CONTINUOUS ACCESS TO MEDICATION AND HEALTH OUTCOMES IN UNINSURED ADULTS WITH TYPE 2 DIABETES

by

Cheryl Dillard Toulouse

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Committee:

Dr. Renee Milligan, Chair

Dr. Marie Kodadek, 1st Reader

Dr. Gary Kreps, 2nd Reader

Dr. Kathy Richards, University Professor and Assistant Dean Doctoral Programs and Research Development

Dr. Shirley Travis, Dean, College of Health and Human Services

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Fairfax, VA

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Cheryl Dillard Toulouse
Master of Science
George Mason University, 1998
Bachelor of Science
University of Tennessee, 1982

Director: Dr. Renee Milligan

Spring Semester 2012
George Mason University
Fairfax, VA

DEDICATION

This work is dedicated to my husband Mike, my sons Michael and Jake, and my daughter Rebecca. Thank you for your loving support and encouragement over the last few years. Your humor has carried me through many frustrations and long days. I could always count on one of you to yell out "Mom, you're living the dream!" as you breezed past me surrounded by stacks of books and articles, eyes glued to the computer. Thank you for keeping me grounded and reminding me that in the big scheme of things, it is after all, "just a paper"!

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ABSTRACT

CONTINUOUS ACCESS TO MEDICATION AND HEALTH OUTCOMES IN UNINSURED ADULTS WITH TYPE 2 DIABETES

Cheryl Dillard Toulouse, Ph.D.

George Mason University, 2012

Dissertation Director: Dr. Renee Milligan

Background and Purpose: Achieving targets for HgbA1c, low density lipids (LDL), and blood pressure (BP) can improve outcomes in adults with diabetes. To meet targets, access to affordable and consistent medication is necessary. The Social Determinants of Health framework guided variable selection in this study that explored the relationship between continuous access to medication (CAM) and HgbA1c, LDL, BP, hospitalizations (HSPs), and emergency department visits (EDVs) in adults with type 2 diabetes who are uninsured and of low socioeconomic status.

Hypothesis: CAM is related to improved HgbA1c, LDL, and BP, and reduced HSPs and EDVs.

Methods: This within-subjects study was conducted in two steps using a sample that received healthcare on a mobile van and medications from a pharmaceutical program. Step1: Pre-Post ($N = 65$) exploratory analysis using Dependent *t*-Tests and McNemar's tests.

Step 2: Time-Series (N = 17) quasi-experimental analysis using RM-ANOVA.

Pre-Post Results: CAM was related to improved HgbA1c (p = .003), LDL (p = .004), and systolic BP (p = .025).

Time-Series Results: CAM was related to improved HgbA1c (p = .011) with a significant reduction in mean HgbA1c (-1.14%) from preintervention to postintervention (p = .014).

Conclusions: Access to a consistent and reliable source of medication is essential to improving outcomes in adults with diabetes. In addition to providing excellent care, healthcare providers must foster opportunities to improve access to medication.

1. BACKGROUND AND SIGNIFICANCE

Diabetes is a serious metabolic disorder that is increasing at an alarmingly rapid rate. The Centers for Disease Control and Prevention (CDC, 2011) estimates that out of a total population of 311 million people (U.S. Census Bureau, n.d.), there are currently 25.8 million United States (US) children and adults with diabetes, 7 million of those with undiagnosed diabetes. This is an increase of more than 2 million people from the previous estimate of 23.6 million in 2009. An additional 79 million have prediabetes. The CDC proposes that the increase in diabetes in the US is related to the aging population, the increasing numbers of high-risk minority groups, and the longer lifespan of people with diabetes.

Estimates of future increases in the incidence of diabetes are even more alarming. Diabetes is a global health problem and worldwide prevalence is expected to increase from 171 million people in 2000 to 366 million people by 2030 (Wild, Roglic, Green, Sicree, & King, 2004). Within the US the prevalence of diabetes is expected to grow rapidly; it is anticipated that by 2034 out of a total estimated population of 386 million (U.S. Census Bureau, n.d.) the combined number of people with diagnosed and undiagnosed diabetes will increase to 44.1 million (Huang, Basu, O'Grady, & Capretta, 2009), and by 2050 out of a total estimated population of 439 million (U.S. Census Bureau, n.d.) the number of people with diagnosed diabetes will increase to 48.3 million

(Deshpande, Harris-Hayes, & Schootman, 2008; Narayan, Boyle, Geiss, Saaddine, & Thompson, 2006).

Complications and comorbid conditions are common among people with diabetes and include both microvascular complications (nephropathy, neuropathy, and retinopathy) and macrovascular complications (heart disease, hypertension, kidney disease, myocardial infarct, and stroke) (CDC, 2011). The cost associated with annual diabetes-related care is expected to increase from $113 billion in 2009 to $336 billion in 2034 (Huang et al., 2009). The health burden for both individuals and society will continue to grow as the overall numbers of those diagnosed with diabetes increases (Deshpande et al., 2008; Huang et al., 2009; Narayan et al., 2006; Wild et al., 2004). Effective measures to reduce the burden of diabetes must be identified in order to slow the onslaught of this relentless disease.

Background

As the number of those diagnosed with diabetes continues to increase, so does the body of knowledge aimed at reducing the complications that are associated with diabetes. Landmark studies conducted in the 1990s expanded knowledge about the benefits of achieving and maintaining near normal glycosylated hemoglobin (HgbA1c) levels in improving long-term health outcomes in people with diabetes. The Diabetes Control and Complications Trial (DCCT Research Group, 1993) and the United Kingdom Prospective Diabetes Study (UKPDS, 1998) found that lowering blood glucose values to near normal levels resulted in significant reductions in microvascular complications. As a follow-up to the DCCT, the Epidemiology of Diabetes Interventions and Complications (EDIC) study

(DCCT / EDIC Research Group, 2005) followed DCCT participants to measure the development of cardiovascular disease (macrovascular) in those with type 1 diabetes. In addition to the positive effects seen in preventing microvascular disease, researchers found that intensive treatment regimens have long-term beneficial effects on the risk of macrovascular disease. By demonstrating the benefits of intensive therapy in people with type 1 diabetes, these studies have resulted in increased provider efforts to avoid long-term complications in their patients with type 1 and type 2 diabetes by lowering blood glucose values to near normal values.

Other studies have advanced the science of the effect of near normal blood glucose values on the development of macrovascular disease in people with type 2 diabetes. The Action to Control Cardiovascular Risk in Diabetes trial (ACCORD Research Group, 2008), the Action in Diabetes and Vascular Disease; Preterax and Diamicron Modified Release Controlled Evaluation trial (ADVANCE Collaborative Group, 2007), the Veterans Affairs Diabetes Trial (Duckworth et al., 2009), and the UKPDS (1998) revealed mixed results when evaluating the effect of near normal blood glucose values on cardiovascular outcomes. To translate these findings into strategies for macrovascular risk reduction in people with diabetes, several researchers have conducted reviews of these large trials. In a meta-analysis by Turnbull et al. (2009), researchers concluded that near normal glycemic values resulted in modest reductions in cardiovascular events; however, this improvement was offset by an increase in severe hypoglycemic events. Additional analysis of these studies indicated that achieving near normal glycemic values in those who are older, with significant comorbidities, and with

longstanding diabetes may result in increased cardiovascular events. However, in those who are younger with relatively few cardiovascular risk factors, achieving near normal glycemic values might decrease overall cardiovascular risk (Montori, 2008; Montori & Fernandez-Balsells, 2009; Terry, Raravikar, Chokrungvaranon, & Reavan, 2011; Turnbull et al., 2009) and might even result in a "legacy effect" or "metabolic memory" that results in reductions in cardiovascular disease years later (Park & Wexler, 2010). Therefore, diabetes' treatment must be tailored based on people's individual characteristics and specific clinical criteria.

Purpose

This study explored the relationship between continuous access to medication and HgbA1c, low density lipids (LDL), systolic blood pressure (SBP), diastolic blood pressure (DBP), hospitalizations, and emergency department visits in uninsured adults with type 2 diabetes.

Study Significance

Adherence Improves Outcomes

Evidence has shown that adherence improves outcomes, yet adherence to medication regimens is a challenge for many people with diabetes and other chronic diseases (Lehane & McCarthy, 2009). The World Health Organization (WHO) defines adherence as "the extent to which a person's behavior—taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (WHO, 2003, p. 3). Adherence to therapeutic regimens reduces the risk of developing the complications and poor health outcomes associated with

chronic disease; yet, nonadherence is a significant problem in both developed countries where adherence averages 50%, and low resource countries where adherence is even lower (WHO, 2003). These results were confirmed by Cramer (2004), who conducted a systematic review of 20 studies from 1966 to 2003 that measured relationships between adherence rates and glycemic control; sadly, results revealed varying and frequently suboptimal levels of adherence. Lehane and McCarthy (2009) suggest that given its prevalence and wide-ranging consequences, nonadherence should be viewed as a serious public health issue that is "one of the leading challenges that professionals face in contemporary health care" (p. 25).

Numerous studies have demonstrated that adherence improves clinical outcomes (DiMatteo, Giordani, Lepper, & Croghan, 2002; Gibson et al., 2010; Ruelas, Roybal, Yang, Goldman, & Peters, 2009; Simpson et al., 2006) and reduces healthcare costs and patient suffering (Gibson et al., 2010). Additionally, good adherence to medication regimens reduces the risk of mortality to about half that of those patients with poor adherence (Simpson et al., 2006). In fact, medication adherence is the strongest predictor of reaching the target A1C of < 8% (Ruelas et al., 2009). Because adherence is associated with improved outcomes, it is important to identify barriers to adherence and implement interventions that improve adherence for individuals, communities, and society.

Problems Related to Adherence

There are numerous obstacles to achieving effective adherence levels, many of which are beyond the control of individuals, including social and economic factors, the characteristics of chronic disease, and complex treatment regimens. To have the greatest

effect on a patient's ability to adhere to therapeutic regimens, all potential barriers to adherence must be examined. In a systematic review, Osterberg and Blaschke (2005) propose that healthcare systems may contribute to nonadherence by limiting access to healthcare and medications by using limited medication formularies with prohibitively high costs. Even minimal increases in out-of-pocket costs may result in adherence problems and poor clinical outcomes in those with diabetes and other chronic diseases (Gibson et al., 2010). Additionally, purposeful underuse of medication is common in those who suffer from cost-related nonadherence (Kennedy & Erb, 2002; Piette, Heisler, & Wagner, 2004; Piette, Wagner, Potter, & Schillinger, 2004). Up to 1 million (11%) of the 11 million adults diagnosed with diabetes may take less than the prescribed amount of hypoglycemic agents because of cost (Piette et al., 2004a). Of those people who choose not to take medication due to cost, more than half suffer health problems because of cost-related adherence issues (Kennedy & Erb, 2002; Piette et al., 2004b).

Interventions to Improve Access, Adherence, and Outcomes

Interventions designed to improve access and adherence have been shown to have a positive effect on both patient outcomes and healthcare resource utilization. Providing healthcare services and medications to people at no cost (Horswell, Wascom, Cerise, Besse, & Johnson, 2008; Nykamp & Ruggles, 2000) results in greater adherence to therapeutic regimens, the use of fewer medical resources, and improved clinical outcomes. Increased access to medication is related to significant reductions in HgbA1c (Horswell et al., 2008) as well as hospital admissions and outpatient visits, which decreased by 39.5% and 64.4% respectively, representing a total cost savings of $378,183

by the hospital (Nykamp & Ruggles, 2000). Thus the importance of improving access to a variety of classes of essential medications at low cost is necessary to improve outcomes (Bright et al., 2010; Horswell et al., 2008; Patel et al., 2006; Strum, Hopkins, West, & Harris, 2005). Additionally, safety net clinics provide an essential source of healthcare services for people without insurance. Researchers have found that the healthcare services provided at safety net clinics are adequate and may reduce the use of emergency departments as a usual source of care (Hall, 2011). Redirecting expenditures from hospital admissions and emergency department visits to interventions designed to improve access may result in overall cost savings for institutions and society (Nykamp & Ruggles, 2000).

In addition to interventions aimed at the local level, a number of national retail centers (e.g., Walmart) have implemented low-cost prescription programs that provide a much-needed service for people who are under- or uninsured by providing low-cost medications to treat many acute and chronic diseases. Advantages of these programs include cost ($4 for a 30-day prescription, $10 for a 90-day prescription), improved access (these retail centers are abundant in most communities), and transferability of prescriptions from store to store within the retail center's electronic medical record system. The effectiveness of these low-cost prescription programs is diminished only by the limited formulary that is offered to treat chronic diseases (Walmart, 2011).

Although not widely studied, regional interventions designed to improve access to medications have had a positive effect on community-based healthcare systems and individuals. Of note is a prescription procurement program (PPP), a nonprofit, stand-

alone, collaborative pharmacy which provides medications to low-income uninsured children and adults in Northern Virginia. PPP partners with 12 safety net clinics and 2 private provider sites in the region. Since its inception in September 2007, over $4.7 million of medication have been dispensed (Knox & Morikawa, 2010). Seven major pharmaceutical manufacturers donate brand-name medications. Additional generic medications are purchased by PPP through low-cost contracts with pharmaceutical companies. PPP offers a comprehensive formulary of over 350 medications to treat acute and chronic diseases. Medications are dispensed for up to 90 days for a $5 fee. Individuals must qualify and reenroll in the program annually. Patients who receive healthcare services at 1 of the PPP's 14 partner sites and who have enrolled in the PPP's pharmaceutical service have continuous access to medication. For many patients, this may be the first time they have had a source for affordable, consistent, medications to treat both acute and chronic conditions (Knox & Morikawa, 2010). There is a need for additional research to explore continuous access to a broad range of essential medications and healthcare outcomes.

One of PPP's 14 partners is the Mobile Health Van (MHV), part of a hospital that belongs to a large system in the Mid-Atlantic region; MHV is the largest consumer of PPP medications. The MHV has two mobile vans that are each staffed by a nurse practitioner and an outreach worker. These healthcare providers travel into communities to regularly scheduled sites to provide care to low-income uninsured clients. PPP medications are ordered for individual patients and are delivered to the mobile health vans in approximately one week. A postcard is mailed to the patient to inform him or her

that a prescription is available for pick up from the van during regular business hours. When patients pick up their medications from the healthcare vans they are charged a nominal fee of $5 for each PPP prescription. The PPP's MHV program is the focus of this study.

The topics of access to medication and clinical outcomes in an uninsured population with type 2 diabetes are significant for several reasons: (a) diabetes is growing at an alarmingly rapid rate (CDC, 2011; Deshpande et al., 2008; Narayan et al., 2006); (b) diabetes rarely occurs in isolation: Comorbidities are common and cause human suffering and result in increased costs to society (Deshpande et al., 2008; Huang et al., 2009; Narayan et al., 2006; Wild et al., 2004); (c) improved adherence to medications improves clinical outcomes (DiMatteo et al., 2002; Gibson et al., 2010; Ruelas et al., 2009; Simpson et al., 2006); (d) improving access to essential medications is necessary to improve adherence and outcomes (Bright et al., 2010; Horswell et al., 2008; Patel et al., 2006; Strum et al., 2005); and (e) there are gaps in the current research regarding health outcomes in an uninsured population that has acquired continuous access to a broad range of essential medications (Jackson et al., 2004 Wagner et al., 2010; Wilper et al., 2008).

Hypotheses

1. Continuous access to medication is related to improved (a) HgbA1c, (b) LDL, (c) SBP, and (d) DBP in uninsured adults with type 2 diabetes.
2. Continuous access to medication is related to reduced (a) emergency department visits (EDV) and (b) hospitalizations (HSP) in uninsured adults with type 2 diabetes.

3. In uninsured adults with type 2 diabetes with HgbA1c measures at entry, preintervention and postintervention; continuous access to medication is related to improved HgbA1c over time.

Theoretical Framework

Social Determinants of Health

In 2005, the WHO established the Commission on the Social Determinants of Health (CSDH) to identify effective measures to reduce health inequities. That group's final report in 2008 issued a challenge to close the health gap within a generation. To accomplish this, the CSDH has developed three principles of action: (a) improving living conditions; (b) tackling the problem of the inequitable distribution of power, money, and resources; and (c) measuring the impact of actions taken to reduce health inequities (WHO CDSH, 2008). The third principle, measuring the effectiveness of interventions to reduce health inequities, requires developing a strong focus on social determinants in future public health research. Achievement of this WHO goal will require a social determinants approach to improve and create public health systems and community programs that are grounded in evidence-based practices (Koh et al., 2010).

To design, implement, and evaluate interventions aimed at reducing health inequalities, it is essential to understand the ways in which social determinants of health (SDOH) influence the health of individuals and communities. Reutter and Kushner (2010) propose that past interventions are limited because they have been designed to target healthcare accessibility and acquired behaviors, yet the nursing profession "has a clear mandate to ensure access to health and health-care by providing sensitive

empowering care to those experiencing inequities and working to change underlying social conditions that result in and perpetuate health inequities" (p. 269). The challenge for nurses is to seek opportunities to affect healthcare from the broader perspective of the social determinants of health.

The Dahlgren and Whitehead (1991) Social Determinants of Health framework has been used extensively to describe the layers of social determinants and the ways in which those layers are interconnected (Figure 1). To fully understand the interconnectedness of the model's different levels, it is important to appreciate each level's components. Dahlgren and Whitehead propose that the most distal layer of the model (Level 1) represents the socioeconomic, cultural, and environmental conditions in which people live. Moving from distal to proximal, Level 2 represents living and working conditions and includes a broad spectrum of determinants such as employment status, housing, education, healthcare, agriculture, and water. Level 3 includes available social and community networks. Level 4 represents individual health behaviors and includes the health choices that people make; for instance, whether a person chooses to smoke, exercise, or make healthy food choices. The center of the model represents individual characteristics including, age, gender, and genetic makeup—these are fixed factors that can not be controlled. Dahlgren and Whitehead suggest that the levels be thought of as a series of layers that interact with each other; representing opportunities for interventions to improve health.

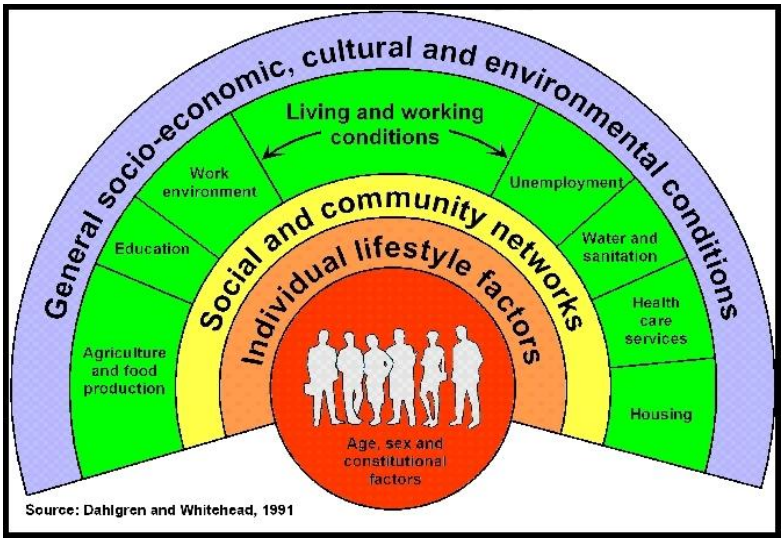

Figure 1. Social Determinants of Health framework.

Researchers are rising to the WHO challenge to close the healthcare gap within a generation by taking steps to identify interventions that effectively reduce health inequalities. Bambra et al. (2010) conducted a systematic review of systematic reviews completed from 2000 to 2007 that described the health effects of interventions based on the wider SDOH, including water and sanitation, agriculture and food, access to health and social services, unemployment and welfare, working conditions, housing and living environment, education, and transportation. Bambra and colleagues determined that the effect of interventions on health inequalities is unclear, but evidence suggests that interventions aimed at housing and the work environment (Level 2) may have a positive impact on disadvantaged groups. Interventions focused on the wider determinants of health (Level 1 and Level 2) provide the best opportunity for sustainable reductions in health inequities (Exworthy, 2008; McLeroy, Bibeau, Stickler, & Glanz, 1988; Williams,

Costa, Odunlami, & Mohammed, 2008; WHO, 2008), and there has been increasing pressure to focus research efforts at these levels.

Reutter and Kushner (2010) echo this recommendation by suggesting that nurses should intervene at "various levels" within the SDOH framework. This multilevel approach will have the most significant influence on health with both direct and indirect effects on health conditions. Williams et al. (2008) have also focused on the wider SDOH by reviewing interventions both within and outside the healthcare system including housing, neighborhood conditions, and socioeconomic status. Williams and colleagues propose that interventions designed to address social determinants of health may reduce health disparities in treatment and outcomes, particularly among those who suffer large disparities because of race/ethnicity and socioeconomic status.

The Social Determinants of Health framework (Figure 1) as conceptualized by Dahlgren and Whitehead (1991) guided this study of the PPP's Mobile Health Van (MHV) program. The specific concepts explored are displayed in Figure 2. The intervention "continuous access to medication" has been previously implemented, so this study explored it conceptually within the context of the SDOH model. Continuous access to medication is an intervention aimed at the segment in the model labeled "Health Care Services" which is part of Level 2, "Living and Working Conditions," and one of the wider social determinants of health. All participants in this study received primary care services at the MHV, a nurse-managed community-based healthcare service. In this study, the healthcare services provided at the MHV were conceptualized in the SDOH model at Level 3, "Social and Community Networks," Healthcare outcomes were

measured at Level 4, the "Individual Lifestyle Factors." Individual lifestyle factors are the healthcare behaviors that people choose to adopt and includes adherence to therapeutic regimens. Physiologic outcomes and healthcare resource utilization measures served as proxies for improved access and adherence behavior. The outcome measures HgbA1c, low density lipids, systolic blood pressure, diastolic blood pressure, emergency department visits, and hospitalizations were explored both before and with the intervention, continuous access to medication.

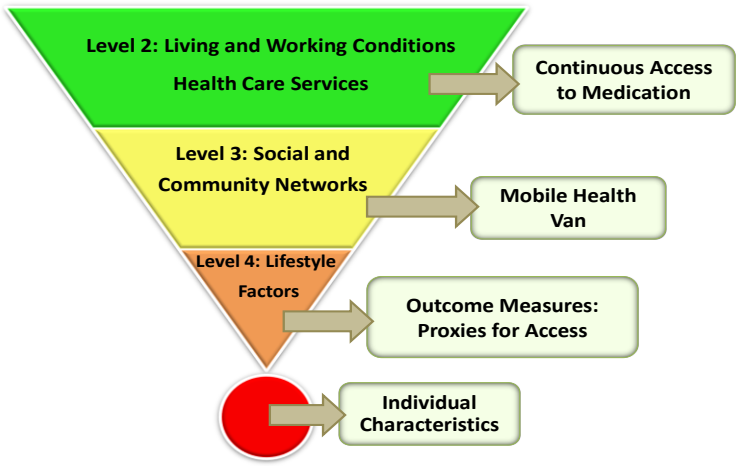

Figure 2. Study components and Social Determinants of Health framework.

Summary

The PPP in this study is a regional nonprofit, stand-alone, collaborative pharmacy that provides low-cost prescription medications to uninsured children and adults from an extensive formulary of over 350 medications (Knox & Morikawa, 2010). In this retrospective study it represented an intervention (continuous access to medication)

aimed at the wider social determinants of health (Level 2) implemented at the Mobile Health Van which provides care to low-income, uninsured people (Level 3 in the SDOH framework). The effect of continuous access to medication was measured by analyzing the outcome measures (HgbA1c, LDL, blood pressure, hospitalizations, and emergency department visits) before and with the intervention. Adherence was demonstrated indirectly in this study by assessing whether or not increasing access to medications resulted in improved outcome measures—the implication being that increased access improves adherence, which results in improved outcome measures. The access outcome measures were represented by Level 4 of the SDOH model.

Diabetes is a serious disorder that currently affects 25.8 million people in the US and is expected to increase to 48.3 million by 2050 (CDC, 2011; Deshpande et al., 2008; Narayan et al., 2006). Diabetes rarely occurs in isolation; complications and comorbid conditions are common and the combined effects of these diseases can be devastating. In terms of suffering for individuals, and healthcare resource utilization for society, this disease is costly. The WHO (2008) states that it is increasingly important to identify and implement interventions aimed at reducing health inequalities by focusing on the wider social determinants of health. Individuals and communities benefit from interventions aimed at the societal context in which people experience daily living. Improving access to needed healthcare services and medicines is just such an intervention (Bambra et al., 2010; Schultz et al., 2005). The long-term effects of diabetes and its common comorbidities can be mitigated by patient adherence to therapeutic regimens. However, for people who are under- or uninsured, there can be no improvements in adherence to

medication without first having access to medication. The results of this important study will add to the body of nursing knowledge by assessing the effect of the intervention of continuous access to medication through the lens of the Social Determinants of Health framework.

2. REVIEW OF THE LITERATURE

This chapter begins with a discussion of what is known about the methodology of using archival data in research and conducting retrospective chart reviews. This is followed by a discussion of the physiologic variables measured in this study, access to care and medicine, resource utilization, and the theoretical framework used to guide this study.

Diabetes is a progressive disease that is costly in terms of suffering for individuals and healthcare resource utilization for society. Interventions aimed at the societal context in which people experience daily living have the potential to reduce both the individual suffering and the healthcare costs of diabetes. In this study, continuous access to medication was explored as an intervention aimed at the wider social determinants of health. Outcomes used to measure the effect of the intervention included HgbA1c, low density lipids (LDL), systolic blood pressure (SBP), diastolic blood pressure (DBP), hospitalizations, and emergency department visits in uninsured adults with type 2 diabetes. It was hypothesized that continuous access to medication improves HgbA1c, LDL, SBP, and DBP, and reduces emergency department visits and hospitalizations. To support this study's hypotheses, a literature review was conducted to explore what is known about archival data collection methodology, this study's major variables and intervention, and the theoretical framework used to guide this study.

Retrospective Research Methodology

Retrospective research involves analyzing data that were originally collected for a purpose other than research. Medical record reviews or chart audits use previously collected patient-focused information as the primary source of data to answer research questions and hypotheses (Polit & Beck, 2008; Worster & Haines, 2004). There are a number of advantages to conducting retrospective chart reviews including the relatively low cost of retrospective studies and the ability to develop research questions and hypotheses for future research (Gearing, Mian, Barber, & Ickowicz, 2006; Polit & Beck, 2008; Smith, 1996). However, even though up to 25% of all studies published in emergency medical journals are medical record reviews, there is very little literature on the methodology to conduct retrospective chart audits (Worster & Haines, 2004).

It is important to approach a chart review in a manner that is well thought out and organized in order to minimize the time-consuming nature of collecting archival data (Polit & Beck, 2008; Smith, 1996). To insure an organized, methodical approach, a nine-step methodology has been proposed. Researchers of archival data should: (a) conceive the research questions and generate clear hypotheses, (b) conduct a literature review, (c) develop the proposal, (d) develop a data abstraction instrumentation that is straightforward and concise, (e) develop coding criteria for data abstractors, (f) become aware of the requirements and nuances specific to each site where data will be abstracted, (g) conduct a statistical power analysis to determine sample size, (h) obtain ethics approval from the appropriate institutional review boards, and (i) conduct a small pilot

study to determine the feasibility of the planned study, adequacy of data collection instruments, and identify methodological pitfalls (Gearing et al., 2006; Smith, 1996).

The process of selecting the sample involves selecting a sampling method, assessing that the available dataset is suitable for the intended research, and applying the inclusion criteria (Polit & Beck, 2008; Worster & Haines, 2004). The sampling methods most often used in retrospective chart audits include convenience sampling, quota sampling, and systematic sampling. The most common of these is convenience sampling, in which cases are selected over a specified time period. Quota sampling uses a predetermined number of cases that are abstracted from each site; in systematic sampling, every "nth" case is abstracted (Gearing et al., 2006). In large databases probability sampling using a random number generator is commonly used to select the sample (Worster & Haines, 2004).

All available databases should be analyzed for the quality and quantity of data (e.g., pharmacy, laboratory, diagnostic imaging, administrative) and consideration should be given to combining datasets and cross-referencing subjects. Only after the researcher has determined that the data is of high quality and available in a sufficient quantity should the inclusion criteria be applied to subjects. Gaining knowledge about the quality of the dataset is important; research involving the study of comorbid conditions has shown that data is frequently entered into administrative databases inadequately (Preen, Holman, Lawrence, Baynham, & Semmens, 2004). For this reason it is recommended that chart audits result in more accurate information than administrative databases about comorbid conditions. Whenever possible, patient-level data that has been abstracted from

computerized records should be double-checked for accuracy against the original patient record (Worster & Haines, 2004).

When existing records are used, researchers must be aware of the limitations and potential sources of bias inherent with this methodology. Medical records are built on the observations of many people and the documentation of these findings is frequently illegible and may be difficult to interpret (Worster & Haines, 2004). Additionally, it is common for researchers using archival data to deal with missing or incomplete documents. Systematic bias in the form of selective deposit and/or selective survival is not uncommon and occurs when the entire set of all records is not available (Polit & Beck, 2008). This limitation inherent to retrospective studies may force the researcher to question how representative the available records are (Polit & Beck, 2008; Worster & Haines, 2004). Missing data can result in nonresponse bias; it must be considered that the missing results may differ from those of other subjects (Gearing et al., 2006). Ideally the management of missing data should be determined prior to the study's onset. This typically involves deleting the case or variable, or inserting the missing variable through averaging or maximum likelihood methods.

Despite the limitations and pitfalls associated with using archival data, it continues to be an important and valued methodology in many fields of healthcare research (Gearing et al., 2006; Polit & Beck, 2008; Worster & Haines, 2004). With careful planning, using existing health records offers opportunities to advance the science and add to the body of nursing knowledge.

Physiologic Variables

Glycemic Control and Comorbid Conditions

Landmark studies conducted in the 1990s expanded knowledge about the benefits of achieving and maintaining near normal HgbA1c levels in improving long-term health outcomes in people with diabetes. The Diabetes Control and Complications Trial (DCCT/Epidemiology of Diabetes Interventions and Complications Research Group, 1993) conducted a randomized controlled trial of 1,441 subjects, 13 to 39 years old, with type 1 diabetes recruited from 29 centers. Subjects were randomly assigned to intensive therapy of three or more insulin injections daily or an insulin pump, or to conventional therapy of one or two daily insulin injections. Subjects were followed for a mean of 6.5 years and subjects were monitored for the development or progression of microvascular complications (retinopathy, nephropathy, and neuropathy). The most common adverse reaction in this study was an increase in the incidence of severe hypoglycemic episodes in the intensive therapy group of almost three times greater than in the conventional therapy group ($p < .001$). Macrovascular differences between the intensive therapy group and the conventional therapy group were not noted and were attributed to the subjects' young age. When all cardiovascular and peripheral vascular events were combined in the intensive therapy group, the risk of macrovascular disease was decreased by 41%, although this was not a significant finding (0.5 events per 100 patient-years, versus 0.8 events), 95% CI, [-10, 68]. Analysis revealed that when compared to usual care, intensive therapy decreased microvascular complications; retinopathy by 76%, 95% CI [62, 85], nephropathy by 54%, 95% CI [39, 66], and clinical neuropathy by 60%, 95% CI [38, 74].

To further analyze the risk of developing microvascular and macrovascular complications, researchers in the United Kingdom Prospective Diabetes Study (UKPDS, 1998) randomized 3,867 adults with newly diagnosed type 2 diabetes to intensive treatment with hypoglycemic agents (sulfonylurea or insulin) or diet therapy. Over 10 years the mean HgbA1c was 7.0% (6.2 - 8.2) in the intensive group and 7.9% (6.9 - 8.8) in the diet therapy group. Researchers discovered that for each 1% reduction in HgbA1c over 10 years there was a 37% reduction of risk for microvascular complications. The risk of complications in the group treated with sulfonylurea or insulin was 12% lower, $p = 0.029$, 95% CI [1, 21], for any diabetes endpoint (sudden death, death from hyper or hypoglycemia, fatal or non-fatal myocardial infarct (MI), angina, heart failure, stroke, renal failure, amputation, retinopathy requiring photocoagulation), 10% lower, $p = 0.34$, 95% CI [-11, 27], for any diabetes-related death (MI, stroke, peripheral vascular disease, renal disease, hyper or hypoglycemia, and sudden death), and 6% lower, $p = 0.44$, 95% CI [-10, 20], for all cause mortality. Risk reduction for any diabetes-related aggregate endpoint was due to a 25% risk reduction, $p = 0.0099$, 95% CI [7, 40], in microvascular endpoints. Although the effect of improved glucose control on macrovascular complications remained unclear, the DCCT and UKPDS trials resulted in provider efforts to lower HgbA1c values in their patients with diabetes. Achieving near normal blood glucose values became the goal of diabetes management.

More recent studies have questioned if achieving near normal blood glucose values reduces the macrovascular complications associated with diabetes including coronary artery disease, MI, stroke, and other vascular disease processes. The Action to

Control Cardiovascular Risk in Diabetes (ACCORD) trial (2008) was conducted to determine whether intensive therapy designed to attain normal HgbA1c values would decrease cardiovascular (CV) events in people with type 2 diabetes. Subjects (n = 10,251) had a mean age of 62.2 years, a mean HgbA1c of 8.1%, and known CV disease or CV risk factors in addition to diabetes. Subjects were assigned to the intensive therapy group (targeted HgbA1c < 6.0%) or to standard therapy (targeted HgbA1c 7.0 - 7.9%). The primary outcome measure was a composite of nonfatal MI, nonfatal stroke, or death from any CV cause. At 1 year the intensive therapy group achieved a mean HgbA1c of 6.4% and the standard therapy group achieved a mean HgbA1c of 7.5%. The primary outcome (CV event) occurred in 352 subjects in the intensive therapy group and 371 subjects in the standard therapy group, *HR* 0.78, p = .16, 95% CI [.78, 1.4]. During the same time period, 257 subjects in the intensive therapy group died as compared to 203 subjects in the standard therapy group, *HR* 1.22, p = .04, 95% CI [1.01, 1.46]. Not surprisingly, severe hypoglycemia and weight gain of more than 10 Kg were more common in the intensive therapy group (p < .001). The intensive therapy intervention was discontinued after 3.5 years of follow-up because of the higher-than-expected mortality rate. Researchers determined that intensive therapy targeted to normal HgbA1c values increased mortality and did not significantly reduce CV events.

The Action in Diabetes and Vascular Disease; Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) study (2007) was a randomized controlled trial conducted in 215 collaborating health centers in 20 countries. Subjects (n = 11,140) were ≥ 30 years old when diagnosed with type 2 diabetes and were ≥ 55 years old at the

beginning of the study. Subjects had a history of major CV disease including stroke, MI, or one other risk factor for CV disease (microvascular disease, current cigarette smoking, elevated lipid levels, or history of diabetes ≥ 10 years). The trial was designed to evaluate the effect of routine administration of a fixed dose of angiotensin converting enzyme inhibitor in combination with a diuretic on macrovascular events in people with type 2 diabetes. Subjects were randomized to the intervention group or to a placebo group without regard to initial blood pressure values or other medications used to reduce blood pressure. Outcome measures were composites of macrovascular events (death from CV disease, non-fatal stroke, and non-fatal myocardial infarct) and microvascular events (new or worsening renal or diabetic eye disease). The mean duration of follow-up was 4.3 years. Analysis revealed that subjects in the intervention group had a mean reduction in systolic blood pressure of 5.6 mmHg and diastolic pressure of 2.2 mmHg, resulting in a 9% reduction in macrovascular and microvascular events, *HR* 0.91, $p = .04$, 95% CI [.83, 1.0]. The relative risk of death from CV was reduced by 18% ($p = .03$) and death from any cause was reduced by 14% ($p = .03$). Treatment with an angiotensin converting enzyme inhibitor and diuretic resulted in decreased blood pressure and significant reductions in mortality—an independent and additive effect. Researchers propose that this treatment should be implemented routinely for those with type 2 diabetes.

Duckworth et al. (2009) conducted the Veterans Affairs Diabetes Trial (VADT) which was designed to evaluate the effect of intensive glucose therapy on CV complications in people with type 2 diabetes. Subjects ($n = 1,791$, mean age 60.4 years) had not reached glycemic goals with past diabetes treatments and were randomized to

intensive therapy or conventional therapy. The glycemic goal of the intensive therapy group was a reduction of 1.5% in HgbA1c compared to the standard therapy group. During the trial the achieved HgbA1cs were 8.4% in the standard therapy group and 6.9% in the intensive therapy group. The primary outcome measure was the length of time from group randomization to the first occurrence of CV event including MI, stroke, death from CV causes, congestive heart failure, surgery for vascular disease, and amputation for ischemic gangrene. The median follow-up was 5.6 years. Significant CV events occurred in 264 subjects in the standard therapy group and 235 subjects in the intensive therapy group, *HR* .88, $p = .14$, 95% CI [.74, 1.05]. Additionally, there was no significant difference between groups in any component of the primary outcome or death from any cause *HR* .1.07, $p = .62$, 95% CI [.81, 1.42]. There was an increase of hypoglycemic events in the intensive therapy group (24.1%) compared to the standard therapy group (17.6%). Researchers concluded that in those with poorly controlled type 2 diabetes, intensive glycemic control had no significant effect on the rate of CV events or microvascular complications.

To learn more about the mixed conclusions of these studies, Turnbull et al. (2009) conducted a meta-analysis of studies designed to evaluate the effect of intensive glucose control on macrovascular complications in people with type 2 diabetes. Four studies met the inclusion criteria and were included in the analysis: the 2008 ACCORD trial, the 2007 ADVANCE trial, the 1998 UKPDS, and the 2009 VADT. The meta-analysis included 27,049 subjects and a total of 2,370 major vascular events. Findings revealed that assignment to intensive glycemic control groups reduced the risk of major CV events

by 9%, *HR* 0.91, 95% CI [.84, .99]. This reduction was due to an overall 15% decrease in MIs, *HR* .85, 95% CI [.76, .95]. Subjects in the intensive glycemic control groups suffered a greater number of severe hypoglycemic events, *HR* 2.48, 95% CI [1.91, 3.21]. Researchers also describe the possibility of a differential effect for cardiovascular events in those with *HR* 1.0, 95% CI [.89, 1.13], and without *HR* .84, 95% CI [.74, .94], pre-existing macrovascular disease ($p = .04$). Researchers conclude that while achieving near normal glycemic values resulted in a modest reduction in cardiovascular events, there was also an increase in severe hypoglycemic events. Therapeutic regimens should thus be tailored individually for those with type 2 diabetes.

To learn more about the variability in cardiovascular and all-cause mortality reported in these trials, Montori and Fernandez-Balsells (2009) reviewed five large randomized trials that targeted tight glycemic control to reduce diabetes complications. Randomized trials included in the review were the 1998 UKPDS, the 2008 ACCORD trial, the 2002 A Diabetes Outcome Progression Trial (ADOPT), the 2009 VADT, and the 2007 ADVANCE trial. Comparison across studies suggests that those with early onset diabetes and those without a previous cardiovascular event may benefit from tight glycemic control. However, those patients with diabetes for a longer duration or those with a previous cardiovascular event may not benefit, and in fact may be harmed by tight glycemic control. Researchers suggest that tight glycemic control introduces a treatment burden for patients that includes complex treatment regiments, hypoglycemia, weight gain, and increased costs. Clinicians must stress healthy lifestyle, cardiovascular risk reduction, and preventive care for patients with diabetes. Glycemic control targets must

be individualized within the context of individual patients' clinical characteristics and personal preferences.

Montori (2008) reviewed and summarized randomized trials designed to determine if reduction of HgbA1c to near normal or normal levels (HgbA1c 6.0 - 6.5%) would result in a reduction in CV event risk. Among the trials reviewed were the 2007 ADVANCE trial and the 2008 ACCORD trial. Taken together, these trials indicated that tight glycemic control might be harmful, particularly for those with longstanding diabetes and with existing coronary artery disease. The ACCORD trial was stopped earlier than planned (at 3.5 years) because of increased mortality in the intensive control arm of the study. Montori suggests prioritizing the treatment approach by addressing CV risk reduction first, followed by self-care and well-being, and lastly glycemic control. Most patients are able to attain a HgbA1c of 7.0 - 7.5% with this plan. Patient preferences and clinical profile must be a primary concern when formulating a therapeutic regimen that maximizes longevity and quality of life.

Researchers continue to analyze the results of the ACCORD trial (2008), ADVANCE trial (2007), and VADT (2009); Terry et al. (2011) reviewed, compared, and summarized findings from these trials. Results indicate that older and/or frail patients with more advanced diabetes, hypoglycemia unawareness, preexisting CV disease, and significant comorbidities do not benefit from intensive glycemic control. Attempts to achieve intensive glycemic control may place these patients at increased risk for severe hypoglycemia episodes, a risk factor for CV events. Research indicates that a more moderate approach to glycemic control (HgbA1c 7 - 8%) is indicated in this population.

However, those who are younger, newly diagnosed, and without CV disease might benefit from aggressive glycemic control. In this group the near normal HgbA1c (< 7%) seems to reduce the long-range risk for macrovascular disease.

Researchers have also studied the effect of glycemic control on specific populations. Greenfield et al. (2009) conducted a 5-year longitudinal observational study of adults residing in Italy with type 2 diabetes (n = 2,613) to determine whether HgbA1c goals of ≤ 6.5% versus ≤ 7% provide different levels of benefit for subjects with low to moderate levels of comorbidity. Abstracted clinical data from the 205 participating practices included HgbA1c, lipid levels, and blood pressure. The Total Illness Burden Index (TIBI), a validated patient-reported measure of comorbidity, was used to dichotomize levels of comorbidity. In the low-to-moderate comorbidity group achieving a HgbA1c of 6.5% or less was associated with a lower 5-year incidence of CV events, adjusted HR 0.60, p = .005, 95% CI [0.42, 0.85]; however, this was not true in the high comorbidity group, adjusted HR 0.92, p = .61, 95% CI [0.68, 1.25]. Additionally, in the low-to-moderate group obtaining a HgbA1c of 7% was associated with fewer CV events, adjusted HR 0.61, p = .001, 95% CI [0.44, 0.83], but not in the high comorbidity group, adjusted HR 0.88, p = .38, 95% CI [0.66, 1.17]. Findings reveal that patients with high levels of comorbidity may not receive the CV benefit of intensive glycemic control. Greenfield et al. conclude that glycemic control should be tailored to individuals based on their level of comorbidity.

Researchers also question if gender in the context of ethnicity might have an effect on CV outcomes. Aviles-Santa, Salinas, Adams-Huet, and Raskin (2006)

conducted a study on Latin American adults aged 18 to 45 years with poorly controlled type 2 diabetes (n = 57) to determine gender-related differences in cardiovascular (CV) risk factors and the effect of an insulin monotherapy intervention on CV risk factors. All female subjects were premenopausal and all subjects were obese (BMI > 30kg/m²). HgbA1c (9.8 % ± 2.5) and low density lipids (3.1 mmol/L ± 0.9) were similar between genders. Highly sensitive C-reactive protein (CRP) levels were elevated and similar between genders (p = .4). In women there was a positive correlation between waist circumference and CRP levels (rho = .53, p = .01). Eighteen subjects remained in the study for up to 104 weeks of postintervention measurements. Although the sample size was small (nearly two-thirds of the subjects did not complete the study), the findings are significant. Analysis revealed a significant decrease in HgbA1c (-2.2%, p = <.0001); however, lipid profiles and CRP did not change significantly. Aviles-Santa et al. concluded that in young, obese, Latin Americans with poorly controlled type 2 diabetes, improved glycemic control with monotherapy insulin was not associated with an improvement in CV disease risk factors. Importantly, premenopausal Latino women with poorly controlled diabetes have CV risk factors that are similar to those of Latino men of the same age with poorly controlled diabetes. Researchers propose that obesity and insulin resistance may diminish the CV improvements associated with insulin therapy.

Researchers continue to identify emerging trends as the results of large trials are evaluated. Park and Wexler (2010) reviewed the results of three large randomized controlled trials on the effect of tight glycemic control on the risk of cardiovascular disease in those with type 2 diabetes. The 2008 ACCORD trial, the 2007 ADVANCE

trial, and the 2009 VADT were reviewed in addition to the long-term follow-up of the 1998 United Kingdom Prospective Diabetes Study (UKPDS). These researchers concur with others who find that tight glycemic control is appropriate in patients with early onset diabetes with no known cardiovascular disease. For this group, tight glycemic control is likely to result in improved outcomes in both microvascular and macrovascular disease. Additionally, the long-term follow-up to the UKPDS revealed that there may be a "legacy effect" or "metabolic memory" related to tight glycemic control that becomes apparent years later. Ten years after the original study, the tight glycemic control group (sulfonylurea and insulin) achieved a median HgbA1c of 7.0%, and the standard care group achieved a median HgbA1c of 7.9%. The metformin group achieved a median HgbA1c of 7.4% compared to 8.0% in the standard care group. At the 10-year follow-up all groups had nearly identical HgbA1c levels (median 8.0% or higher). In the sulfonylurea and insulin group, the tight glycemic control group had significantly fewer CV events than the standard care group (24.8% versus 28%, $p = .01$), resulting in an overall risk reduction of 15%. In the metformin group, the tight glycemic control group had significantly fewer cardiovascular events than the standard care group (38.8% versus 48%, $p = .005$), resulting in a relative risk reduction of 33%. It appears the overall rate of CV events is improving in people with diabetes, likely due to aggressive management of other clinical risk factors including hyperlipidemia and hypertension. In addition to managing diabetes and comorbid conditions, it is important to modify lifestyle risk factors for CV disease such as smoking and weight.

Diabetes is a serious metabolic disorder with significant morbidity and mortality from both microvascular and macrovascular causes. Early studies (DCCT, 1993; UKPDS, 1998) revealed the relationship between tight glycemic control and reductions in microvascular disease. However, because mortality in people with diabetes is strongly associated with macrovascular disease, it is important to discover the links between disease management and CV event risk reduction. Studies conducted over recent decades have shed light on this relationship (ACCORD, 2008; ADVANCE, 2007; VADT, 2009; UKPDS, 1998). It has become increasingly clear that for people who are newly diagnosed, are younger, and who have no known CV disease or risk factors, tight glycemic control results in decreased macrovascular disease. Conversely, for people with long-standing disease, comorbid conditions, hypoglycemic unawareness, or known CV disease or risk factors, tight glycemic control is not likely to be beneficial in CV event risk reduction and, in fact, may be harmful. Researchers agree that therapeutic regimens designed to prevent or delay the onset or progression of macrovascular disease must be tailored to individual patients.

Treatment Guidelines and Clinical Goals

Given the complexity of type 2 diabetes and the associated comorbid conditions, the American Diabetes Association (ADA) has developed standards of care which are updated annually. The ADA Standards of Care (2011) recommended treatment goals for most people with diabetes are as follows: HgbA1c < 7.0%, blood pressure < 130/80 mmHg, and low-density lipoprotein (LDL) cholesterol < 100 mg/dl. The Standards of Care are comprehensive and include recommendations about the diagnosis of diabetes

and prediabetes, medication treatment regimens, screening for comorbid conditions, and suggested lifestyle measures to improve long-term outcomes for people with diabetes. They are evidence-based and have changed over the years as more has been learned about diabetes. In light of what has been learned in recent large trials about microvascular and macrovascular risk reduction (ADVANCE, 2007; ACCORD, 2008; Duckworth et al., 2009; UKPDS, 1998), the ADA recommends that therapeutic regimens be developed based on the characteristics of individuals with type 2 diabetes.

Researchers have focused on affordable yet effective treatment regimens that have a low risk of adverse effects. Gross et al. (2011) conducted a meta-analysis of randomized trials at least 24 weeks in duration that evaluated the effect of adding a third antidiabetic drug to the treatment regimen of adults with type 2 diabetes and HgbA1c > 7% who were taking metformin and a sulfonylurea. Outcome measures were HgbA1c, weight change, and frequency of severe hypoglycemia. Eighteen studies that evaluated 4,535 participants were included in the analysis. HgbA1c reduction ranged from -0.70%, 95% credible interval (Crl) [-1.33, -0.08] for acarbose, to -1.08%, Crl [-1.41%, -0.77] for insulin. Weight gain was seen with the addition of insulin (2.84 kg, Crl [1.76, 3.9]) and with thiazolidinediones (4.25 kg, Crl [2.76, 5.66]). Weight loss was seen with glucagon-like peptide-1 agonists (-1.63 kg, Crl [-2.71, -0.60]). Additionally, researchers report that the addition of insulin to a regimen of metformin and sulfonylurea doubled the frequency of severe hypoglycemic episodes when compared to other classes of medications. Findings revealed that there is no significant difference in benefit among drug classes

when selecting a third antidiabetic agent. Gross et al. conclude that selection of a third agent be based on each patient's preferences and specific clinical characteristics.

Other researchers have analyzed national trends in achievement of therapeutic goals. Cheung et al. (2009) analyzed data from the National Health and Nutrition Examination Survey to study the prevalence, treatment, and management of diabetes in the United States from 1999 to 2006. Subjects (n = 17,306) aged 20 and older were analyzed on whether or not they met 2008 American Diabetes Association (ADA) standards of medical care targets for HgbA1c (< 7%), blood pressure (< 130/80), and LDL (< 100 mg/dl). Data were pooled into two 4-year periods: 1999 to 2002 and 2003 to 2006. During the two time periods studied, the prevalence of diagnosed diabetes increased from 6.6% to 7.8%. Subjects achieving the target for HgbA1c increased from 43.1% to 57.1%, significant in people aged 20 to 30 years and those over 60 years in both sexes, non-Hispanic Whites, and in overweight/obese people. Subjects achieving blood pressure control increased from 39.2% to 45.5%, although the results were not significant. Those reaching the LDL target increased from 36.1% to 46.5%, significant in men, non-Hispanic Blacks, and obese people. The percentage of subjects achieving all three target levels increased from 7% to 12.2% (p = .06). Sadly, only one in eight people met the ADA goals for HgbA1c, blood pressure, and LDL (Cheung et al., 2009; Kuritzky & Samraj, 2011). This number highlights the difficulty for patients and clinicians to achieve treatment goals. Diabetes continues to be a major healthcare challenge that requires targeted treatment to reach all three goals simultaneously.

Access to Care

Methods of Measuring Access to Medicine

To date there has been no consensus on effective methods of measuring access to medicine. The WHO and Management Sciences for Health (Center for Pharmaceutical Management, 2003) organized a joint meeting involving 40 experts from 15 countries to develop an operational definition of access and to identify testable indicators to measure access to essential drugs, vaccines, and other health commodities. The group identified four dimensions of access that were deemed to be of particular importance: physical availability, affordability, geographical accessibility, and acceptability. The group proposed that key indicators to measure access must reflect data collected at the household level and also at the level of public and private sectors. Preliminary key indicators were proposed for each dimension and are currently under development.

To increase knowledge about the conceptual and methodological development of quantitative techniques to measure access to medicine, Paniz, Fassa, Maia, Domingues, and Bertoldi (2010) conducted a comprehensive review of the literature. After a preliminary review of 9,000 titles, the researchers identified 9 papers that met the inclusion criteria of quantitative analysis, medicine access measured at the household level as the primary (n = 6) or secondary (n = 3) outcome, and published dates prior to July 2008. All studies were cross-sectional, nearly half were national, and most were published after 2004. Researchers express surprise at the small number of studies designed to measure access to medicine, and disappointment that the term "medicine access" is not recognized as a search keyword. Standardization of medicine access

indicators is required to enhance the study of medication access. Paniz et al. (2010) suggest using the indicators that were originally identified at the 2000 WHO and Management Sciences for Health meeting including acquisition, expense, and categorization by the dimension to be measured including availability, affordability, geographic accessibility, and acceptability.

Insurance and Access to Care

It has been well documented that people without insurance have greater difficulty accessing needed healthcare services. Wagner et al. (2010) conducted a cross-sectional analysis using World Health Survey data (2002 to 2003) to describe access to healthcare and medicine across countries and to assess the effect of insurance coverage and public sector care on household access to care and economic burden. Logistic regression was used to analyze data from 286,803 households and 276,362 respondents from 70 countries stratified by income (22 low, 18 lower middle, 10 upper middle, and 20 high). Most households (90%) had access to acute care. However, for those living in poor households access to care for chronic disease was lower; in high-income countries 51% reported treatment and in low-income countries 27% of those with chronic disease reported treatment within the previous 12 months. Having insurance for all members of a household improved the odds of gaining access to care for chronic conditions, *OR* 1.38, 95% CI [1.31, 1.44], and accessing care when needed, *OR* 1.54, 95% CI [1.30, 1.83]. Researchers propose that policymakers can improve access to care and medicine by providing for convenient and affordable high-quality care and expanding insurance coverage.

Uninsured people with chronic disease are less likely to visit a healthcare provider or have a usual source of care. Wilper et al. (2008) conducted a cross-sectional study (n = 12,486) using data from the National Health and Nutritional Examination Survey (1999 to 2004). Researchers found that 11.4 million working-age Americans with chronic disease are uninsured, including 16.1%, 95% CI [12.6, 19.6] of the 7.8 million with cardiovascular disease; 15.5%, 95% CI [13.4, 17.6] of the 38.2 million with hypertension; and 16.6%, 95% CI [13.2, 20.0] of the 8.5 million with diabetes. When controlling for age, sex, and race/ethnicity, uninsured people were less likely than those with insurance to have visited a health professional (6.2% vs. 22.6%, p <.001). They were also more likely to not have a regular site for care (6.2% vs. 26.1%, p <.001), and more likely to identify an emergency department as their standard site for healthcare services (7.1% vs. 1.1%, p <.001). The authors conclude that millions of uninsured working-age Americans with chronic disease have poorer access to healthcare than those who are insured. Future research should determine whether access to care decreases the use of the emergency department as a standard site of care.

Research has shown that people with insurance are more likely to visit a healthcare provider and less likely to be self-medicated. Pagan and Puig (2005) conducted a study of adults with diabetes (n = 1,901) using the Mexican Health and Aging Study database (n = 15,156), a nationally representative prospective panel study of adults born before 1951. Researchers found that 39% of subjects were uninsured and 16% had a diagnosis of diabetes. Of those with diabetes, 28% were uninsured. Respondents reported comorbid conditions including high blood pressure (57%), heart disease (6%),

stroke (5%), arthritis (26%), and vision problems (50%). Logistic regression results revealed that insured adults were more likely to have visited a doctor (43%, *OR* 0.56) and less likely to have visited a complementary or alternative medicine provider (44%, OR 0.56), or to be self-medicated (66%, *OR* 0.34). Researchers conclude that since diabetes should be closely monitored to improve outcomes, it is encouraging that acquiring insurance is positively associated with the number of physician visits.

Zhang et al. (2010) examined the relationship between access to care and undiagnosed diabetes in adults (n = 3,470) using survey and fasting plasma glucose data from Phase I of the U.S.-Mexico Border Diabetes Prevention and Control Project. Access to care was operationalized using type of health insurance, number of healthcare visits in the previous year, routine pattern of healthcare utilization, and country of residence. The study identified 178 adults with undiagnosed diabetes, 326 with diagnosed diabetes, and 2,966 without diabetes. Those without insurance and no usual source for routine healthcarewere more likely to be undiagnosed, *OR* 2.6, 95% CI [1.0, 6.6] than those with insurance and a place for routine care, *OR* 4.5, 95% CI [1.4, 14.1]. On the U.S. side of the border people were more likely to be undiagnosed if they were uninsured, 28.9%, 95% CI [11.5, 46.3] instead of insured, 9.1%, 95% CI [1.5, 16.7], and if they had no healthcare visits in the previous year, 40.8%, $p < .05$, 95% CI [19.6%, 62], versus one to three visits, 23.4%, $p < .05$, 95% CI [9.9, 36.9], or four or more visits, 2.4%, $p < .05$, 95% CI [-.09, 5.7]. Researchers conclude that not having insurance and/or a usual source for healthcare services is significantly associated with undiagnosed diabetes.

Other researchers have investigated whether having insurance has an effect on health-seeking behavior. Law and VanDerslice (2011) conducted a cross-sectional study using data on adults (n = 653) residing in El Paso County, Texas, from the 2005 Behavioral Risk Factor Surveillance System (BRFSS) annual telephone survey. The study's purpose was to identify primary determinants associated with Hispanics having insurance and the likelihood of individuals not seeking medical care due to cost. Analysis revealed that almost half of adult Hispanics lack health insurance, 46.4%, $p < .0001$, 95% CI [40.8, 52.0], compared to their non-Hispanic counterparts, 15.1%, $p < .0001$, 95% CI [9.8, 22.7]. Additionally, three times more Hispanics, 32%, $p < .02$, 95% CI [26.8, 37.8], reported not seeking healthcare due to cost than non-Hispanics, 9.7%, $p < .02$, 95% CI [5.7, 16.2]. As income increases the likelihood of having insurance increases; 89.1% of those earning more than $50,000 per year compared to 38.9% of those earning less than $25,000 per year had insurance ($p < .0001$). Researchers propose that disparity in insurance coverage is likely to perpetuate inequities in health status. Future research should focus on analyzing the underlying and proximal determinants of access to healthcare.

Within the United States, even people with insurance are not confident that they can afford effective healthcare. Schoen et al. (2010) conducted a computer-assisted telephone survey of adults (n = 19,738) residing in 11 high-income countries to examine access, cost, and care experiences by income. Even when insured, adults in the US were more likely to have high medical costs; 35% had out-of-pocket costs of $1,000 or more in the previous year. Only 70% of US adults were confident that they would receive the

most effective treatment if they were seriously ill, and only 58% were confident that they would be able to afford needed care. Interestingly, US adults (21%) were more likely to skip doses or not fill a prescription, and 28% did not seek care when needed due to cost. Within the US, when compared to people with above-average income, people with below-average income were less confident that the most effective treatment would be received and that needed care would be affordable ($p < .05$). They conclude that poorer adults in the US are more likely to need healthcare and are less likely to be able to afford healthcare services.

Insurance status not only has an effect on whether or not people have access to healthcare services, but it also has an effect on whether or not people have access to medication. Jackson, Doescher, Saver, and Fishman (2004) conducted a cross-sectional study to examine drug coverage, perceived health status, and medication access using primary survey data on subjects aged 67 and older ($n = 3,037$). Subjects were continuously enrolled in a Medicare program for 2+ years and had a diagnosis of hypertension, diabetes, congestive heart failure, and/or coronary artery disease. Multivariate analyses revealed that people with no prescription benefit had access to fewer classes of essential medications ($M = 1.9$, $p < .001$, 95% CI [1.8, 2.0] and had lower refill adherence ($M = 0.12$ %, $p < .01$). Additionally, researchers found that perceived health played a role in whether or not people filled prescriptions. People without drug coverage were less likely to fill prescriptions when they felt well ($M = 0.14$, $p < .05$, 95% CI [0.12, 0.16], but people with drug coverage filled similar numbers of prescriptions whether they felt ill or well. This difference in filling medications based on

whether or not people have drug coverage is important since a primary goal of treating chronic disease is preventing end organ damage.

People without insurance have greater difficulty accessing healthcare and medicine (Wagner et al., 2010), and are less likely to visit a healthcare provider or have a usual source of care (Law & VanDerslice, 2011; Pagan & Puig, 2005; Schoen et al., 2010; Wilpur et al., 2008). Unfortunately, people without insurance or a usual source of care are more likely to have undiagnosed diabetes (Zhang et al., 2010) and to cite an emergency department as their usual source of care (Wilpur et al., 2008). Sadly, even people with insurance but no drug coverage are less likely to have access to essential classes of medication (Jackson et al., 2004). Acquiring insurance improves access to healthcare and medicines (Pagan & Puig, 2005) and may allow those with chronic disease to obtain healthcare and medical management on a regular basis.

Immigrants and Access to Care

Researchers have compared U.S. and Canadian immigrants to learn about similarities and differences regarding access to care, and whether or not universal healthcare has an effect on health status. Siddiqi, Zuberi, and Nguyen (2009) conducted a cross-national (cross-sectional) comparison of the effect of health insurance on access to primary healthcare among U.S. and Canadian immigrants versus nonimmigrants using data from the 2002 to 2003 Joint Canada/United States Survey of Health (n = 4,989 U.S. respondents). Access was measured as self-reported unmet medical needs and lack of a regular doctor. A comparison of U.S. immigrants to nonimmigrants revealed that immigrants reported more unmet medical needs (17.3% versus 12.5%, $p < .005$) and lack

of a regular doctor (34.7% versus 17.7%, $p < .001$). When controlling for sex, race, age, marital status, education, employment, and self-rated health, uninsured U.S. immigrants were more likely to report unmet medical needs, *adj OR* 3.04, $p < .05$, 95% CI [1.94, 4.77], than their insured counterparts, *adj OR* 0.85, 95% CI [.58, 1.26]. Additionally, uninsured immigrants were more likely to report lack of a regular doctor, *adj OR* 16.97, $p < .05$, 95% [CI 10.84, 26.57], than their insured counterparts, *adj OR* 1.56, $p < .05$, 95% CI [1.17, 2.08]. Within Canada, which has universal healthcare, disparities between immigrants and nonimmigrants were similar to the disparities seen in insured Americans. Researchers propose that health insurance greatly reduces inequities in access to healthcare for immigrants.

Other researchers have asked similar questions when seeking to learn more about immigrant healthcare in countries with universal healthcare. Lebrun and Dubay (2010) conducted a cross-country (cross-sectional) comparison of access to primary care among foreign-born adults ($n = 6,620$) residing in Canada and the United States using secondary data from the 2002 to 2003 Joint Canada/United States Survey of Health. Findings revealed that in both Canada and the US foreign-born residents had less access to care than their native-born counterparts. When controlling for covariates (including insurance status), within-country multiple regression analyses revealed that among U.S. residents, 74.2% of foreign-born versus 83.5% of native-born adults have a regular medical doctor ($p < .01$). Similarly, 93.5% of foreign-born and 96.2% of native-born U.S. residents had a consultation with a health professional in the previous year. Lebrun and Dubay found that immigrants have worse access to healthcare than nonimmigrants. Researchers

hypothesized that access to healthcare for foreign-born immigrants would be better in Canada because of universal healthcare when compared to the US where insurance coverage is fragmented. This was found to be true in unadjusted analyses; however, immigrants who gained access to care in either country were equally satisfied with their healthcare experience.

Access to care for children is also affected by immigrant status. Javier, Huffman, Mendoza, and Wise (2010) conducted a cross-sectional study to examine how immigrant status is related to healthcare access, healthcare utilization, and health status in special needs children (n = 1,404) using data from the 2003 California Health Interview Survey. Chi-square analysis revealed that compared to children with special healthcare needs (CSHCN) in nonimmigrant families, CSHCN living in immigrant families are more likely to be uninsured (10.4% versus 4.8%, p = .0018), lack a usual source of healthcare (5.9% versus 1.9%, p = .0054), report delayed medical care (13.0% versus 8.1%, p = .0179), and report no physician visit in the previous year (6.8% versus 16%, p = .0047). This was true despite the perceived health status of the child being rated as fair to poor (33.2% versus 15.9%, p = .0001). Logistic regression analysis revealed that immigrant status, *OR* 0.05, p = < .05, 95% CI [0.01, 0.37], and interview language, *OR* 42.23, p = < .05, 95% CI [7.71, 231.42], affected whether a physician was visited in the previous year. Those who are uninsured are nearly four times more likely to delay or not fill a prescription in the previous year, *OR* 3.88, p = < .05, 95% CI [1.40, 10.77]. Researchers emphasize the importance of funding safety net providers and improving access to

publicly funded programs to reduce healthcare disparities and costly emergency room and hospital services

There are many barriers to acquiring access to healthcare; immigration status appears to amplify the effect of these barriers (Javier et al., 2010; Lebrun & Dubay, 2010; Siddiqi et al., 2009). Universal healthcare has not been a solution to the disparities noted among immigrant groups (Lebrun & Dubay, 2010; Siddiqi et al., 2009). Additionally, the uninsured immigrant population may rely on safety net clinics as their usual source of care however, English language proficiency is a significant barrier to access—even when a clinic is located within two miles of a person's home (Cordusco, Ponce, Gatchell, Traudt, & Escarce, 2011).

Medication Cost as a Barrier to Access and Adherence

The trend among both insured and uninsured people appears to be diminishing access to medication as a result of cost; this is particularly true for the elderly and vulnerable populations. Kennedy and Erb (2002) analyzed the results of 25,805 respondents to the Disability Follow-Back survey, a supplement to the 1994 and 1995 National Health Surveys. They found that 1.3 million adults with disabilities or chronic disease did not take medication as prescribed due to cost-related issues. Of those who did not take medication due to cost, more than half suffered health problems because of cost-related adherence issues.

Findings reported by other researchers support the thought that access to medication is decreasing, particularly among vulnerable populations. Reed (2005) analyzed data from the Community Tracking Household Survey, a nationally

representative telephone survey of civilian, noninstitutionalized adults for the years 2001 (n = 46,400) and 2003 (n = 36,500). When comparing 2001 to 2003 data, the proportion of American adults who report having problems with affording medication increased from 12% to 12.8% ($p < .05$). This inability to afford medications is seen more acutely in those suffering from chronic conditions, increasing from 16.5% to 18.3% ($p < .05$). Additionally, compared to low-income people with insurance, 58% of uninsured low-income adults with chronic conditions did not buy at least one prescription medication due to cost ($p < .05$). Among people with chronic disease, there is a difference seen across races and age: 30% ($p < .05$) of non-Hispanic Blacks and 17% ($p < .05$) of the elderly with Medicare did not purchase at least one medication due to cost.

Researchers have also explored the link between low-cost medications and clinical outcomes, adherence, and resource utilization. Schoen, DiDomenico, Connor, Dischler, and Bauman (2001) conducted a prospective cohort study to determine the effect of economic relief for prescription drugs on indicators of disease control in inner city uninsured, low socioeconomic patients with heart disease (n = 163) whose insurance did not provide prescription drug coverage. Researchers determined that patients who were assisted in obtaining free prescription drugs had improved clinical outcomes and increased adherence to medication regimens. Specifically, in patients with hypertension, mean blood pressure decreased from 138 ± 20/80 ± 11 mm Hg at baseline to 138 ± 19/78 ± 12 mm Hg at 6 months ($p < .05$ for diastolic blood pressure), and in those on lipid lowering medications LDL decreased from 126 ± 39 mg/dl at baseline to 108 ± 38 mg/dl at 6 months ($p < .0001$). Drug adherence improved from 48.5% at baseline to 72.7% at 6

months ($p < .0001$) and hospitalizations decreased from 85 at baseline to 49 at 6 months. Researchers determined that providing low-cost medications improves clinical outcomes and adherence. Additionally, the lack of low-cost prescription drugs may result in increased costs due to poor disease control and increased hospitalizations.

Reducing cost-related barriers is associated with improved clinical outcomes for people with diabetes. Gibson et al. (2010) examined the relationship between the patient cost sharing index (a score based on the patient copay) and adherence to medication in patients with type 2 diabetes. Gibson and colleagues found that even minimal increases in out-of-pocket costs may result in adherence problems and poor clinical outcomes in those with diabetes and other chronic diseases; an increase in the patient cost-sharing index of $10 resulted in a 5.4% reduction in adherence to oral antidiabetic medications. Medication adherence was associated with lower rates of complications including leg ulcers, amputations, and retinopathy and was also associated with fewer emergency department visits.

Underuse of medications is not uncommon in people with diabetes and other chronic diseases. Piette et al. (2004a) analyzed survey responses of 4,055 participants with chronic illness, ≥ 50 years to gain insight into cost-related underuse of medications. Their findings revealed that cost-related medication underuse occurred in 78% of respondents regardless of medication type or purpose. Piette and colleagues propose that up to 1 million (11%) of the 11 million adults diagnosed with diabetes (2004 data) may have been taking less than the prescribed amount of hypoglycemic agents because of cost, and up to 750,000 of these people underused their hypoglycemic medications at

least once per month (7%). Purposeful underuse of medication creates additional challenges related to disease management and reduction of comorbid complications.

People without insurance have higher rates of purposeful underuse of medication. Piette et al. (2004b) analyzed a patient survey linked to insurance information and HgbA1c in 766 adults with diabetes who received care at three sites, including a Veterans Affairs (VA) facility, a county healthcare facility, and a university healthcare system. They found VA patients reported less cost-related medication underuse (9%) than those with private insurance (18%), Medicare (25%), Medicaid (31%), or no health insurance (40%, $p < .0001$). Piette and colleagues concluded that many patients with diabetes use less than the prescribed amount of their medication due to cost-related adherence problems and those patients who take less medication due to cost are more likely to have comorbid conditions and poorer health.

One solution to cost-related nonadherence is the increased use of generic medications. Briesacher, Andrade, Fourayzi, and Chan (2009) conducted a secondary data analysis of 2001 to 2004 healthcare claims data from 45 large employers. Participants ($n = 327,629$) were 18 years or older and had one or more of five chronic conditions (hyperlipidemia, hypertension, hypothyroidism, seizure disorders, type 2 diabetes), and new use of generic-only or brand name-only medication therapy for the medical condition. Researchers found that generic medications were associated with greater adherence than brand name medications in patients with hyperlipidemia and diabetes ($p < .05$), and copayments of $0 were associated with improved medication adherence across all five chronic conditions.

When addressing issues related to nonadherence, it is important to consider cost in addition to drug effectiveness and quality of life when developing a treatment regimen. Klarenbach, Cameron, Singh, and Ur (2011) used the United Kingdom Prospective Diabetes Outcomes Model to predict diabetes complications, quality-adjusted life-years, and costs of second-line therapies for the treatment of adults with type 2 diabetes who reside in Canada. Researchers aimed to determine the costs, benefits, and cost-effective options for second-line treatments to be added to the therapeutic regimen. The addition of sulfonylureas to an existing regimen of metformin offered the most cost-effective second-line medication addition, offering a reported $12,757 per quality-adjusted life-year gained, relative to monotherapy with metformin. The reduction in HgbA1c was similar across second-line medications and resulted in only minor differences in long-term complications. However, alternative treatments including thiazolididiones and dipeptidyl peptidase-4 inhibitors had increased costs per quality-adjusted life-year gained. Therefore, researchers suggest the addition of a sulfonylurea as an appropriate second-line medication for most people with type 2 diabetes to control individual costs and improve quality of life.

Among people who are uninsured or do not have prescription drug coverage, medication cost may be a barrier to acquiring access to medications. Without adequate access to medication, there can be no adherence. In other words, people can not adhere to a medication regimen if they do not first have access to medication. People have been shown to self-select which medications should be underused (Piette et al., 2004a; Piette et al., 2004b). Research has shown that low-cost medication (Gibson et al., 2010; Kennedy

& Erb, 2002; Reed, 2005; Schoen et al., 2001), the use of generic medication (Briesacher et al., 2009), and thoughtful planning of an individually tailored medication program (Klarenbach et al., 2011) may increase a person's access and adherence to a medication regimen.

Some researchers have shown that there may be differences in adherence to medication regimens across race. Tinacty et al. (2009) conducted a longitudinal retrospective cohort study to examine differences in adherence to oral antidiabetic medications among Black and White adults (n = 1,906) using 10 years of patient-level claims and electronic medical record data from a managed care setting in which all members had prescription drug coverage. Outcome measures include time from diabetes diagnosis to first prescription of medication, time from first prescription to first refill, time from first prescription to discontinuation of medication, and long-term adherence over a 24-month period. Analysis revealed no racial difference in time to first prescription after diagnosis or in time to first refill, but Black patients discontinued medication at higher rates than White patients, *HR* 1.8, $p < .01$, 95% CI [1.2, 2.7]. Black patients were also less adherent to medication regimens over time. By the end of the 24-month study period more than half of Black patients and 44% of White patients had stopped medication for 60 days ($p < .0001$). Researchers conclude that racial differences persist over time even within a system that provides uniform access to care and medications. Early and continued education may improve adherence over time; however, additional studies are needed to identify barriers and focus on patient-centered approaches to adherence.

Improving Access Through Better Safety Net Systems

For vulnerable populations, perceived health status as well as actual health status may be affected by the burden of disease. Cashman et al. (2005) conducted a case study of a vulnerable population of low socioeconomic status using the 12-item Short-Form Health Survey and selected years of healthy life questions from the National Health Interview Survey to assess the self-perceived health status of 513 adult patients at a federally funded community health center in central Massachusetts. Physical and mental component summary scores were significantly lower than national norms for all age groups ($p < .001$); subjects were significantly more likely to be unable to perform major activities ($p < .0001$) and to be in fair or poor health ($p < .0001$). This analysis highlights the degree of difference in self-perceived health status between a vulnerable population of low socioeconomic status and society at large. Researchers determined that it is important to insure long-term funding of safety net clinics to provide healthcare services for the uninsured and other vulnerable populations.

In a descriptive study conducted by Hall (2011), the adequacy of access to care provided by safety net (SN) programs ($n = 5$) was compared to the levels of access offered by public or private insurance. Each of the programs in the study offer primary care, hospital care, medications, and specialty care services. Results revealed that physician use by SN members was similar to physician use in insured groups. In four of the five SN programs, subjects used emergency department services less than Medicaid members, but at rates higher than individuals with commercial insurance. The five SN program were able to meet the healthcare needs of uninsured adults at a level that was

similar to that of people with insurance. Coverage of services and providers was found to be adequate; however, in all but one of the five SN programs the area's needs surpassed the SN capacity, resulting in programs that serve only half or less of a community's low-income, uninsured adults. Hall proposes that well-structured SN programs offer approaches to care that may improve healthcare access for the uninsured.

Language proficiency may be an additional barrier to accessing healthcare services. Cordasco et al. (2011) examined the relationship of limited English language proficiency (LEP) and distance to the nearest safety net clinic (SNC) and access to care in nonrural, uninsured adults (n = 2,740) residing in California. Data from the 2005 California Health Interview Survey was analyzed to determine the distance from subjects' home address to the nearest safety net clinic. Multivariate regression was used to examine the associations between the calculated distance and the subject's probability of having a usual source of care and having visited a physician within the previous 12 months. Interactions between distance and language proficiency were included in the analysis. Researchers found that uninsured LEP adults living within 2 miles of a SNC were 9.3% (p = 0.046) less likely than English proficient (EP) adults to have a usual source of care. There was an inverse relationship between distance to the nearest SNC and the probability of having a usual source of care among LEP adults but not among EP adults. LEP adults residing within 5 to 10 miles of the nearest SNC were 25.2% (p = .003) less likely to have a usual source of care than those residing within 2 miles, and 27.3% (p = .002) less likely than those residing within 2 to 5 miles from a SNC. Among adults who live within 2 miles of a SNC, researchers found no difference in physician

visits. However, among LEP adults distance was inversely related with the probability of having a physician visit. Researchers determined that LEP is a barrier to healthcare access which is increased as distance to the nearest SNC increases.

Safety net clinics provide an essential source of healthcare services for people without insurance. Researchers have found that the healthcare services provided at safety net clinics are adequate and may reduce the use of emergency departments as a usual source of care (Hall, 2011). However, when possible, it is valuable to provide services in a patient's native language (Cordasco et al., 2011) as this may increase the use of safety net clinics as a usual source of care.

Increased Access Improves Adherence and Outcomes

It has long been known that adherence to medication regimens is associated with improved clinical outcomes and of course, people must have access to medication before they can adhere to medication regimens. Simpson et al. (2006) conducted a meta-analysis of the association between medication adherence and mortality. The authors included randomized controlled trials, retrospective analyses of data from randomized controlled trials, and observational research. Studies were included if they were original research, offered an explanation of the methods used to measure adherence, defined how adherence was operationalized, stratified patients into groups of good and poor adherers, and reported mortality by adherence group. The meta-analysis of 21 studies involving 46,847 participants revealed that good adherence reduced the risk of mortality to about half that of those patients with poor adherence.

In another large meta-analysis, DiMatteo et al. (2002) evaluated 63 studies covering a time period of over 30 years and involving more than 19,000 people which examined patient adherence and medical outcomes. Studies were analyzed by disease (acute or chronic and severity), population (adult or child), type of regimen (preventive or treatment of disease), and measurement methods of adherence and outcomes. DiMatteo and colleagues determined that 26% more patients experienced improved outcomes by adhering to therapeutic regimens than by not adhering to therapeutic regimens.

Researchers have examined interventions designed to improve the health of individuals and communities targeted at increasing access and adherence to medication regimens. Ruelas et al. (2009) established a disease management program in which medications were supplied to patients free of charge in an underserved East Los Angeles health center serving Latino patients. Patients (n = 162) were enrolled in either the control group (n = 79) which received the disease management program for 6 months and then was discharged to annual follow-up, or the episodic group (n = 83) which received the disease management program for 6 months and follow-up evaluations every 3 months. Finding no difference in the number of visits between the control group (discharged to annual follow-up) or the episodic group (follow-up every 3 months), Ruelas and her colleagues determined that when comparing adherence to the number of follow-up visits, medication adherence was the strongest predictor of reaching the target A1C of < 8%.

A number of studies have shown that providing free or low-cost medications results in increased access to medication and adherence. Horswell et al. (2008) conducted

a retrospective study of the effect of a medication assistance program (MAP) on HgbA1c in uninsured people with type 2 diabetes. In this medical center program, people who qualified for state-supported free healthcare services received outpatient primary care, specialty care, and inpatient care. Financial coverage for outpatient prescription medications was not included in this program. The MAP provided a 30-day supply of medications free of charge from drug manufacturers' pharmacy assistance programs. Typical eligibility criteria for these programs include the requirement that participants are uninsured and have incomes below 200% of the federal poverty level. In this study, Horswell and colleagues examined the effect of the "number of refill opportunities taken" (p. 677) on HgbA1c. The MAP had a mean effect of -.60% on HgbA1c levels; however, greater adherence resulted in greater improvements: Those who were completely adherent to the medication regimen had an estimated .88% improvement in HgbA1c.

Other researchers have revealed that low-cost generic medication programs increase the number of prescriptions filled by uninsured or underinsured people, thereby increasing access to medication. Bright et al. (2010) described the implementation of a $4 generic prescription drug program at a federally qualified health center designed to improve access to medication. A total of 93 medications were offered on the clinic's formulary. Patients at the clinic either had prescription coverage through Medicaid or no prescription coverage. Of the prescriptions filled at the center, 89% had no form of prescription coverage and were for patients whose incomes were 200% below the federal poverty level. A total of 7,134 prescriptions were filled from January to March 2009,

compared to 6,166 for the same period in 2008. Reducing the cost of prescriptions resulted in increased access to medications.

Pharmaceutical manufacturer assistance programs have helped increase access to medication for many people. Patel et al. (2006) conducted a pre-post study at a university hospital outpatient clinic on the effect of a pharmacy-managed medication assistance program that procured medications from pharmaceutical manufacturers for low socioeconomic patients with type 2 diabetes (n = 143) on HgbA1c and total cholesterol. Manufacturers generally take four to six weeks to approve applications and ship medications to patients. To offset this delay, eligible patients were authorized a free prescription from the university clinic pharmacy. Six months after program implementation mean HgbA1c was significantly reduced, M = -0.85%, p = .002, 95% CI [-.034, -1.37], and there was a 33% increase in the percentage of patients who achieved the goal HgbA1c level of < 7% (p = .008). Additionally, significant reductions in mean total cholesterol were achieved, M = 25.7 mg/dl, p = .001, 95% CI [-11.1, 40.2]. By coordinating efforts between pharmaceutical manufacturers and a clinic pharmacy, gaps in access to medication can be alleviated, resulting in improved clinical outcome measures.

In a similar study, Strum et al. (2005) conducted a retrospective analysis (pre-post design) of the effect of a university clinic-based medication assistance program on health outcomes and medication use in patients with type 2 diabetes (n = 52). The clinic-based pharmacy-managed program procures mediations for patients of low socioeconomic status from pharmaceutical manufacturer's drug assistance programs. Manufacturer's

medication assistance programs take four to six weeks to ship medications, so once the pharmaceutical manufacturer's applications are completed, patients receive medications from the clinic outpatient pharmacy for a $5 fee. Patients received more prescription medications ($p < .0001$) and antihyperglycemic medications ($p = .001$) after enrollment in the program. Mean HgbA1c was significantly reduced from 9.3% ±2.4 to 8.5% ± 1.5, ($p < .001$) as was mean LDL cholesterol from 118 mg/dl ± 36 to 102 mg/dl ± 31 ($p < .001$). Researchers concluded the medication assistance program increased patients' access to antihyperglycemic medications and improved clinical outcomes.

The importance of improving access to essential medications from a variety of classes at low cost is essential to improving access to medication (Bright et al., 2010; Horswell et al., 2008; Patel et al., 2006; Strum et al., 2005). When access to medication is improved, people are more likely to adhere to medication regimens as prescribed and not engage in purposeful underuse or rationing medications due to cost (Piette et al., 2004a; Piette et al., 2004b). Improved access and adherence have been shown to improve long-term outcomes and reduce mortality (DiMatteo et al., 2002; Simpson et al., 2006).

Resource Utilization

Burden of Chronic Disease

The burden of chronic disease on society is substantial from both a clinical and an economic standpoint. Druss, Marcus, Olfson, Tanielian, and Pincus (2001) completed a secondary data analysis of the Medical Expenditure Panel Survey (MEPS) conducted by the Agency for Healthcare Research and Quality ($n = 23,000$). The MEPS provides nationally representative estimates of healthcare cost and use, sources of payment, and

insurance coverage for families and individuals. Druss and colleagues examined patterns of economic burden across five chronic diseases including mood disorders, diabetes, heart disease, asthma, and hypertension. It was found that almost one quarter of the U.S. population has one or more of these five conditions—which accounted for almost half of U.S. healthcare costs in 1996. Approximately one quarter of total expenditures was for treating one of the five conditions; the remainder was spent on treating comorbid conditions. Among the five conditions, comorbidity was most common in people with diabetes. Conditions including infection and microvascular and macrovascular disease account for a large portion of the clinical and economic burden of diabetes. Researchers suggest that policymakers focus cost control efforts on issues that drive the high cost of healthcare including comorbidity and prevalence, socioeconomic factors, and insurance.

The economic burden of chronic disease is also significant for individuals who are insured. Shen and McFeeters (2006) conducted a secondary data analysis of the 2002 National Survey of America's Families to analyze out-of-pocket spending on healthcare in low-income people with insurance and higher income people with insurance (n = 33,897). It was found that insured, low-income people with serious health needs are financially stretched and spend less on healthcare than higher income people. Additionally, families with the same insurance plan and the same medical expenditures may have different levels of financial burden due to the financial constraints related to differences in income. Researchers discovered that health insurance does not prevent people from having high healthcare expenses. In fact, a substantial number of the two million Americans who experienced a medical bankruptcy in 2002 had health insurance.

This study revealed that even among people who have health insurance the economic burden of disease can be high.

To examine health resource utilization and the cost of care associated with heart failure (HF) and diabetes (DM), Bogner, Miller, De Vries, Chhatre, and Jayadevappa (2010) conducted a retrospective case-control design at a large urban academic healthcare system in people over age 65 with Medicare. HF and DM are the most common chronic illnesses in the elderly. Data were abstracted from the Medicare claims database for 2000 and 2001 on resource utilization in four groups of elderly patients: those with HF and DM (n = 498), those with HF only (n = 1089), those with DM only (n = 971), and those with no HF and no DM (n = 5438). Researchers found the mean total costs were highest ($32,676) in people with HF and DM, second highest in those with HF only ($22.230), and third highest in those with DM only ($10,566). Researchers propose that in those with HF, a coexisting diagnosis of DM increases utilization of all medical care resources with specific increases in inpatient care utilization.

People with sporadic health insurance are more likely to decrease prescription fills and increase emergency department use. Banerjee, Ziegenfuss, and Shah (2010) conducted a secondary data analysis of the 2000 to 2004 Medical Expenditure Survey (MEPS) to examine the effect of health insurance instability on resource utilization in adults enrolled in Medicaid (n = 6,247). Insurance instability was defined as the number of times an individual transitioned into or out of Medicaid. After controlling for employment and health status, researchers determined that individuals with more than one transition in health insurance status are likely to have higher healthcare utilization

than individuals with one or no transitions. In people who are unstably insured (without continuous Medicaid coverage), emergency department use, office visits, and hospitalizations increase by 10% and 36%, while the use of prescription medications falls by 19%.

Conversely, programs that provide medical care and medications may result in overall reductions in resource utilization. Nykamp and Ruggles (2000) conducted a small pre-post study of 36 patients of lower socioeconomic status who were enrolled in a program that provided medical care and prescription drugs at no cost to patients. Inpatient charges for the 6 months prior to the study's implementation were $838,145, while the total charge for these patients during the 6-month program was $459,962. The cost of drugs that were supplied to the patients during the study was $27,588. Hospital admissions decreased by 39.5% and outpatient visits decreased by 64.4%, representing a total cost avoidance of $378,183 by the hospital, representing more than $10,000 per patient.

Among people who are under- or uninsured, the cost of chronic disease management is high for both individuals and society (Banerjee et al., 2010; Bogner et al., 2010; Druss et al., 2001; Shen & McFeeters, 2006). For those with diabetes and heart disease the cost is even greater (Shen & McFeeters, 2006). Since the most common cause of mortality for people with diabetes is macrovascular disease, it can be expected that the clinical and economic burden will be high for individuals and society. However, redirecting expenditures from hospital admissions and emergency department visits may result in overall cost savings for institutions and society (Nykamp & Ruggles, 2000).

Medication Adherence and Resource Utilization

It has been documented that medication adherence varies. Additionally, measuring medication adherence can be difficult and inaccurate. Cramer (2004) conducted a systematic review of studies conducted from 1966 to 2003 using quantitative data on adherence to oral hypoglycemic agents (OHAs) and insulin. The systematic review was based on 20 reports that examined correlations between adherence rates and glycemic control. When comparing retrospective studies to prospective studies it was found that retrospective studies revealed adherence to OHAs ranging from 36 to 96% in patients who remained on medication for 6 to 24 months. Prospective studies that used electronic monitoring devices to measure adherence revealed that patients adhered to OHAs as prescribed 67 to 87% of the time. Electronic measuring devices provide a more accurate measure of adherence, meaning that people may take 11% more medication than estimated in retrospective analyses. However, adherence rates in both retrospective and prospective studies revealed varying and frequently suboptimal levels of adherence.

The association between medication adherence and healthcare resource utilization has been well documented. Asche, LaFleur, and Conner (2011) conducted a review of studies (n = 37) that examined the association between adherence and glycemic control, healthcare resource utilization, and quality of life and mortality in patients with diabetes. Articles were identified through a PubMed database search and were included in the review if they met four criteria: analyzed empirical data on patient adherence; described methods of measuring adherence; evaluated clinical, economic, or humanistic outcomes; and had a primary research goal to evaluate the link between adherence and outcomes. Of

the 37 articles, 59% (n = 22) used objective methods to measure adherence; 1 study used pill counts to assess adherence and the remaining 21 studies used pharmacy refill records to assess patient refill behavior. In studies (n = 23) that examined glycemic control, 57% reported a positive relationship between adherence and glycemic control. Studies that used prescription refill behavior as a measure of adherence (n = 7) were more likely to identify a relationship between adherence and glycemic control. Ten studies examined the link between adherence and healthcare resource utilization; 8 studies examined hospitalization as an outcome and 3 studies examined emergency department visits as an outcome. Seven of 8 studies (87%) revealed a significant relationship between higher levels of adherence and decreased hospitalizations. Two studies of 3 (66.7%) revealed a significant relationship between increased adherence and decreased emergency department visits. Future research should include longer observation periods and focus on additional mediators. Researchers conclude that increased adherence is associated with improved glycemic control and decreased healthcare resource utilization.

People who are less adherent to medication regimens are more likely to be hospitalized. Lau and Nau (2004) conducted a study to examine the association between oral antihyperglycemic nonadherence and hospitalizations in people with type 2 diabetes (n = 900) using administrative claims data from 2000 to 2001. Nonadherence was defined as a medication possession ratio (MPR) of < 80%. The MPR is commonly used to measure the proportion of days that a patient possesses a supply of medication: The denominator in the MPR is the total number of days between the first and last refill date of medication and the numerator is calculated by summing the number of days dispensed

for all but the most recent refill of medication. In 2001, 28.9% of patients were nonadherent to the antihyperglycemic drug regimen, 18.8% were nonadherent to antihypertensive drug regimens, and 26.9% were nonadherent to lipid modifying drug regimen. Nonadherence to antihyperglycemic drugs was 28.8% in 2000. Patients who were nonadherent (MPR < 80%) to antihyperglycemic agents in 2000 were at greater risk of hospitalization in 2001, *OR* 2.53, 95% CI [1.38, 4.64]. However, nonadherence to medications for hypertension and dyslipidemia was not significantly associated with hospitalizations. Researchers propose that patients with type 2 diabetes who fail to obtain 80% of their antihyperglycemic medications across the period of a year are at greater risk of hospitalization in the following year. Interventions aimed at increasing adherence may provide "substantial benefits" to both patients and payers of healthcare services.

Findings are mixed regarding adherence to medication and overall medical care expenditures. Hepke, Martus, and Share (2004) conducted a retrospective cohort study using insurance claims to determine whether adherence to pharmaceutical therapy affects well-being and total costs associated with diabetes treatment. Subjects (n = 57,687) were under age 65 and continuously enrolled in a medical insurance plan with drug coverage. Researchers found a threshold effect indicating that a target level of adherence (20 to 39%) was required before nonpharmacy medical care costs were reduced. Nonpharmacy care included emergency department visits and hospitalizations for any diagnosis (R^2 = 0.5465). This was true except in those with diabetes as a primary diagnosis, in which case a higher adherence threshold was required (40 to 50%) before a decrease in cost and nonpharmacy care (R^2 = 0.1213) was appreciated. Researchers found that increased

pharmaceutical adherence is associated with decreased emergency department visits and inpatient hospitalizations, suggesting that improved well-being is associated with better disease control. Increased medication adherence is associated with decreased medical care costs; however, increased adherence may not be associated with decreased overall healthcare costs because the cost of medication offsets the savings in medical care expenditures.

Similar findings regarding medication adherence and healthcare expenditures were reported by Sokol, McGuigan, Verbrugge, and Epstein (2005). Researchers conducted a large retrospective cohort observation of patients (n = 137,277) continuously enrolled in medical and prescription plans from June 1997 through May 1999 to evaluate the impact of medication adherence on healthcare utilization and cost for four chronic conditions that drive drug spending: diabetes, hypertension, hypercholesterolemia, and congestive heart failure. During the study's first 12 months patients were identified for disease-specific analysis based on claims for outpatient, emergency room, or inpatient services. During the second 12 months medical and drug utilization were measured using analysis of administrative data. For adherence levels of 80 to 100% (measured as days' supply of medication), diabetes medical costs were reduced to $3,808 ($Adj\ r^2$ = 0.18, F = 36.62, p = < .0001), and drug costs were increased to $763 ($Adj\ r^2$ = 0.36, F = 88.57, p = < .0001). In all four chronic conditions, hospitalization rates were significantly lower for patients with high adherence (p < .05). Researchers found that for diabetes and hypercholesterolemia, high medication adherence was associated with lower disease-

related medical costs ($p < .05$) because higher medication costs (related to increased adherence) were offset by medical care cost reductions.

Adherence rates are variable in both retrospective and prospective studies and methods of measuring adherence are frequently inaccurate (Cramer, 2004). Despite the difficulties with measuring adherence, it is clear that medication adherence reduces healthcare utilization (Asche et al., 2011). However, researchers report mixed results regarding overall health expenditures. Some studies find that increased adherence to medication decreases overall healthcare expenditures by decreasing hospitalizations (Lau & Nau, 2004), while other studies have found that the cost associated with increased adherence offsets the savings associated with decreased resource utilization (Hepke et al., 2004; Sokol et al., 2005).

Theoretical Framework

It is widely accepted that adherence improves health outcomes; however, identifying the most effective interventions has proven to be elusive. Van Dulmen et al. (2007) conducted an analysis of 38 systematic reviews on the effectiveness of adherence interventions published between 1990 and 2005 to identify underlying theories for effective interventions. Significant differences in the effectiveness of adherence interventions were found in 23 of the 38 systematic reviews. Researchers found that adherence interventions based on technical solutions (simplification of regimen) may be effective despite the lack of a theoretical explanation. Other successful interventions including incentives and reminders are grounded in behavioral theories. Van Dulmen et al. found that of the 38 systematic reviews that were evaluated, few studies have

examined theoretical models as they relate to adherence interventions. As use of a theoretical framework is essential to assess the effectiveness of adherence interventions, future research should focus on identifying a theoretical framework that will be useful in adherence studies.

Individuals Are Responsible for Chronic Disease Outcomes

In recent decades, there has been a slow but progressive paradigm shift from "compliance" to "adherence" when analyzing whether people decide to adopt or continue healthcare behaviors. This shift reflects not only a change in labeling patient behavior, but also a change in how researchers think about the interactions between complex, and often competing, personal, community, and societal demands on individuals as they make health decisions. Brawley and Culos-Reed (2000) state that compliance characterizes the extent to which people obey or follow through on instructions and expected behaviors as defined by a healthcare provider. Adherence, however, refers to behaviors that are freely selected by people after careful consideration and active collaboration developing and adjusting treatment plans; it has become the conceptual lens through which individual patient behaviors are analyzed. Conceptualizing patient behaviors within a framework of "adherence" is a positive change; however, this paradigm is one that continues to hold the individual responsible for disease outcomes and does not acknowledge the importance of the forces imposed by the societal context in which people live. Leonard (2005) states that focusing on individual behaviors, without considering the social determinants which affect those behaviors, has resulted in the belief that individuals are solely responsible for engaging in self-care behaviors and perpetuates the mentality of holding individuals

responsible for chronic disease outcomes. It is becoming increasingly important to use a conceptual framework that can identify and measure the mediating factors that affect behavior through the context in which people experience daily living.

Although it is important to identify mediators conceptually, increasing knowledge about mediating variables in behavior does not necessarily result in interventions that improve adherence (Rejeski, Brawley, McAuley, & Rapp, 2000). The gap between knowledge and effective interventions may occur because "existing research typically has been designed to garner support for theory, as opposed to testing support for behavior change strategies that are based on theory" (p. 164S). Baranowski, Lin, Wetter, Resnicow, and Hearn (1997) found that the amount of variance in outcome variables is low after introducing interventions designed to produce change in mediating variables. When the variance in outcomes is low, Sirur, Richardson, Wishart, and Hanna (2009) propose that additional mediating variables are not identified or measured, or that the theoretical framework used in the study is not complete. Efforts to develop interventions that result in behavioral change should focus on using a theoretical framework that views individual behavior from a broader social determinants perspective. In this way it becomes possible to fully appreciate the complexity and interconnectedness of factors that result in individual behavior choices.

Social Determinants of Health

A theoretical framework that has been used to guide studies that evaluate the effectiveness of interventions designed to improve outcomes is the Social Determinants of Health (SDOH). Bambra et al. (2010) conducted a systematic review to identify

systematic reviews completed from 2000 to 2007 that described the health effects of interventions based on the wider social determinants of health, including water and sanitation, agriculture and food, access to health and social services, unemployment and welfare, working conditions, housing and living environment, education, and transportation. Two reviewers independently screened titles and abstracts from the literature (n = 1,694) and those articles deemed relevant were reviewed in detail (n = 84). Thirty systematic reviews that met the inclusion criteria were included in the review. Inclusion criteria specified that subjects were adults (16 or older) who live in developed countries. Although the overall health effect was considered in these studies, outcome data included the impact of inequalities on health or well-being by socioeconomic status. The effect of interventions on health inequalities is unclear, but evidence suggests that interventions aimed at housing and the work environment may have a positive impact on disadvantaged groups. Numerous studies have explored the social determinants with descriptive epidemiological studies however, researchers suggest that future studies examine specific interventions aimed at the wider social determinants of health.

Schulz et al. (2005) conducted a case study description and analysis of a community-based participatory diabetes intervention to identify facilitators and barriers to community efforts aimed at addressing the social determinants that contribute to health. Barriers included prevailing conceptual models which "emphasize behavioral and biomedical paradigms that exclude social determinants of health" (p. 645). Facilitators included opportunities to link individual outcomes to social contexts and availability of support "from diverse partners with a range of complementary resources" (p. 645). The

community-based intervention provided in-depth information about diabetes, the increased community resources for healthy eating and physical activity, addressed aspects of SDOH that affect people who are vulnerable to diabetes, and strengthened relationships among community organizations, healthcare providers, and academic institutions. Partnerships that offer tangible resources to manage disease within a social determinants framework can facilitate "sustained engagement of community members and health professionals in multilevel efforts to address health disparities" (p. 645).

Numerous studies have used a traditional linear approach to analyze interventions designed to affect the social determinants of health. Because of this linear approach, Glasgow, Lichtenstein, and Marcus (2003) state that it has been difficult to translate health promotion research into clinical interventions that have a positive effect on health outcomes. Rather than proceeding in a traditional linear approach, research must advance to a multilevel approach that promotes a comprehensive view of our complex world. Exworthy (2008) asserts that the social determinants of health are "multi-faceted phenomena" (p. 320) that must be acknowledged in designing interventions. Along the same lines, Glasgow and colleagues state that there must be a "greater understanding of, and research on, setting-level social contextual factors" (2003, p. 1266) if successful and sustainable interventions are to be designed and implemented.

The challenge for researchers is to design and report studies that increase the quality of research and advance the current knowledge of social contextual factors' effects on health outcomes. To accomplish this Ansari, Carson, Ackland, Vaughan, and Serraglio (2003) propose a theoretical framework "which encompasses a role for the

social determinants of health while also acknowledging the importance of behavior and biology, and the interconnectedness of all these factors" (p.242). The model must provide a framework for testing the causal pathways linking the social determinants of health with characteristics of the healthcare system and behaviors which affect disease and health outcomes (Ansari et al., 2003; Exworthy, 2008). A multilevel model of this type supports analyzing the social contexts in which people live their lives while guiding the development of interventions focused on the social determinants of health.

Tarlov (1999) proposes that genes, biology, and health behaviors account for roughly 25% of population health (Figure 1). Three social determinants of health—societal characteristics, physical environment (total ecology), and medical care/healthcare services—account for the remaining estimated 75% of population health. These three social determinants interact with health behaviors to affect health outcomes and represent an opportunity to mediate change through interventions designed to improve population health.

Researchers have traditionally examined individual behaviors and personal choices in the quest for increased knowledge about the "best" ways to improve individual adherence (DiMatteo et al., 2002; Gibson et al., 2010; Simpson et al., 2006;). The findings of these studies have been mixed; there is no clearly defined intervention that is likely to improve adherence and result in better outcomes.

Diabetes is a serious metabolic disorder that can cause significant suffering for individuals and increased burden for society. Many of the longterm effects of diabetes can be delayed or reduced with improved glycemic control through medication

management (DCCT, 1993; UKPDS, 1998; ACCORD, 2008; ADVANCE, 2007; VADT, 2009). However, people without insurance have difficulty accessing healthcare and medicine (Wagner et al., 2010), and are less likely to visit a healthcare provider or have a usual source of care (Law & VanDerslice, 2011; Pagan & Puig, 2005; Schoen et al., 2010; Wilpur et al., 2008). The importance of improving access to essential medications from a variety of classes at low cost is an essential component to improving access (Bright et al., 2010; Horswell et al., 2008; Patel et al., 2006; Strum et al., 2005). In other words, improved access to medication must include the availability of many medications from a variety of classes used for the treatment of chronic disease. When access to medication is improved, people are more likely to adhere to medication regimens which may improve long-term outcomes and reduce mortality (DiMatteo et al., 2002; Simpson et al., 2006). This study aims to examine the relationship between continuous access to a wide variety of essential medications and healthcare outcomes. The methodology of this study will be discussed in chapter 3.

3. METHODOLOGY

This chapter presents the research design and the sample plan, including a review of the major variables, hypotheses, conceptual and operational definitions, data collection process, data analysis plans, and ethical considerations.

Purpose

This study's purpose is to explore the relationship between continuous access to medication (CAM) and HgbA1c, systolic blood pressure (SBP), diastolic blood pressure (DBP), low density lipids (LDL), emergency department visits (EDVs), and hospitalizations (HSPs) in uninsured people with type 2 diabetes.

Research Design

This was a quasi-experimental within-subjects study to examine the relationship between continuous access to medication and healthcare outcomes. Quasi-experimental designs are commonly used in social science and health sciences research and differ from experimental designs in that they do not randomize subjects to control and intervention groups (Polit & Beck, 2008). Without randomization it can not be assumed that the groups are equivalent at the outset of the study and alternative explanations of results must be explored. This research was conducted in two steps.

Step One was a pretest–posttest study design of the physiologic variables and healthcare resource outcome variables. In this design subjects serve as their own control;

outcomes are measured both before the intervention and with the intervention on each subject, then pretest–posttest results are compared. The one-group pretest–posttest design has a major weakness: the inability to identify and/or measure mediating factors that may affect the dependent variable. Pretest–posttest studies without a comparison group are considered preexperimental (Campbell & Stanley, 1963); however, as exploratory studies they may be used to discover trends and gather information to guide future research (Polit & Beck, 2008).

Step Two of this study was a quasi-experimental longitudinal time-series analysis of subjects who had more than one outcome measure in the preintervention period. It is an extension of the pre-post within-subjects design in which subjects serve as their own control. The primary advantage of the time-series design is the ability to achieve a specified level of power with fewer subjects by reducing within-subjects variability (Laerd Statistics, 2012).

Charts from a 5-year period (January 1, 2006 to December 31, 2010) were included in the analysis. A retrospective chart audit was conducted to collect existing data. This secondary data analysis examined data that were originally collected during patient primary care visits to the Mobile Health Van (MHV). The MHV data set includes both demographic data (date of birth to determine age, gender, and ethnicity) and physiologic data (HgbA1c, LDL, BP, height, and weight). Other data that were originally collected at the MHV's hospital during visits to the outpatient laboratory, the emergency department, and during patient hospitalizations were also examined. The outpatient laboratory data set includes values for HgbA1c and LDL. If these data were not located in

the MHV record they were abstracted from the outpatient laboratory data set. Hospital data included the actual number of emergency department visits and hospital visits in the preintervention and postintervention periods. Lastly, pharmaceutical data (prescription names and dosages, days' supply of medication dispensed, and refill dates) that were originally collected by the MHV's associated prescription procurement program (PPP) were examined.

Sample Description and Power Analysis

A convenience sample of all MHV patients with type 2 diabetes who were 18 years or older during the study dates (January 1, 2006 to December 31, 2010) were considered for inclusion. Those with comorbid conditions including hypertension, dyslipidemia, and depression were included. All subjects were uninsured and were at or below 200% of the federal poverty level. All subjects were MHV patients prior to enrolling in PPP. Subjects represent many ethnic backgrounds, but most were White, Hispanic, African, or African-American. A smaller number of subjects represented ethnic groups from North Africa, the Middle East, and Central Asia. Many did not speak English.

Sample size is related to the selected significance level, power, and effect size. In the pre-post group, Cohen's (1988) *t*-test tables were used to determine sample size. Dependent *t*-test tables are not presented in the text. Cohen recommends using independent *t*-test tables for sample size calculations; however, he states that in pre-post designs the sample size is smaller than that indicated in the independent *t*-test tables since there is an existing correlation between each subject's pre- and post-measures. For this

study an effect size of .5 was selected, alpha was set at .05, and power was set at .8. Based on the selected effect size, alpha level, and desired power, sample size for the pre-post group was estimated at 64 subjects. Data were collected on 65 subjects.

In the time-series group, Cohen's (1988) analysis of variance (ANOVA) tables were used to determine sample size. With an effect size of .5, alpha set at .05, and power set at .8, sample size was estimated at 16. Data were collected on 17 subjects.

Exclusion Criteria

Subjects were excluded if they were less than 18 years old or were pregnant during the inclusion dates. Subjects with a diagnosis of prediabetes and those who developed diabetes during the study inclusion dates were excluded. Those with a diagnosis of emotional or mental disease or disability other than depression were excluded. Many mental illnesses preclude an individual's ability for independent self-care behaviors. However, about 20 to 25% of people with diabetes have depression—nearly twice as many as those people without diabetes (CDC, 2011). Because depression is not uncommon in people with type 2 diabetes, those with depression as a comorbid condition were included in the study, but those with other mental illnesses were not included.

Variables

The physiologic outcome measures in this study (dependent variables) were HgbA1c, LDL, SBP, and DBP in both the preintervention and the postintervention periods. The healthcare resource utilization outcome measures were the actual number of emergency department visits (EDVs) and the actual number of hospitalizations (HSPs) in

both the preintervention and postintervention periods. Demographic variables included in the study were age, gender, ethnicity (country of origin), primary language, and comorbid conditions.

Hypotheses of the Pre-Post Group

1. Continuous access to medication is related to improved (a) HgbA1c, (b) LDL, (c) SBP, and (d) DBP in uninsured adults with type 2 diabetes.
2. Continuous access to medication is related to reduced emergency department visits (EDVs) and hospitalizations (HSPs) in uninsured adults with type 2 diabetes.

Hypothesis of the Time-Series Group

1. In uninsured adults with type 2 diabetes with HgbA1c measures at entry, preintervention, and postintervention; continuous access to medication is related to improved HgbA1c over time.

Conceptual and Operational Definitions

Conceptual and operational definitions of the study variables are presented in Table 1. The independent variable, continuous access to medication (CAM) is an intervention that was implemented on September 1, 2007. However, the date that CAM was obtained differs for each subject depending on the date that their initial prescription was faxed to the prescription procurement program. The dependent variables were measured at three time points: at entry to the study, prior to implementing the intervention, and with implementing the intervention. The mediating factors of age, gender, and ethnicity were used to describe the subjects in the study.

Independent Variable: Continuous Access to Medication (CAM)

Continuous access to medication was operationalized as the date of the first prescription procurement program (PPP) prescription request. This is the date that PPP received the prescription request and entered information into the PPP electronic record. The date of the first PPP request does not represent the date that the patient took possession of the medication. Because the date that patients picked up their prescriptions from the MHV mobile vans can not be tracked accurately for each subject, the date of the first PPP request was used to operationalize CAM since it is a more accurate measure of the intervention.

Dependent Variables

- Entry Data: The outcome measure immediately prior to the preintervention measure. The measure must have occurred not less than 3 months prior to the preintervention measure but not more than 12 months prior to CAM.
- Preintervention Physiologic Data: The single measure of systolic blood pressure, diastolic blood pressure, weight, HgbA1c, and LDL measures immediately prior to CAM.
- Postintervention Physiologic Data: The average value for systolic blood pressure, diastolic blood pressure, weight, HgbA1c, and LDL measures in the 1-year postintervention period. The number of values differed for individual subjects based on the number of visits to the MHV and the hospital laboratory. An average value for each outcome variable provided a more accurate analysis of postintervention disease.

- Preintervention Emergency Department Visits: The total number of emergency department visits in the preintervention period.
- Postintervention Emergency Department Visits: The total number of emergency department visits in the postintervention period.
- Preintervention Hospitalizations: The total number of hospitalizations in the preintervention period.
- Postintervention Hospitalizations: The total number of hospitalizations in the postintervention period.

Table 1

Conceptual and Operational Definitions

Variable	Conceptual Definition	Operational Definition
Independent Variable		
Continuous access to medication (CAM)	Having affordable medications available on a sustainable basis (United Nations, 2008). Social Determinants of Health Model: Level 2, Living and Working Conditions (Dahlgren & Whitehead, 1991).	The date that the prescription procurement program (PPP) received the prescription request.
Dependent Variables		
Glycosylated Hemoglobin (HgbA1c): Glycoprotein formed when glucose binds to hemoglobin ("HgbA1c," n.d.).	Social Determinants of Health Model: Level 4, Individual Lifestyle Factors (Dahlgren & Whitehead, 1991).	Entry: The HgbA1c immediately prior to the preintervention measure: not less than 3 months prior to the preintervention measure but not more than 12 months prior to CAM. Preintervention: For each measure of HgbA1c, the value immediately prior to CAM. Postintervention: For each measure of HgbA1c, the average of all values during the 1 year with CAM.
Low Density Lipids (LDL): Lipoprotein of blood that is associated with increased probability of developing atherosclerosis ("LDL," n.d.).	Social Determinants of Health Model: Level 4, Individual Lifestyle Factors (Dahlgren & Whitehead, 1991).	Preintervention: For each measure of LDL, the value immediately prior to CAM. Postintervention: For each measure of LDL, the average of all values during the 1 year with CAM.
Systolic Blood Pressure (SBP): Highest arterial blood pressure of a cardiac cycle occurring immediately after systole ("SBP," n.d.).	Social Determinants of Health Model: Level 4, Individual Lifestyle Factors (Dahlgren & Whitehead, 1991).	Preintervention: For each measure of SBP, the value immediately prior to CAM. Postintervention: For each measure of SBP, the average of all values during the 1 year with CAM.

(continued)

Table 1 Conceptual and Operational Definitions (continued)

Variable	Conceptual Definition	Operational Definition
Dependent Variables		
Diastolic Blood Pressure (DBP): Lowest arterial blood pressure of a cardiac cycle occurring during diastole of the heart ("DBP," n.d.).	Social Determinants of Health Model: Level 4, Individual Lifestyle Factors (Dahlgren & Whitehead, 1991).	Preintervention: For each measure of DBP, the value immediately prior to CAM. Postintervention: For each measure of DBP, the average of all values during the 1 year with CAM.
Emergency Department Visits (EDVs): The emergency department is a hospital area staffed and equipped to treat people with illness or trauma requiring immediate medical care ("Emergency Department," n.d.).	Social Determinants of Health Model; Level 4, Individual Lifestyle Factors (Dahlgren & Whitehead, 1991)	Preintervention: The actual number of EDVs in the 1 year prior to CAM. Postintervention: The actual number of EDVs in the 1 year with CAM.
Hospitalizations (HSPs): Hospitalization is the act or process of being hospitalized ("Hospitalization," n.d.).	Social Determinants of Health Model; Level 4, Individual Lifestyle Factors (Dahlgren & Whitehead, 1991)	Preintervention: The actual number of HSPs in the 1 year prior to CAM. Postintervention: The actual number of HSPs in the 1 year with CAM.

Data Collection and Analysis

Collection

Data were abstracted from the medical records at the three sites where the data were originally collected: the hospital, the MHV, and the PPP. As data were abstracted they were documented and stored in a Microsoft Excel spreadsheet. Although the data storage systems differ significantly at each site, patients were identified by the same medical record number at each of the data collection sites. Additionally, both the hospital

and the MHV are part of the same healthcare system, at the hospital data are stored electronically; at the MHV data are collected and stored on paper charts. Because of this, hospital laboratory values and emergency department visit data can be accessed by computer from the MHV. At the PPP data are stored electronically using a different electronic medical record (EMR) system than the one in use at the hospital. The EMR at the hospital and the EMR at the PPP do not have the technical ability to communicate with each other.

Step-wise data collection was conducted as follows:

1. Data collection was initiated at the prescription procurement program (PPP). Using an electronic medical record system, potential subjects were identified by whether or not they were prescribed a medication for diabetes management during the study inclusion dates. Medication data were collected on each of these subjects.
2. Following data collection at the PPP, data were collected on subjects at the Mobile Health Van (MHV). Paper charts were reviewed on both mobile health clinic vans. Demographic data, blood pressure, height, weight, and laboratory data were collected from these records.
3. Following data collection at the MHV, data about emergency department visits and hospitalizations in the preintervention and postintervention periods were collected from the hospital's electronic medical record system (EMR).

Analysis

Descriptive statistics were used to describe and summarize the data collected on the subjects in the study. Univariate analyses were used to describe the sample by the demographics of gender, ethnicity, age, comorbid conditions, and number of medications.

The first pre-post research hypothesis was answered using dependent *t*-test statistical analyses (see Table 2). In dependent *t*-tests, data are compared before the intervention and after the intervention on each subject. This is a within-subjects design; the groups analyzed are not independent of each other and subjects serve as their own control (Polit, 2010). Variance between groups is typically smaller since the groups are made of the same people and characteristics specific to each subject have similar effects on both the pre- and postintervention group means. There are three assumptions associated with dependent *t*-tests: the independent variable is categorical and has two levels, the distribution of the dependent variable is normal, and the variances for the dependent variable are similar across groups. The third assumption is a protection against Type II errors, that is, incorrectly accepting the null hypothesis. In this study the three assumptions were met. The IV, continuous access to medication (CAM) was categorical with two time period levels: preintervention (pre-CAM) and postintervention (with CAM). Dependent *t*-tests were used to analyze whether there is a statistical difference in the means of the outcome variables (HgbA1c, SBP, DBP, and LDL) in the preintervention and postintervention periods.

The second pre-post hypothesis was answered using the McNemar Test. It is used to test differences in dependent groups in a 2x2 design. In this study, the test was used to

determine change in the number of EDVs and HSPs from the preintervention period to the postintervention period.

The time-series research hypothesis was answered using RM-ANOVA statistical analysis, an extension of the dependent *t*-test analysis. In this study, the within-subjects factor (IV) is time, which was measured at three time periods: entry to study, preintervention, and postintervention. The assumptions of RM-ANOVA include those of the *t*-test (normal distribution of DV and similar variances among groups). Compound symmetry is the assumption of equality of correlations and variances across measurements (Munro, 2005). This assumption is evaluated using Mauchly's Test of Sphericity which tests the null hypothesis that the variances of the means are equal. RM-ANOVA was used to analyze whether there is a statistical difference in the major outcome variable, HgbA1c, over the three time periods.

Table 2

Data Analysis Plans

Pre-Post Hypotheses	Independent Variable	Dependent Variables	Statistical Analysis
HA1. Continuous access to medication improves (a) Glycosylated Hemoglobin (HgbA1c), (b) low density lipids (LDL), and (c) systolic blood pressure in uninsured people with type 2 diabetes.	CAM Nominal Level: 0 = no, 1 = yes	Ratio Level: HgbA1c LDL Systolic Blood Pressure (SBP) Diastolic Blood Pressure (DBP)	Dependent *t*-test
HA2. Continuous access to medication reduces emergency department visits (EDVs) and hospitalizations (HSPs) in uninsured people with type 2 diabetes.	CAM Nominal Level: 0 = no, 1 = yes	Nominal: EDVs HSPs	McNemar's Test

Time-Series Hypothesis	Independent Variable	Dependent Variables	Statistical Analysis
HA1. In uninsured adults with type 2 diabetes with HgbA1c measures at entry, preintervention, and postintervention, HgbA1c will improve over time with exposure to continuous access to medication.	Time Period: 1. Entry to Study 2. Preintervention 3. Postintervention	Ratio Level: HgbA1c	RM-ANOVA

Validity

Validity refers to the degree to which it can be inferred that an observed outcome was caused by the independent variable rather than by mediating factors (Polit, 2010). In Step One of this study, data were analyzed with a one-group pretest-posttest design. This design is preexperimental and lacks internal validity, that is, the ability to identify and/or measure mediating factors that may affect the dependent variable. Therefore it is difficult to determine whether the IV is truly influencing the DV (Polit & Beck, 2008). In this

study, other threats to internal validity include history (the occurrence of external events that take place concurrently with the IV) and maturation (processes occurring within subjects during the study). In this preexperimental design there are also threats to external validity; in short, without a control group the results of Step One cannot be generalized.

Step Two of this study was a quasi-experimental time-series design. Threats to internal validity are the same as mentioned for Step One, although history and maturation are controlled somewhat by repeated measurements of the outcome variables. External validity is improved substantially with the RM design. Results are generalizable however, since this study that takes place at one site it is likely to be generalizable primarily to similar sites and populations.

Human Subjects Protection and Confidentiality

Human Subjects Review Board approval was obtained from George Mason University (Appendix A). Institutional Review Board approval was obtained from the hospital (Appendix B). Patients' medical record numbers were used to collect data from the Mobile Health Van, the hospital, and the prescription procurement program; however, these records were not linked except in the patients' records and in the researcher's locked files. Data were abstracted and stored electronically. Two computers (the primary investigator's computer and the student investigator's computer) were used to access the data. Both computers were virus and password protected and in locked offices. Data were stored in a computer file which is password protected. Frequent backup of data occurred. When not in use, the electronic storage device (thumb drive) was protected in a locked file cabinet in the investigator's locked office. Three copies of the data were stored to

protect against inadvertent data loss: two copies in the primary investigator's office and one copy in the student investigator's office. After the data were collected from the three sites, it was deidentified and subject identifiers were destroyed. Identifiable paper records were shredded. The primary investigator's and student investigator's electronic records with identifiable data were deleted. Only anonymous records were preserved.

To briefly summarize; this study was conducted in a two step process. Step one involved an exploratory pre-post design to examine the relationship between continuous access to medication and the physiologic outcome variables; HgbA1c, LDL, SBP, and DBP, and the healthcare resource outcome variables, EDVs and HSPS. Step two of this study was a quasi-experimental analysis of the HgbA1c measured at three time points to determine if continuous access to medication was related to improved HgbA1c. Data were collected on a total of 82 subjects; 65 subjects had preintervention and postintervention measures on all outcome variables and were assigned to the pre-post group. The remaining 17 subjects had three measures of the major outcome variable HgbA1c and were assigned to the time-series group. Each of the two groups met power analysis recommendations for sample size. The results of this study are presented and discussed in Chapter 4.

4. RESULTS

This results chapter begins by describing the data collection process. This is followed by discussing the sample, and presenting the sample consort and the demographic results. The chapter concludes with a presentation of the research hypotheses' results.

Data Collection

A convenience sample of all Mobile Health Van (MHV) patients with type 2 diabetes who were 18 years or older during the study dates (January 1, 2006 to December 31, 2010) were considered for inclusion in this study. All subjects were uninsured and were at or below 200% of the federal poverty level. Those with comorbid conditions including hypertension, dyslipidemia, and depression were included. All subjects were MHV patients prior to enrolling in the prescription procurement program (PPP).

The process of data collection presented many challenges. Of 152 potential subjects initially identified through a search of the PPP electronic medical record (EMR) system, paper charts were located for only 96 subjects at the MHV. An exhaustive search for the missing records was undertaken. This began with a manual search through the paper records located on MHV Van One and Van Two on three separate occasions. This search failed to locate additional charts. For a short period of time during the study inclusion dates, the MHV paper records were digitally scanned and uploaded to an EMR

system. Once records were stored digitally the paper records were destroyed. The EMR system was also searched on three separate occasions for the records of MHV patients. As a result of this search a small number of records were located and data were abstracted.

Due to space limitations on each of the MHV vans, charts are periodically "thinned," boxed, and sent to an off-site storage facility. Stored charts were requested on three occasions and a small number of records were located using this process. Once located, data were abstracted from these charts.

In the end, of the 152 potential subjects initially identified through a search of PPP medication records, 49 charts were not located at the MHV and therefore were not available for data abstraction. Data were collected on 82 subjects; 65 subjects had one measure of HgbA1c prior to the intervention and 17 subjects had two measures of HgbA1c prior to the intervention. Subjects with one measure of HgbA1c prior to the intervention were assigned to the pre-post analysis group. Subjects with two measures of HgbA1c prior to the intervention were assigned to the time-series analysis group. In the time-series group the first HgbA1c measure was labeled "entry level" and was operationalized as the HgbA1c measure immediately prior to the preintervention measure. The entry measure must have occurred not less than 3 months prior to the preintervention measure but not more than 12 months prior to the first PPP prescription. The sample consort is presented in Figure 3.

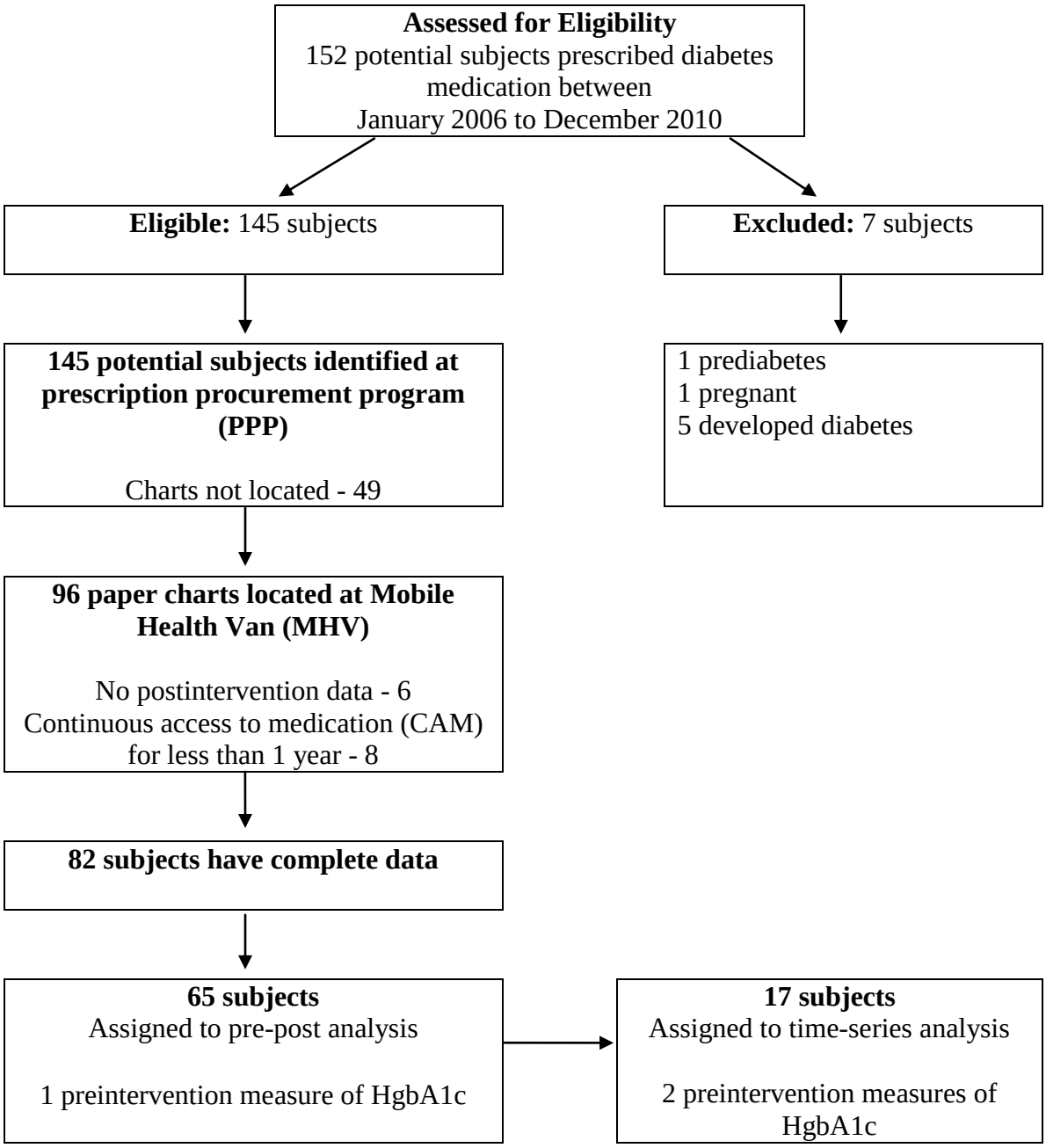

Figure 3. Sample consort.

Sample

Sample Size and Power Analysis

At the outset of this study, a power analysis was conducted to estimate sample size. With an effect size of .5, power set at .8, and alpha set at .05, the sample size was estimated at 64. After the data were analyzed, power analysis was conducted again as a check of the effect size with the final sample size that was obtained. The HgbA1c pre-post mean difference was -.692 and the pre-post HgbA1c standard deviation was 1.805. Using this information and the previously selected alpha of .05 and power of .80, a power analysis for dependent *t*-test sample size was conducted using Columbia University Medical Center's online tool (n.d.). This analysis resulted in a recommended sample size of 56 subjects and an effect size of .69. Data were collected on 65 subjects.

Before statistical testing was conducted on the time-series group, power analysis indicated that with an estimated effect size of .5, power set at .8 and alpha set at .05, the recommended sample size was 16 subjects (Cohen, 1988). Data were collected on 17 subjects.

Intra-Rater Reliability

In this study, the investigator collected all of the data with the assistance of a research assistant. The research assistant was responsible for navigating the computer system, assisting with locating lost records, and requesting medical records from the storage facility. The investigator made all final decisions regarding the interpretation of hand-written data. As a check of data abstraction accuracy, the investigator reviewed

approximately 20% of the charts from which data had been previously abstracted. These records were compared to the Microsoft Excel data collection spreadsheet for accuracy.

Preanalysis Data Screening

Prior to analysis, data for both the pre-post and time-series groups were screened for accuracy, missing values, and outliers. To insure the accuracy of data, all values that were entered into SPSS were compared to the values in the original data collection tool, a Microsoft Excel spreadsheet. In the pre-post group, there were two missing values for each of the outcome variables SBP, DBP, and LDL. As these missing values occurred in different cases and appeared to be random, they were replaced with the mean score for the missing value. This is a reasonable method of dealing with missing values when less than 10% of values are missing. When this method is selected, sample size and power are maintained but there is decreased variability in the group (Polit, 2010).

Boxplots for each outcome variable were reviewed to identify outliers. There were no outliers identified, with the exception of one preintervention SBP (case 66, SBP 200 mm Hg), and one postintervention SBP (case 78, SBP 170). Both of these cases were assigned to the time-series group. Statistical analyses were conducted on only the major outcome variable (HgbA1c) in the time-series group due to multiple missing values for entry level LDL, SBP, and DBP (up to 40% per variable).

Descriptive Data

In the pre-post group (N = 65), there were 23 (35.4%) males and 42 (64.6%) females ranging in age from 26 to 76 years (M = 50). Just over half of these subjects reported English as their primary language (n = 35, 53.8%), just under half reported

Spanish as their primary language (n = 29, 44.6%), and one subject (1.5%) reported other. Subjects self-reported 15 ethnicities or countries of origin. The largest groups were self-described El Salvadorans (n = 15, 23.1%), African Americans (n = 11, 16.9%), and Pakistanis (n = 10, 15.4%), overall representing 55.4% of the sample. Those from Mexico, Central America (Guatemala, Honduras, El Salvador, Nicaragua), and South America (Peru, Bolivia, Guyana) comprised 55.4% (n = 36) of the sample.

In the time-series group (N = 17) there were 3 males (17.6%) and 14 females (82.4%). In terms of language, the subjects in the repeated measures group were similar to those in the pre-post sample: 11 (64.7%) reported English as their primary language and 6 (35.3%) reported Spanish as their primary language. The groups were also similar in terms of self-reported ethnicity or country of origin. Self-described El Salvadorans (n = 6, 35.3%) represented the largest group, while other subjects were spread fairly evenly across ethnicities. Those from the United States represented 11.8% (n = 4) of the sample, those from Mexico, Central America, and South America represented 47.1% (n = 8) of the sample.

All subjects in both the pre-post group and the time-series group received healthcare services at the MHV for a sustained period of time prior to the intervention (M = 2.5, M = 2.8 years; respectively). All subjects had diabetes. There was evidence of substantial comorbidity: most subjects had hypertension, dyslipidemia, or both hypertension and dyslipidemia. In the pre-post group 93% (n = 62) received medications for comorbid conditions as did 100% in the time-series group. Seven subjects (10.8%) in

the pre-post group were treated for depression in addition to diabetes as were 2 subjects (11.8%) in the time-series group. Demographic data are presented in Table 3.

Table 3

Individual Characteristics of Intervention and Comparison Groups

	Pre-Post (N = 65)		Time-Series (N = 17)	
Age	26 to 76 years	M = 50	41 to 74 years	M = 55
	n	percentage	*n*	percentage
Gender				
Male	23	35.4	3	17.6
Female	42	64.6	14	82.4
Preferred Language				
English	35	53.8	11	64.7
Spanish	29	44.6	6	35.3
Other	1	1.5		
Ethnicity/Country of Origin				
United States	16	24.6	4	23.6
African American	11	16.9	2	11.8
Caucasian	5	7.7	2	11.8
Mexico	7	10.8		
Central America	25	38.4	7	41.2
El Salvador	15	23.1	6	35.3
Guatemala	5	7.7		
Honduras	3	4.6	1	5.9
Nicaragua	2	3.1		
South America	4	6.2	1	5.9
Bolivia	1	1.5		
Guyana	2	3.1	1	5.9
Peru	1	1.5		
Asia	1	1.5		
Africa	2	3.1	3	17.7
Ghana	1	1.5	2	11.8
Liberia	1	1.5		
Sierra Leone			1	5.9
Central Asia	10	15.4	2	11.8
Pakistan	10	15.4	2	11.8
Years Patient	M = 2.5		M = 2.8	
0 – 1 years	19	29.2	1	5.9
1 – 3 years	11	16.9	6	35.3
3 – 5 years	18	27.7	4	23.5
5+ years	17	26.2	6	35.3
Comorbid Conditions				
None	3	4.6		
HTN	4	6.2	4	23.5
DLD	14	21.5	2	11.8
HTN, DLD	37	56.9	9	52.9
DEP, HTN	2	3.1		
DEP, DLD	2	3.1		
DEP, HTN, DLD	3	4.6	2	11.8

Note. HTN = hypertension, DLD = dyslipidemia, DEP = depression.

All subjects were prescribed medication to manage diabetes. In the pre-post group, the majority of subjects (*n* = 59, 91%) were prescribed one to two medications for diabetes management. Most subjects (*n* = 53, 81.5%) were prescribed medication to manage hypertension, with the majority (*n* = 44, 67.6%) requiring one to two medications. Additionally, most subjects (*n* = 51, 78.4%) were treated for dyslipidemia, and the majority of those (*n* = 39, 60%) were treated with one medication. The total number of medications to manage diabetes and comorbid conditions ranged from one to seven medications. The majority of subjects (*n* = 54, 83%) were prescribed three, four, five, or six medications for disease management.

In the time-series group 17 subjects (88%) were prescribed one or two medications for diabetes management. All subjects (*N* = 17) were prescribed medication to manage hypertension, with most (*n* = 11, 64.7%) requiring one, two, or three medications. Most subjects (*n* = 12, 70.5%) were treated for dyslipidemia with one medication. The total number of medications to manage diabetes and comorbid conditions ranged from one to eight medications, with no clearly defined trend in the total number of medications. Prescription data are presented in Table 4.

Table 4

Prescriptions to Manage Diabetes and Comorbid Conditions

	Pre-Post (N = 65)		Time-Series (N = 17)	
Total Number	*n*	percentage	*n*	percentage
1	3	4.6	1	5.9
2	5	7.7	3	17.6
3	10	15.4	3	17.6
4	15	23.1	2	11.8
5	17	26.2	2	11.8
6	12	18.5	3	17.6
7	3	4.6	1	5.9
8			2	11.8
Diabetes				
1	22	33.8	7	41.2
2	37	56.9	8	47.1
3	14	21.5	2	11.8
4	2	3.1		
Hypertension				
0	12	18.5	3	17.6
1	24	36.9	6	35.3
2	20	30.8	2	11.8
3	8	12.3	3	17.6
4	1	1.5	2	11.8
5			1	5.9
Dyslipidemia				
0	14	21.5	5	29.4
1	39	60.0	10	58.8
2	12	18.5	2	11.8

Initial statistical tests of the pre-post group were conducted. Means and standard deviations of the outcome variables are presented in Table 5.

Table 5

Means and Standard Deviations for Physiologic and Healthcare Resource Outcomes

	Preintervention		Postintervention	
	Mean	Standard Deviation	Mean	Standard Deviation
HgbA1c	8.96	2.29	8.26	1.63
LDL	108.8	41.0	94.8	35.0
SBP	130.2	19.8	125.7	13.0
DBP	80.6	11.7	78.3	8.0
EDVs	.06	.35	.25	.64
HSPs	.09	.29	.09	.29

Note. SBP = systolic blood pressure, DBP = diastolic blood pressure, LDL = low density lipids, EDVs = emergency department visits, HSPs = hospitalizations.

Hypotheses of the Pre-Post Group

1. Continuous access to medication is related to improved (a) HgbA1c, (b) LDL, (c) SBP, and (d) DBP in uninsured adults with type 2 diabetes.
2. Continuous access to medication is related to reduced (a) emergency department visits (EDVs) and (b) hospitalizations (HSPs) in uninsured adults with type 2 diabetes.

Research hypothesis number one was examined with dependent *t*-test analyses. The Kologorov-Smirnov test of normality was used to determine if the outcome variables were normally distributed. The significance level for all variables was greater than .01; therefore the assumption of normality was met (Mertler & Vannatta, 2005).

Research hypothesis 1(a) states that continuous access to medication is related to improved HgbA1c in uninsured adults with type 2 diabetes. This hypothesis was examined with a dependent-samples *t*-test to compare the preintervention mean HgbA1c to the postintervention mean HgbA1c (Table 6). The preintervention mean HgbA1c was

8.96 ± 2.29%, and the postintervention mean HgbA1c was 8.26 ± 1.63%. A significant decrease in mean HgbA1c was noted from the preintervention period to the postintervention period: -.69 ± 1.8%, 95% CI [-1.14, -.25], t (64) = -3.11, p = .003.

Research hypothesis 1(b) states that continuous access to medication is related to improved LDL in uninsured adults with type 2 diabetes. This hypothesis was examined with a dependent-samples t-test to compare the preintervention mean LDL level to the postintervention mean LDL (Table 6). Two postintervention missing values were replaced with the mean for the postintervention value. The preintervention mean LDL was 108.8 ± 41 mg/dl, and the postintervention mean LDL was 94.8 ± 35 mg/dl. A significant decrease in LDL was noted from the preintervention period to the postintervention period: -13.9 ± 37.4 mg/dl, 95% CI [-23.1, -4.6], t (64) = -2.99, p = .004.

Research hypothesis 1(c) states that continuous access to medication is related to improved SBP in uninsured adults with type 2 diabetes. This hypothesis was examined with a dependent-samples t-test to compare the preintervention mean SBP to the postintervention mean SBP (Table 6). Two postintervention missing values were replaced with the mean for the postintervention value. The preintervention mean SBP was 130.2 ± 19.8 mmHg, and the postintervention SBP was 125.7 ± 13.0 mmHg. A significant decrease in mean SBP was noted from the preintervention period to the postintervention period: -4.5 mmHg ± 15.8 mmHg, 95% CI [-8.4, -.59], t (64) = -2.30, p = .025.

Research hypothesis 1(d) states that continuous access to medication is related to improved DBP in uninsured adults with type 2 diabetes. This hypothesis was examined with a dependent-samples t-test to compare the preintervention mean DBP to the

postintervention mean DBP (Table 6). Two postintervention missing values were replaced with the mean for the postintervention value. The preintervention mean DBP was 80.6 ± 11.7 mmHg, and the postintervention mean DBP was 78.3 ± 8.0 mm Hg). No significant decrease in mean DBP was noted from the preintervention period to the postintervention period: t (64) = -1.73, p = .089.

Table 6

Dependent t-Test for Physiologic Outcomes

Pre and Post CAM	Mean Difference	Standard Deviation	95% Confidence Interval		*t*	*df*	*p* 2-tailed
HgbA1c	-.70	1.8	-1.1	-.25	-3.11	64	.003
LDL	-13.9	37.36	-23.1	-4.63	-2.99	64	.004
SBP	-4.49	15.76	-8.40	-.59	-2.30	64	.025
DBP	-2.57	11.99	-5.5	.40	-1.73	64	.089

Note. CAM = continuous access to medication, SBP = systolic blood pressure, DBP = diastolic blood pressure, LDL = low density lipids, EDVs = emergency department visits, HSPs = hospitalizations.

Descriptive statistics (frequencies) of emergency department visits in the preintervention and the postintervention period are displayed in Table 7. In the preintervention period 2 subjects visited the emergency department (ED) two times for a total of four EDVs in the preintervention period. In the postintervention period 5 subjects visited the ED once, 4 subjects visited the ED twice and 1 subject visited the ED three times. The total number of EDVs increased from four visits to 16 visits; representing a four-fold increase from the preintervention to the postintervention period. Subject 65 visited the ED twice in the preintervention period (50% of visits) and three times in the postintervention period (18.7% of visits). All other ED visits were by different subjects in the preintervention and postintervention period.

Descriptive statistics (frequencies) of hospitalizations in the preintervention period and the postintervention period are displayed in Table 7. In the preintervention period six subjects were admitted to the hospital once and in the postintervention period six subjects were hospitalized once. None of the subjects hospitalized in the preintervention period were hospitalized in the postintervention period. There was no change noted in the number of HSPs from the preintervention period to the postintervention period.

Table 7

Frequencies for Healthcare Resource Outcomes

	Pre-CAM				Post-CAM			
	n	Percentage	Number	Cumulative Total	*n*	Percentage	Number	Cumulative Total
EDVs	63	96.9	0	0	55	84.6	0	0
	2	3.1	2	4	5	7.7	1	5
					4	6.2	2	13
					1	1.5	3	16
HSPs	59	90.8	0	0	59	90.8	0	0
	6	9.2	1	6	6	9.2	1	6

Note. CAM = continuous access to medication, EDVs = emergency department visits, HPSs = hospitalizations.

The second pre-post research hypothesis states that continuous access to medication is related to reduced (a) emergency department visits (EDVs) and (b) hospitalizations (HSPs) in uninsured adults with type 2 diabetes.

Research hypothesis 2(a) states that continuous access to medication is related to reduced EDVs in uninsured adults with type 2 diabetes. This hypothesis was examined using a McNemar test (Table 8). There was a significant tendency for subjects to visit

the emergency department in the postintervention period (15.4%) than in the preintervention period (3.1%), McNemars's $p = .021$.

Research hypothesis 2(b) states that continuous access to medication is related to reduced HSPs in uninsured adults with type 2 diabetes. This hypothesis was examined using a McNemar test (Table 8). There was no significant tendency for subjects to be hospitalized more in the preintervention period than in the postintervention period, $p = 1.0$.

Table 8

McNemar's Test Results

	n	df	*p*
EDVs	65	1	.021
HSPs	65	1	1.0

Note. EDVs = emergency department visits, HPSs = hospitalizations.

Initial statistical testing of the time-series group was conducted. Means, standard deviations, and variances of the HgbA1c at three different time periods, entry, preintervention, and postintervention, are displayed in Table 9.

Table 9

Means, Standard Deviations, and Variances for Time-Series Group

HgbA1c	Mean	Standard Deviation	Variance
Entry Level	9.12	1.79	3.20
Preintervention	9.61	1.97	3.88
Postintervention	8.47	1.34	1.78

Figure 4 presents a profile-plot of the means of the HgbA1c at three different time periods, entry, preintervention, and postintervention.

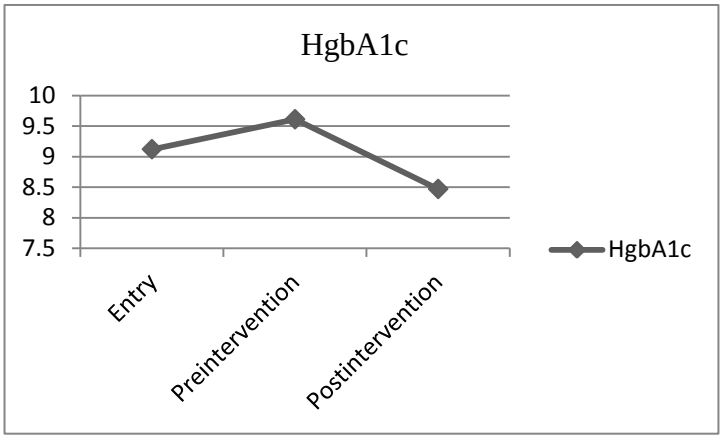

Figure 4. Profile-plot of HgbA1c over time.

Hypothesis of the Time-Series Group

In a sample of 17 uninsured adults with type 2 diabetes with HgbA1c measures at entry, preintervention and postintervention, continuous access to medication is related to improved HgbA1c over time.

The time series research hypothesis was examined with RM-ANOVA statistical analysis on the main outcome variable HgbA1c. Mauchly's Test of Sphericity indicated that the assumption of sphericity had not been violated, χ^2 (2) = 2.40, p = .300. Therefore analysis of the time-series group was conducted without corrections to the degrees of freedom. RM-ANOVA results indicated that there was a statistically significant difference in mean HgbA1c between time points F(2, 32) = 5.26, p = .011 (Table 10).

Table 10

RM-ANOVA on HgbA1c

Source	Sum of the Squares	*df*	Mean Square	F	*p* 2-tailed	Partial Eta Squared	Observed Power
Time	11.06	2	5.53	5.26	.011	.25	.797
Error	33.66	32	1.05				

Post Hoc Analyses

Post hoc testing was used to discover at which time point the significant difference occurred. In this study, post hoc testing using the Bonferroni correction revealed a statistically significant (p = .014) reduction from preintervention mean HgbA1c to postintervention mean HgbA1c (9.61 ± 1.97% vs.8.47 ± 1.34%, respectively, p = .014). There was no significant change from entry to preintervention mean HgbA1c (9.12 ± 1.72% vs. 9.61 ± 1.97%, respectively, p = .764) or from entry to postintervention (9.12 ± 1.72% vs. 8.47 ± 1.34%, respectively, p = .116). The results are displayed in Table 11.

Table 11

Post Hoc Test Results

Time Period	Mean Difference	*p*	95% Confidence Interval	
Entry to Preintervention	.482	.764	-.609	1.57
Preintervention to Postintervention	-1.14	.014	-2.06	-.210
Entry to Postintervention	-.654	.116	-1.431	.123

Summary

Many records were not available for data abstraction and analysis in this study. Of a possible 152 records, data was successfully abstracted from only 96 records. Of those 96 records, it was discovered that 6 subjects had no postintervention data and 8 had exposure to the intervention for less than 1 year. Therefore, 82 records were included in the analysis.

In the pre-post group, continuous access to medication was found to be related to reduced HgbA1c, low-density lipids, and systolic blood pressure. However, continuous access to medication was found to be related to increased emergency department visits. In the time-series group, analysis of the major outcome variable supported the finding that continuous access to medication is related to reduced HgbA1c at one time point: from preintervention to postintervention. The results of the quasi-experimental time-series group verified the validity of the results in the pre-post group; providing a cross-validation of results. These findings are displayed in Table 12 and discussed in detail in Chapter 5.

Table 12

Summary of Findings

Research Hypothesis: Pre-Post Group Analysis	Null Hypothesis
In uninsured adults with type 2 diabetes, continuous access to medication is related to improved:	
HgbA1c.	Rejected
LDL.	Rejected
SBP.	Rejected
DBP.	Failed to Reject
In uninsured adults with type 2 diabetes, continuous access to medication is related to reduced:	
Emergency department visits.	Failed to Reject
Hospitalizations.	Failed to Reject
Research Hypotheses: Time-Series Group Analysis	Null Hypothesis
In uninsured adults with type 2 diabetes with HgbA1c measures at entry, preintervention, and postintervention; continuous access to medication is related to improved HgbA1c over time.	Rejected

Note. LDL = low density lipids, SBP = systolic blood pressure, DBP = diastolic blood pressure.

5. CONCLUSIONS

The conclusions chapter begins with an examination of findings that support the research hypotheses. This is followed by an examination of findings that failed to support the research hypotheses and findings as viewed through the lens of the Social Determinants of Health theoretical framework. This chapter ends with a discussion of this study's limitations, implications for future research, and contributions to the body of nursing knowledge

Examination of Findings That Support Research Hypotheses

HgbA1c

In this study continuous access to medication was related to reduced HgbA1c, low-density lipid levels, and systolic blood pressure. These results are consistent with the findings of previous researchers that improving access to medications improves healthcare outcomes (Ruelas et al., 2009; Schoen et al., 2001). The intervention in this study, continuous access to medication, resolved many of the problems associated with poor access for this sample of uninsured adults with type 2 diabetes. More specifically, continuous access to medication resulted in a regular and sustained source of essential medications to manage chronic disease. It is known that adherence to medication regimens is associated with improved clinical outcomes (DiMatteo et al., 2002; Simpson et al., 2006), but of course, people must have access to medication before they can adhere

to medication regimens. Although this study did not measure adherence, other researchers have focused on the link between access and adherence as they relate to healthcare outcomes. These researchers have shown that providing free or low-cost medications is related to both improved adherence and improved outcomes in people with diabetes (Horswell et al., 2008; Ruelas et al., 2009).

HgbA1c was reduced from the preintervention period to the postintervention by an average of 0.7% in the pre-post group and 1.14% in the time-series group. This reduction is clinically important. Previous research has shown that reducing HgbA1c decreases microvascular complications (DCCT, 1993; UKPDS, 1998). In fact, for each 1% reduction in HgbA1c over 10 years there is a 37% reduction in microvascular complications (UKPDS, 1998); therefore, even small improvements in HgbA1c are important in preventing long-term microvascular disease. For people without underlying cardiovascular (CV) disease and without longstanding diabetes, improvements in HgbA1c may reduce the occurrence of macrovascular disease (ACCORD, 2008; UKPDS, 1998; VADT, 2009).

Given the complexity of type 2 diabetes and its associated comorbid conditions, the American Diabetes Association (ADA) has developed standards of care that are updated annually. The most recent ADA Standards of Medical Care in Diabetes (Standards of Care) (2011) recommend a treatment HgbA1c goal of < 7.0% for most people with diabetes. This goal should be tailored for people who are older, have longstanding disease, have underlying cardiovascular disease, or who are frail. In this study, with continuous access to medication as the intervention, subjects achieved

average HgbA1c values of 8.26% in the pre-post group (26 to 76 years old) and 8.46% in the time-series group (42 to 75 years old) over a period of 1 year. Although statistically significant improvements were achieved in this study, the HgbA1cs do not meet the current ADA Standards of Care guidelines. However, despite not meeting ADA HgbA1c targets, even modest reductions in HgbA1c are associated with improvements in long-term healthcare outcomes. Additionally, glycemic control targets are most appropriate and achievable when they are tailored to specific patients in light of their individual characteristics (Montori, 2008; Park & Wexler, 2010; Terry et al., 2011; Turnbull et al., 2009).

Researchers have found that tight glycemic control introduces a treatment burden for patients that includes hypoglycemia (Montori, 2008; Park & Wexler, 2010; Terry et al., 2011; Turnbull et al., 2009). It is important to consider this risk when tailoring treatment plans for individuals. As patients get closer to glycemic targets they are required to check their blood glucose values up to three or four times a day to document glycemic trends. These blood glucose logs are essential to detect recent hypoglycemic episodes and tailor medication regimens to avoid future hypoglycemic episodes. Without patient blood glucose logs to assist in making clinical decisions, both patients and providers may be less willing to push blood glucose values to lower levels. Blood glucose test strips tend to be expensive, and this cost is compounded when patients are asked to test their blood glucose three to four times a day. In this study, the prescription procurement program (PPP) was unable to procure blood glucose testing supplies to dispense to patients; therefore, patients had to purchase these supplies at full cost.

Anecdotally, very few Mobile Health Van (MHV) patients bring blood glucose logs to their visits, citing the high cost of the testing supplies.

Of interest in the time-series group was a worsening of disease control from entry into the study to preintervention. During this time period average HgbA1c increased from 9.1% to 9.6%, an increase of .5% in a relatively short period of time (3 to 9 months). This was not a statistically significant finding, but this increase most likely speaks to the progressive nature of diabetes. However, there may be additional explanations for the worsening disease control prior to the intervention. Before the PPP was implemented, nurse practitioners dispensed donated medications and wrote prescriptions for low-cost generic medications (M. Clay, personal communication, January 7, 2012). Both of these methods for obtaining medications for patients were less than adequate. Donated medications do not represent a reliable and/or sustainable source of medications. Generic medications may be more cost effective than brand name medications; however, they may still be expensive and some medications may not be available in generic formulations. Nurse practitioners were limited by the availability and quantity of donated drugs, as well as by the restricted formularies of generic medications. Inconsistency in medication availability may have added to the overall effect of worsening disease control.

Additional anecdotal information that might explain worsening disease control is the somewhat unpredictable lifestyle of many MHV patients. In this study, 75% in the pre-post group and 76% in the time-series group were self-described immigrants. Many MHV patients are day laborers; when they have work they are less likely to keep appointments, get lab work done, or pick up medications; they choose between making a

living and taking care of their healthcare needs. Additionally, it is not uncommon for patients to go to their "home country" for 2 to 3 months at a time. For these patients, fragmented care may lead to worsening disease control.

Low Density Lipids (LDL)

In the pre-post group, low density lipids (LDL) were decreased in the postintervention period; this is an improvement that may reduce overall CV risk by as much as 20 to 50% (CDC, 2011). The preintervention average LDL was 107.6 mg/dl and the postintervention LDL was 94.5 mg/dl, resulting in an average reduction of 13.1 mg/dl. The preintervention value is above the ADA Standards of Care (2011) goal of < 100 mg/dl; however, the postintervention value is below the targeted goal. This finding is consistent with the findings of other researchers who have found that providing low-cost medications improves clinical outcomes (Gibson et al., 2010; Kennedy & Erb, 2002; Reed, 2005; Schoen et al., 2001).

Sadly, only one in eight people meet the ADA goals for HgbA1c, blood pressure, and LDL (Cheung et al., 2009, Kuritzky & Samraj, 2011). This number highlights the difficulty for patients and clinicians to achieve treatment goals. People with diabetes die from CV disease at a rate that is two to four times higher than that of people without diabetes (CDC, 2011). In fact, diabetes is a coronary heart disease (CHD) risk equivalent, meaning that a person with diabetes and no known CHD has the same risk of heart disease as person with known CHD (Kannel & McGee, 1979). Risk factors for CV disease such as LDL, SBP, and DBP are modifiable; the importance of controlling these risk factors in people with diabetes cannot be overstated. Therefore, the decrease noted in

the LDL in this study is remarkable. Additionally, although the DBP reduction was not statistically significant, both the preintervention and postintervention values were below the ADA goals.

Systolic Blood Pressure

CAM was related to reductions in systolic blood pressure (SBP) in the pre-post group. The preintervention average SBP was 130.2 mmHg and the postintervention SBP average was 125.7 mmHg, an average reduction of -4.5 mmHg. Achieving blood pressure target levels reduces macrovascular disease by 33 to 50% and microvascular complications by about 33% (CDC, 2011). Both the preintervention and the postintervention SBP and DBP values were at or below the ADA Standards of Care (2011) target goal of ≤ 130/80 mmHg. Small reductions in blood pressure may have clinical importance; even when targets are met, additional improvements in SBP may reduce CV risk in people with diabetes. The ADVANCE study (2007) found that reducing blood pressure to goal levels is related to an independent and additive effect in reducing CV disease. That these patients are at goal at the outset of the study and remained at goal is likely related to an increased availability of hypertension medications and having a usual source of care at this nurse-managed mobile clinic.

Examination of Findings That Failed to Support Research Hypotheses

Diastolic Blood Pressure

It was hypothesized that CAM is related to decreased diastolic blood pressure (DBP) in the pre-post group; however CAM was not related to reductions in DBP. The preintervention average DBP was 80.6 mmHg and the postintervention average DBP was

78.3 mmHg, an average reduction of 1.73 mmHg. As mentioned previously, both the preintervention and the postintervention SBP and DBP values were at or below the ADA Standards of Care (2011) target goal of ≤ 130/80 mmHg and is likely related to the availability and low-cost of hypertension medications as well as having a usual source of care at this nurse-managed mobile clinic.

Emergency Department Visits

It was hypothesized that continuous access to medication (CAM) is related to decreased emergency department visits (EDVs); however, just the opposite was found to occur in this study: CAM was related to an increased number of emergency department visits. People without insurance or a usual source of care are more likely to cite an emergency department as their usual source of care (Wilpur et al., 2008). In this study it was anticipated that emergency department visits would decrease since MHV patients have a usual source of care. The total number of visits was small, with a total of four visits in the preintervention period and a total of 16 visits in the postintervention period. While unexpected, this finding was similar to that of Hall (2011) who found that in four of five safety net (SN) clinics that offered primary care services and medications, SN patients used emergency department services at rates higher than individuals with commercial insurance.

Explanations for this increase are most likely multifactorial. A possible explanation is that patients are now in a healthcare system that will assist them with chronic disease management. Many of these patients are quite ill and have substantial comorbidities when they become MHV patients; in fact, many are referred to the MHV

from the emergency department. The increase in emergency department visits might be due to improved illness monitoring, meaning that these patients may be referred to the emergency department by one of the MHV nurse practitioners. As an alternative explanation, MHV patients get their lab work done at the hospital free of charge; once they are MHV patients they are also recognized as patients of the hospital system. It might be that patients feel more comfortable using the hospital emergency department once they have become MHV patients.

Hospitalizations

It was hypothesized that continuous access to medication (CAM) is related to decreased hospitalizations (HSPs); however, there was precisely no change in hospitalizations from the preintervention to the postintervention period, with a total of six hospitalizations in each time period. CAM was not found to be related to the number of hospitalizations. This most likely occurred because hospitalization requires a determination by a physician that a patient requires a higher level of care or care for an extended period of time. Therefore, the determination to hospitalize a patient has less to do with insurance status or socioeconomic status than it does with a patient's clinical condition.

Additional Findings

There are many barriers to obtaining access to healthcare and medicine. People without insurance have greater difficulty accessing healthcare and medicine (Wagner et al., 2010), and are less likely to visit a healthcare provider or have a usual source of care (Law & VanDerslice, 2011; Pagan & Puig, 2005; Schoen et al., 2010; Wilpur et al.,

2008). It is also known that immigrants are less likely to have a usual source of care (Javier et al., 2010; Lebrun & Dubay, 2010; Siddiqi et al., 2009). Many people in this study were self-described immigrants (n = 49, 75% in the pre-post group vs. n = 13, 76% in the time-series group). In this study, since people must be MHV patients prior to enrollment in the pharmaceutical procurement program (PPP), not only do they have continuous access to medication but they also have a usual source of care. That patients view the MHV as their usual source of care is verified by the length of time that people have received care at the MHV. In the pre-post group patients had received care for an average of 2.5 years and in the time-series group patients had received care for an average of 2.8 years. In the combined groups the number of years that people received care at the MHV prior to the intervention ranged from 0 to 10.9 years. Receiving healthcare services from a consistent source may have positive results since people who have a usual source of care tend to have improved outcomes (Pagan & Puig, 2005; Zhang et al., 2010).

In this study, CAM provides a wide range of medications (over 350) that is available for the management of acute and chronic diseases. A side-by-side comparison of the PPP formulary to the large retail store formularies (e.g., Walmart, 2011) reveals that the PPP has a more comprehensive formulary and provides access to a greater number of medications to manage chronic disease. The PPP prescriptions are typically written for 90 days and patients are charged a $5 fee for each medication. In this study, patients were prescribed up to eight medications to be taken daily for chronic disease management, including diabetes, hypertension, and dyslipidemia. At $5 per prescription,

the expense may be as high as $40 for eight 90-day prescriptions. For many people, this may still represent a significant cost. Although medication use was not measured in this study, it is not uncommon for people to selectively underuse medications due to cost (Piette et al., 2004a; Piette et al., 2004b). Research has shown that low-cost medication (Gibson et al., 2010; Kennedy & Erb, 2002; Reed, 2005; Schoen et al., 2001), using generic medication (Briesacher et al., 2009), and thoughtful planning of an individually tailored medication program (Klarenbach et al., 2011) may increase a person's access and adherence to a medication regimen.

Implications for Social Determinants of Health Framework

The Social Determinants of Health framework (SDOH, Dahlgren & Whitehead, 1991) was used to guide this study (Figure 1). In the SDOH model, Level 2 represents living and working conditions and includes a broad spectrum of determinants such as employment status, housing, education, and access to healthcare. Level 3 includes available social and community networks and Level 4 represents individual health behaviors and includes the health choices that people make.

Interventions designed to impact the wider SDOH are believed to have both direct and indirect effects on health conditions (Reutter & Kusher, 2010) and may be related to reduced health disparities in treatment and healthcare outcomes (Williams et al., 2008). In this study, the SDOH framework was instrumental in providing an opportunity to view continuous access to medication as an intervention aimed at one of the wider social determinants of health (Level 2). It is important to note that the MHV nurse-managed clinic represents Level 3 of the SDOH and stands as an important conduit between the

PPP and the healthcare services that are provided to underserved patients. It is important to note that the MHV nurse-managed clinic represents Level 3 of the SDOH and stands as an important conduit between the PPP and the healthcare services that are provided to underserved patients. Sustained decreases in these physiologic markers can improve overall health, resulting in improved quality of life and decreased risk for microvascular and macrovascular disease in the future (ACCORD, 2008; ADVANCE, 2007; VADT, 2009; UKPDS, 1998).

Many people who come to the mobile health van for their first visit state that they have heard about the prescription procurement program from other patients: the PPP has provided an impetus for people to seek healthcare services. Because of this desire to have access to affordable medications, the major indirect effect of the intervention is that these patients now have a usual source of care. Also, when patients pick up their medications from the van, they are encouraged to make follow-up appointments, get lab work done, and follow through on lifestyle changes. The end result is that in addition to gaining access to a reliable, regular, and sustainable source of essential medications, patients also gain a usual source of care. Because of the work at SDOH Level 2 and Level 3, patients' long-term healthcare outcomes (Level 4) may be improved.

Limitations That Affect Validity or Generalizability

Although archived medical information is a rich source of data for research, there are inherent limitations with this methodological approach. Medical records are built on the observations of other people and, frequently, on the observations of many people (Worster & Haines, 2004). Records may be incomplete or illegible, resulting in

inaccurate interpretation of the data by researchers. There may also be limitations related to records' storage and survival (Polit & Beck, 2008). These types of systematic bias are common in studies that use archived medical information as a source of data.

In this study systematic bias was apparent in the storage and survival of archived documents. Although the potential for missing data was anticipated and was considered in the study design, the relatively high level of missing data was not expected. Of the 152 charts identified for potential inclusion in the study, only 96 were located. Despite extensive searches, the 56 missing charts were not located and therefore could not be retrieved from an off-site storage facility. This missing data (37%) represents a significant source of systematic bias with only 63% of the charts available for data abstraction. In this study, there is the potential that data in the missing charts contains results that differ significantly from data in the charts that were available for data abstraction.

Systematic bias was also evident in the lack of data to support a quasi-experimental time-series design with three time points for the outcome measures of LDL, SBP, and DBP. Up to 40% of these data were missing. Data at the three time points were only available for the major outcome variable, HgbA1c.

The missing data resulted in a large group of subjects with only preintervention and postintervention data for analysis. Without a control group for the pre-post group, the generalizability of the findings for this group is limited. However, the pre-post results serve as a valuable source of exploratory information about the relationship between the independent variable and multiple physiologic and healthcare resource utilization

outcome variables. The findings from the data abstracted on the pre-post group may guide future research.

Recommendations for Future Research

Future research should focus on the relationship between continuous access to medication, attainment of a usual source of care, and healthcare outcome measures. Specifically, a longitudinal study might be designed to see if physiologic outcomes, hospital costs and emergency department visits level out or decrease after a period of time with continuous access to medication and a usual source of care. Research should also examine the exploratory pre-post findings in this study through further examination of both the physiologic and healthcare resource outcome variables. The addition of in-depth qualitative interviews of both providers and patients will allow researchers to explore how continuous access to medication has affected behavioral and psychological health outcomes.

Implications for Practice and Healthcare Settings

This study analyzed the complex relationship between access to medication and healthcare outcomes in uninsured adults with type 2 diabetes. An important component of this study is the interdisciplinary approach between a freestanding prescription procurement program, a nurse-managed clinic, and a large hospital system in the Mid-Atlantic region. The importance of this collaboration cannot be overstated for this study or for future research endeavors, particularly as viewed through a theoretical framework such as the Social Determinants of Health.

Previous knowledge about improved access to medication and healthcare outcomes was verified in this study. New knowledge was gained about (a) an effective way to improve access to medication and healthcare services for the underserved, (b) the potential promise for nontraditional healthcare delivery systems, and (c) the effectiveness of collaboration between a nurse-managed clinic, a prescription procurement program, and a large healthcare system. This study reached beyond the traditional boundaries of nursing research to view a pharmaceutical program as an intervention in a nurse-managed clinic that employs nurse practitioners and outreach workers to care for the uninsured and medically underserved. This study's results have demonstrated that interventions aimed at the wider SDOH may impact the healthcare outcomes of adults who suffer healthcare disparities related to socioeconomic status, insurance status, and possibly ethnicity and immigrant status.

APPENDIX A. REVIEW BOARD APPROVAL

GEORGE MASON UNIVERSITY
Office of Research Subject Protections
Research 1 Building
4400 University Drive, MS 4C6, Fairfax, Virginia 22030
Phone: 703-993-4121; Fax: 703-993-9590

TO: Renee Milligan, College of Health and Human Service

FROM: Keith R. Bushey
Chief of Staff, Office of Research

PROTOCOL NO.: 7200 Research Category: Class Project (G)

PROPOSAL NO.: N/A

TITLE: Effect of Continuous Access to Medication on Emergency Department Visits/Hospitalizations and Clinical Outcomes

DATE: July 8, 2011

Cc: Cheryl Toulouse

On 7/8/2011, the George Mason University Human Subjects Review Board (GMU HSRB) reviewed and approved the above-cited protocol following expedited review procedures.

Please note the following:

1. **Any modification to your research (including the protocol, consent, advertisements, instruments, funding, etc.) must be submitted to the Office of Research Subject Protections for review and approval prior to implementation.**
2. Any adverse events or unanticipated problems involving risks to subjects including problems involving confidentiality of the data identifying the participants must be reported to Office of Research Subject Protections and reviewed by the HSRB.

The anniversary date of this study is 7/7/2012. **You may not collect data beyond that date without GMU HSRB approval.** A continuing review form must be completed and submitted to the Office of Research Subject Protections 30 days prior to the anniversary date or upon completion of the project. A copy of the continuing review form is attached. In addition, prior to that date, the Office of Research Subject Protections will send you a reminder regarding continuing review procedures.

If you have any questions, please do not hesitate to contact me at 703-993-4015.

APPENDIX B. FACILITY APPROVAL

[redacted]

5/25/2011

Margaret Mahon
College of Health and Human Service
4400 University Drive
Fairfax, VA 22030

Re: The Effect of Continuous Access to Medication on Emergency Department Visits, Hospitalizations,and Clinical Outcomes in Uninsured People with Type 2 Diabetes
[redacted]

Dear Margaret Mahon:

This is to inform you that the Medical Affairs Committee, at its 4/5/2011 meeting, approved the above referenced protocol. You are approved to begin this study at [redacted] immediately.

Please note [redacted] approval for this research study will expire on 11/10/2011. Please submit a copy of your IRB Continuing Review Report no later than 10/1/2011 so that the [redacted] Medical Affairs Committee may provide timely review.

Please do not hesitate to contact [redacted] Research Quality Assurance at [redacted] if you have comments or questions regarding this matter.

Thank you,

[redacted]
Director
[redacted]

[redacted]

[redacted]

[redacted]

1/27/2012

Renee Milligan
College of Health and Human Service
4400 University Drive
Fairfax, VA 22030

Re: The Effect of Continuous Access to Medication on Emergency Department Visits, Hospitalizations,and Clinical Outcomes in Uninsured People with Type 2 Diabetes.
[redacted]

Dear Renee Milligan:

This is to inform you that we are in receipt of your updated continuing review letter for the above referenced protocol

Please note the new expiration date for [redacted] approval for this research study will be 7/7/2012. Please submit a copy of your IRB Continuing Review Report no later than 6/1/2012 so that the [redacted] Medical Affairs Committee may provide timely review.

Please do not hesitate to contact [redacted] Research Quality Assurance at [redacted] if you have comments or questions regarding this matter.

Thank you,

[redacted]
Director
[redacted]

[redacted]

REFERENCES

REFERENCES

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CURRICULUM VITAE

Cheryl L. Dillard Toulouse was born in Pittsburgh, Pennsylvania. She obtained her Bachelor's of Science in Nursing from the University of Tennessee (1982). She obtained her Family Nurse Practitioner Certificate at Georgia Southern College (1986). Her Master's of Science in Nursing was completed at George Mason University (1998) in the Clinical Specialist Track. Toulouse has held a variety of nurse practitioner primary care positions in Georgia and Virginia (1986 to 2012). She currently practices in a primary care setting providing care to low-income uninsured adults. Toulouse has been an instructional faculty member at George Mason University since 2007. She is a member of Sigma Theta Tau and the American Association of Diabetes Educators.