, J. A., Williams, M. V., Peel, J., & Baker, D. W. (2003). Health literacy and knowledge of chronic diseases. *Patient Education and Counseling, 51*, 267-275.

Healthy people 2010: Understanding and improving health. (2000). Washington, DC: U.S. Department of Health and Human Services.

Higby, G. J. (2010). *Social and behavioral aspects of pharmaceutical care (2nd ed.).* Sudbury, MA: Jones and Barlett.

Hogue, M. D., & Bluml, B. M. (Eds.). (2009). *The pharmacist's guide to compensation for MTM services*. Washington, DC: American Pharmacists Association.

Howard, D. H., Gazmararian, J. A., & Parker, R. M. (2005). The impact of low health literacy on the medical costs of Medicare managed care enrollees. *American Journal of Medicine, 118*(4), 371-377.

Johnson, J. A., & Bootman, J. l. (1995). Drug-related morbidity and mortality: A cost-of-illness model. *Archives of Internal Medicine, 155*, 1949-1956.

Kalichman, S. C., Pope, H., White, D., Cherry, C., Amaral, C. M., Swetzes, C., . . . Kalichman, M. O. (2008). Association between health literacy and HIV adherence: Further evidence from objectively measured medication adherence. *Journal of the International Association of Physicians in AIDS Care, 7*(6), 317-323.

Kalichman, S. C., Ramachandran, B., & Catz, S. (1999). Adherence to combination antiretroviral therapies in HIV patients of low health literacy. *Journal of General Internal Medicine, 14*(5), 267-273.

Kirsch, I., Jungeblit, A., Jenkins, L., & et al. (1993). *Adult literacy in America. A first look at the results of the National Adult Literacy Survey*. Princeton, NJ: National Center for Educational Statistics. Educational Testing Service.

Knapp-Dlugosz, C. (2008). Medication therapy management services: Opportunities for Pharmacists to improve medication adherence in patients with chronic obstructive pulmonary disease. Washington, DC: American Pharmacists Association.

Kripalani, S., Henderson, L. E., Chiu, E. Y., Robertson, R., Kolm, P., & Jacobson, T. A. (2006). Predictors of medication self-mangement skill in a lower-literacy population. *Journal of General Internal Medicine, 21*(8), 852-856.

Kutner, M., Greenberg, E., & Baer, J. (2006). A first look at the literacy of America's adults in the 21st century. Retrieved from http://eric.ed.gov/ERICWebPortal/detail?accno=ED489066

Lloyd-Jones, D. M., Hong, Y., Labarthe, D., Mozaffarian, L. J., Van Horn, L., Greenlund, K., . . . Rosamond, W. D. (2010). Defining and setting national goals for cardiovascular health promotion and disease reduction: The American Heart Association's strategic impact goal through 2020 and beyond. *Circulation, 121*, 586-613.

Mancuso, C. A., & Rincon, M. (2006). Impact of health literacy on longitudinal asthma outcomes. *Journal of General Internal Medicine, 21*(8), 813-817.

Mayer, G. G., & Villaire, M. (2007). *Health literacy in primary care: A clinician's guide*. New York, NY: Springer Publishing Company, LLC.

Meichenbaum, D., & Turk, D. C. (1987). *Facilitating treatment adherence: A practitioner's guidebook*. New York: Plenum.

Morisky, D. E., Green, L. W., & Levine, D. M. (1986). Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care, 24*(1), 67-74.

Morris, N. S., MacLean, C. D., & Littenberg, B. (2006). Literacy and health outcomes: A cross-sectional study in 1002 adults. *BMC Family Practice, 7*(49), doi: 10.11 1186/1471-2296-1187-1149.

Mullins, C. D., Baldwin, R., & Perfetto, E. M. (1996). What are outcomes? *Journal of the American Pharmaceutical Association, NS36*(1), 39-49.

Murphy, D. A., Lam, P., Naar-King, S., Harris, R. H., Parsons, J. T., & Muenz, L. R. (2010). Health literacy and antiretroviral adherence among HIV-infected adolescents. *Patient Education and Counseling, 79*(1), 25-29.

Murray, M. D., Young, J., Hoke, S., Wanzhu, T., Weiner, M. D., Morrow, D., . . . Brater, D.C. (2007). Pharmacist intervention to improve medication adherence in heart failure: A randomized trial. *Annals of Internal Medcine, 146*(10), 714-725.

Nathan, R. A., Sorkness, C.A., Kosinski, M.A., Schatz, M., Li, J.T., Marcus, P., Murray, J.J., Pendergraft, T.B. (2004). Development of the Asthma Control Test: A survey for assessing asthma control. *Journal of Allergy and Clinical Immunology, 113*(1), 59-65.

National Heart, Lung, and Blood Institute (US). (2007). *Expert panel report 3: Guidelines for the diagnosis and management of asthma* (Report No. 07-4051 ed.). Washington, DC: National Heart, Lung, and Blood Institute (US).

Neal, B., MacMahon, S., & Chapman, N. (2000). Effects of ACE inhibitors, calcium antagonists, and other blood-pressure-lowering drugs: Results of prospectively designed overviews of randomised trials. Blood Pressure Lowering Treatment Trialists' Collaboration. *Lancet, 356*(9246), 1955-1964.

Nielsen-Bohlman, L., Panzer, A. M., & Kindig, D. A. (2004). *Health literacy: A prescription to end confusion*. Washington, D.C.: National Academies Press.

Nokes, K. M., Coleman, C. L., Cashen, M., Sefcik, E., Hamilton, M. J., Kirksey, K. M., . . . Holzemer, W. (2007). Health literacy and health outcomes in HIV seropositive persons. *Research in Nursing & Health, 30*(6), 620-627.

Pandit, A. U., Tang, J. W., Cooper Bailey, S., Davis, T. C., Bocchini, M. V., Persell, S. D., . . . Wolf, M. S. (2009). Education, literacy, and health: Medication effects on hypertension knowledge and control. *Patient Education and Couseling, 75*(3), 381-385.

Parker, R. M., Ratzan, S. C., & Lurie, N. (2003). Health literacy: A policy challenge for advancing high-quality health care. *Health Affairs, 22*(4), 147-.

Pearson, T. A., Laurora, I., Chu, H., & Kafonek, S. (2000). The lipid treatment assessment project (L-TAP): A multi-center survey to evaluate the perceptions of dyslipidemic patients receiving lipid-lowering therapy and achieving low-density lipoprotein cholesterol goals. *Archives of Internal Medicine, 160*(4), 459-467.

Pharmacy educators utilize key partnerships to provide patient care. (2010). *Academic Pharmacy Now, 3*(4), 19-23.

Poureslami, I. M., Rootman, I., Balka, E., Devarakonda, R., Hatch, J., & FitzGerald, J. M. (2007). A systematic review of asthma and health literacy: A cultural-ethnic perspective in

Canada. *Medscape General Medicine, 9*(3), 40. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2100106/.

Powers, B. J., Olsen, M. K., Oddone, E. Z., Thorpe, C. T., & Bosworth, H. B. (2008). Literacy and blood pressure- do healthcare systems influence this relatioship? A cross-sectional study. *BMC Health Services Research, 8*, 219.

QualityMetric Incorporated. (2002). Asthma Control Test.

Radloff, L. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement, 1*(3), 385-401.

Ratzan, S. C., & Parker, R. M. (2000). *Introduction. In: National library of medicine current bibliographies in medicine: Health literacy* (Vol. NLM Pub. CBM 2000-1). Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services.

Santschi, V., Chiolero, A., Burnand, B., Colosimo, A. L., & Paradis, G. (2011). Impact of pharmacist care in the managment of cardiovascular disease riskt factors. *Archives of Internal Medicine, 171*(16), 1441-1447.

Sigurdardottir, A. K. (2005). Self-care in diabetes: Model of factors affecting self-care. *Journal of Clinical Nursing, 14*(3), 301-314.

Sudore, R. L., Mehta, K. M., Simonick, E. M., Harris, T. B., Newman, A. B., Satterfield, S., . . . Yaffey, K. (2006). Limited health literacy in older people and disparities in health and healthcare access. *Journal of American Geriatrics Society, 54*(5), 770-776.

Wallace, A. (2010). Low health literacy: Overview, assessment, and steps toward providing high-quality diabetes care. *Diabetes Spectrum, 23*(4), 220-227.

Warshaw, G. (2006). Introduction: Advances and challenges in care of older people with chronic illness. *Generation, 30*(3), 5-10.

Weiss, B. D., Mays, M. Z., Martz, W., Castro, K. M., DeWalt, D. A., Pignone, M. P., . . . Hale, F. A. (2005). Quick assessment of literacy in primary care: The newest vital sign. *Annals of Family Medicine, 3*(6), 514-522.

Wilkinson, G. S. (1993). *WRAT-33: Wide Range Achievement Test administration manual*. Wilmington, DE: Wide Range, Inc.

Williams, M. V., Parker, R. M., Baker, D. W., & al, e. (1995). Inadequate functional health literacy among patients at two public hospitals. *Journal of the American Medical Association, 274,* 1677-1682.

Wilson, F. L. (1996). Patient education materials nurses use in community health. *Western Journal of Nursing Research, 18*(2), 195+.

Wolf, M. S., Davis, T. C., Arozullah, A., Penn, R., Arnold, C., & Bennett, C. L. (2005). Relationship between literacy and HIV treatment knowledge among individuals enrolled in HAART regimens. *AIDS Care, 17*(7), 863-873.

Wolf, M. S., Gazmararian, J. A., & Baker, D. W. (2005). Health literacy and functional status among older adults. *Archives of Internal Medicine, 165*(17), 1946-1952.

Wolf, M. S., Gazmararian, J. A., & Baker, D. W. (2007). Health literacy and health risk behaviors among older adults. *American Journal of Preventative Medicine, 32*(1), 19-24.

World Health Organization. (1998). Health promotion glossary. *Health Promotion Int., 13*(4), 349-364.

Youmans, S. L., & Schillinger, D. (2003). Functional health literacy and medication use: The pharmacist's role. *The Annals of Pharmacotherapy, 37*, 1726-1729.

Zung, W. W. K. (1965). A self-rating depression scale. *Archives of General Psychiatry, 12*, 63-70.

ABSTRACT

ASSESSEMENT OF HEALTH LITERACY AS A PART OF A UNIVERSITY MEDICATION THERAPY MANAGEMENT PROGRAM FOR PATIENTS WITH CHRONIC CONDITIONS

by

JASON T. RANGE

December 2011

Advisor: Dr. Karen L. Tonso

Major: Curriculum and Instruction

Degree: Doctor of Philosophy

The role of pharmacists in the U.S. continues to evolve. Pharmacists are now being trained to be drug information specialists and medication counselors. More than ever, pharmacists are helping patients with chronic conditions manage their diseases through the use of medication therapy management programs. As a part of these programs, it is important that pharmacists are aware of what effect their patients' health literacy level may have on health outcomes.

The purpose of this study was to examine the extent to which health literacy was associated with different demographic factors and the extent to which health literacy was associated with clinical outcomes for patients with asthma, diabetes mellitus, cardiovascular disease/hypertension, and depression/anxiety in a well-defined, self-insured university population.

To answer the research question, data from the pharmacist-led program "Medication Therapy Management and Health Literacy Assessment through Health Horizons: Manage My

Medications" was analyzed. Data were collected on demographic, psychosocial, and physical functioning using standard assessment instruments and patient interviews. Additionally, certain clinical tests were performed to assess and gain an understanding of the control of patients' disease state(s). Data was collected at two points – upon entering the program and at six months. This study only examined baseline data.

For this study, patients were categorized by having either limited health literacy or adequate health literacy. Of the 90 participants enrolled, 11.11% had limited health literacy; 88.89% demonstrated adequate health literacy. The results revealed that at the $p<0.05$ level, men were significantly more likely to have limited health literacy than women ($p=0.049$). Age was also found to be associated with health literacy. When divided in groups <50 years of age and $\geq$ 50, there was a significant association between health literacy and age ($p=0.02$). When considering years of formal education, patients with lower levels of educational had greater lower health literacy. Among different educational levels, there was a significant association between health literacy and education ($p=0.024$).

When considered individually, health literacy was not found to be associated with any clinical outcomes of asthma, diabetes, mellitus, cardiovascular disease/hypertension, and depression/anxiety; higher body mass index (BMI), higher blood pressure, higher fasting blood glucose levels, and dyslipidemia; lower medication adherence; the need for patient education; and sub-optimal medication regimens.

However, when a logistic regression model was constructed, self-reported diagnoses of asthma, hypertension and dyslipidemia were found associated with heath literacy along with gender, age, and education. The final model was highly significant ($p < 0.001$).

The results of this study demonstrate the need for more research on the role of health literacy assessment in medication therapy management programs. Likewise, information on the relationship between health literacy, patient demographics, and health outcomes of patients with chronic conditions should be included in pharmacy education curriculum.

AUTOBIOGRAPHICAL STATEMENT

JASON T. RANGE

Dr. Range is Assistant Professor of Social and Administrative Sciences at Butler University College of Pharmacy and Health Sciences (Indianapolis, IN). He also serves as the College's Director of Grants and Budget. Dr. Range received his BA in Business Administration from Michigan State University (Lansing, MI), his Doctor of Jurisprudence from University of Detroit School of Law (Detroit, MI), and both his Master's in Bilingual-Bicultural Education and PhD in Curriculum and Instruction from Wayne State University (Detroit, MI). Dr. Range's research interests include health outcomes, bioethics, and the development of educational materials for health care professionals.