A RETROSPECTIVE STUDY COMPARING SHARED MEDICAL APPOINTMENTS WITH USUAL CARE ON CLINICAL OUTCOMES & QUALITY MEASURES IN VETERANS WITH TYPE 2 DIABETES

by

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A Retrospective Study Comparing Shared Medical Appointments with Usual Health Care on Clinical Outcomes and Quality Measures in Veterans with Type 2 Diabetes

Abstract

by

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The Center for Disease Control (CDC) reports that chronic disease accounts for more than 75% of the nation's $2 trillion in medical care costs, and the direct and indirect costs of a chronic disease such as diabetes alone is estimated at $174 billion dollars a year. Diabetes and heart disease frequently occur reciprocally because over time, elevated blood sugar levels lead to microvascular alterations in the intimal layer of the blood vessels. Despite the serious risks of these two medical conditions, our current health care system has yet to develop effective strategies for managing diabetes, and minimizing heart disease risk. One model of care that shows promise, however, is shared medical appointments (SMA), also known as group medical visits where a multidisciplinary team of health professionals provide health care to a cohort of patients at the same time in a supportive, educational, and interactive environment. There are a limited number of studies on utilizing shared medical appointments to manage diabetes and heart disease, and most show mixed results. Therefore, the author proposed to continue to build evidence on this topic and promulgates the following hypothesis: Compared to veterans who receive usual care (UC), (n=617) veterans with type 2 diabetes who utilize shared medical appointments (n=371) will have significantly better clinical outcomes, and higher levels of provider adherence to accepted VA Department of

Defense (DoD) diabetes clinical practice guidelines. This 3-year retrospective two-group observational study utilized an existing Veterans Administration (VA) VISN 10 database warehouse, and Computerized Patient Record System (CPRS). Emergency room data was also abstracted retrospectively over the same 3-year study period. Additional co-morbidities that were tracked included hypertension, dyslipidemia, coronary artery disease, and obesity, as well as demographic variables such as age, sex, marital status, and gender. Three moderator variables were tracked in the study: the presence of a mental health diagnosis, number of health care visits (UC and SMA) and participation in other VA self-management programs over the three-year study period. The study variables were analyzed using *t*-tests, X^2, repeated measures ANOVA, and multiple regression to reveal the relationships among the variables. The clinical outcome variables of HbA1c, lipid panel and blood pressure were not significantly different in the SMA cohort over UC during the three year study period; however, several clinical practice guidelines were met annually for the SMA veterans that included having an angiotension-converting enzyme inhibitor/angiotension-receptor blockers and aspirin prescribed and having annual ophthalmology and podiatry exams. This research project enhances our knowledge on how using SMAs may produce improved provider adherence to diabetes care quality standards in veterans with type 2 diabetes who are at substantial risk for cardiovascular disease.

CHAPTER ONE

Specific Aims

Approximately 133 million people, or almost half of all Americans, live with a chronic condition (CDC, 2008). Caring for patients with chronic illness such as diabetes and heart disease is a costly endeavor. The Center for Disease Control (CDC) reports that chronic disease accounts for more than 75% of the nation's $2 trillion in medical care costs, and the direct and indirect costs of a chronic disease such as diabetes alone is estimated at $174 billion dollars a year (CDC, 2008). Diabetes and heart disease frequently occur together because over time, elevated blood sugar levels lead to microvascular alterations in the intimal layer of the blood vessels (Beckman, et al, 2003; Beckman, et al, 2006). Despite the serious risks of these two medical conditions, our current health care system has yet to develop effective strategies for managing diabetes and minimizing heart disease risk.

One model of care that shows promise, however, is shared medical appointments (SMA), also known as group medical care. Shared medical appointments are a multidisciplinary approach in which a team of health professionals provide health care to a cohort of patients at the same time in a supportive, educational, interactive environment (Noffsinger & Scott, 2000, (Noffsinger, 2003). There are a limited number of studies on utilizing group medical care models to manage diabetes and heart disease. Two studies by Clancy and colleagues (2003, 2007) revealed that group medical visits significantly improved provider adherence to American Diabetes Association (ADA) clinical practice guidelines but did not produce statistically significant reductions in participants' clinical

outcomes of low-density lipoprotein (LDL) cholesterol, hemoglobin A1c (HbA1c), or blood pressure (Clancy, et al, 2003; Clancy, et al, 2007). On the other hand, Trento and colleagues reported that participants who received group medical care maintained or improved clinical outcomes at two years (Trento et al, 2001), four years (Trento et al, 2002), and five years (Trento et al, 2004). Given the promising but mixed results on the use of shared medical appointments, further investigation was needed to determine the utility of this model for providing care to persons with type 2 diabetes.

Research Questions

The purpose of this 2- group observational study was to investigate differences in clinical outcomes and quality measures of two groups of veterans with type 2 diabetes at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC): veterans who receive care via shared medical appointments versus veterans who receive care under the usual physician-patient model. There were 3 research questions for proposed for this study. For veterans with type 2 diabetes:

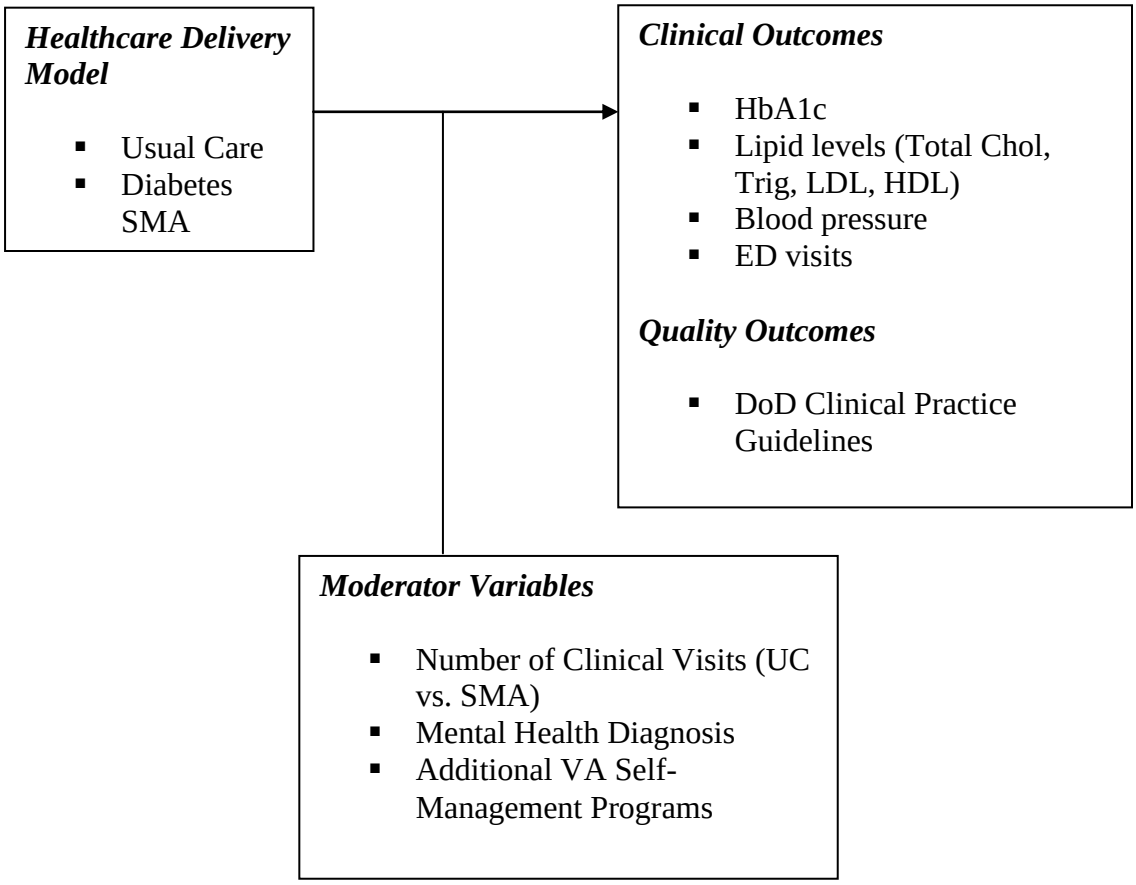
1. Are there differences in two types of clinical outcomes:
    1) Cardiac risk factors (HbA1c, lipid panel, and blood pressure) and
    2) Healthcare utilization rates (Emergency room visits) based on healthcare delivery model (SMA versus usual care)?
2. Are there differences in healthcare provider adherence rates to Veterans' Administration (VA) Department of Defense (DoD) Diabetes clinical practice guidelines based on healthcare delivery model?

3. How will moderator variables including number of clinical visits (SMA versus usual care) absence or presence of a mental health diagnosis (PTSD, depression, bipolar disorder, anxiety, substance abuse) and participation in other disease self-management programs (Renal Diabetes, MOVE!, Nurse Case manager, PharmD Clinic) influence the relationship of clinical outcome variables in veterans with type 2 diabetes?

The hypothesis for this study was as follows: For veterans with type 2 diabetes, those who utilize shared medical appointments will have significantly better clinical outcomes and their providers will have higher levels of adherence to accepted VA DoD diabetes clinical practice guidelines compared to veterans who receive usual care.

Figure 1

Model of the Research



Explanation of the Research Model

The diagram provided outlines the model for the research (Figure 1). The main independent predictor variable was type of health care delivery model for veterans with type 2 diabetes that included the shared medical appointment or the traditional one-on one physician and patient dyad which is termed "usual care." These types of visits were selected because they represent a few examples of care delivery paradigms offered at the Louis Stokes Department of Veterans Medical Center (LSCDVAMC), and comparing outcomes from the shared medical appointment model versus traditional care is

advantageous from a quality and cost containment perspective. The dependent outcomes include both clinical outcomes, and quality measures. The clinical outcomes include physiologic measures of HbA1c, lipid levels, (Total cholesterol, Triglycerides, LDL and HDL), and blood pressures (systolic and diastolic) as well as Emergency room utilization. Physiologic measures are of interest because these measures are cardiac risk factors common in type 2 diabetics, and may predict increase risk of cardiovascular disease in an already vulnerable population. Health care utilization is important to ascertain if care model may curtail admission and urgent care use in this cohort.

The quality outcomes are derived from 10 accepted VA Department of Defense (DoD) clinical practice guidelines for the management of type 2 diabetics. These clinical practice guidelines model the ADA practice guidelines and are accepted quality care standards that may reduce mortality in diabetics that include using an angiotensin-converting enzyme inhibitors (ACE-I) and angiotension-receptor blockers (ARB's) to protect renal functioning, aspirin for its anti-platelet aggregation activity, measuring and treating lipids, obtaining regular HbA1c and urine microalbumin to monitor progression of disease, specific vaccinations such as influenza and pneumovax, and annual referrals for foot and eye exams. This research model explores if type of health care delivery model enhances provider adherence to meeting all of these important diabetes care measures, and thus ensuring a high level of clinical excellence. Clinical practice guidelines for disease management are a means to standardize clinical care practices based on current evidence-based practice, and not conjecture.

There are three moderator variables for this model which include number of health care visits (SMA and usual care) absence or presence of a mental health diagnosis (PTSD, anxiety, depression, substance abuse, and bipolar disorder) and participation in other VA self- management programs (MOVE!, RN Case Manager, PharmD clinic, Renal Diabetes Clinic). Number of health care visits is an important moderator to investigate to determine if there was a 'dose effect' on the clinical and quality outcome metrics. Mental health issues are common in US veterans who have served in active combat, or related military services (Jakupcak, Luterek, Hunt, Conybeare, McFall, 2008), and assessing how having a mental health diagnosis relates to clinical or quality health care outcomes is essential. Currently, the concept of shared medical appointments to manage chronic disease is not specifically used in patients with a mental health diagnosis, so it is unknown how this variable will modify disease self-management. Managing the complexities of type 2 diabetes requires a concerted, rigorous effort and there may be additional self- management strategies needed for those battling a mental health disorder and concomitant chronic disease that may be assisted by shared medical appointments. Because veterans with type 2 diabetes utilize other VA self-management programs (Renal Diabetes, Nurse Case manager, PharmD clinic, MOVE!), the type and amount of these additional programs with be tracked to assess if these additional programs with improve or detract from disease outcomes for diabetes and heart disease.

Background and Significance

Type 2 diabetes is an acquired condition of disordered metabolism characterized by prolonged hyperglycemia, inadequate insulin secretion of the pancreatic beta-cells,

and insulin resistance that is often associated with visceral obesity (Masharani, & Karam, 2002). Type 2 diabetes, which accounts for 90-95% of all cases of diabetes, is a widespread chronic disease that is linked to physical inactivity and excess weight that can be controlled with proper diet, weight reduction, and exercise (CDC, 2009). In 2007, 1.6 million new cases of diabetes were diagnosed and it is projected that if this current trend continues, that 1-3 Americans will develop type 2 diabetes sometime in their lifetime (CDC, 2009). As the number of Americans with obesity continue to rise, our current health care delivery system needs to develop innovative strategies to more effectively manage type 2 diabetes, and the costly burden of concomitant cardiovascular disease.

Because type 2 diabetes confers an increased risk of developing cardiovascular disease (Haffner, Lehto, Ronnemaa, 1998; Stolar & Chilton, 2003), older adults diagnosed with type 2 diabetes alone have the same cardiovascular mortality risk as patients that have an established diagnosis of coronary heart disease (Carnethon, Biggs, Barzilay, Kuller, et al, 2010). According to the American Heart Association, an estimated 81 million or 1-3 Americans have cardiovascular disease, and approximately 38 million are aged 60 years or over (AHA, 2010). Cardiovascular disease remains the number one killer of Americans and claims more lives annually than cancer, respiratory disease, and accidents combined (AHA, 2010). Insulin resistance, dyslipidemia, and chronic hyperglycemia are common in persons with type 2 diabetes. This abnormal metabolic milieu renders arteries susceptible to atherosclerosis through endothelial cell dysfunction, vascular smooth muscle dysfunction, impaired platelet functioning and coagulopathy (Beckman, Creager, & Libby, 2002). After atherosclerosis develops, persistent

hyperglycemia contributes to plaque instability and rupture, (Stolar & Chilton, 2003) which leads to clinical events including myocardial infarction, stroke, and death. Medical therapies that address the global systemic derangements of hypertension, dyslipidemia, hyperglycemia, hyperinsulinemia, and coagulopathy can attenuate the cardiovascular disease progression in this high risk cohort (Beckman, Creager, & Libby, 2002). A comprehensive, effective medical management plan is needed to control the hyperglycemia as well as the composite multisystem microvascular (neuropathy, nephropathy, and retinopathy) and macrovascular (coronary, carotid and peripheral) alterations that will reduce morbidity and mortality associated with this complex disease (Stolar & Chilton, 2003).

Over the past few decades, one of the potential solutions for this problem is to have patients managed in a shared medical appointment, or group medical visit (Jaber, et al, 2003) The shared medical appointments model utilizes a team of health care professionals who provide health care to multiple patients, at the same time and in the same setting, while also offering education and facilitating peer support (Noffsinger, & Scott, 2000; Bronson & Maxwell, 2005). Shared medical appointments are 90-minutes or longer and it is postulated that the longer duration of these sessions affords participants more health education and time with health care providers who in turn have a greater opportunity to address important screening and clinical care recommendations (Clancy, et al, 2003). In a 4-year Italian study Trento et al (2002) reported that compared to a control group, type 2 diabetics had improved quality of life scores, knowledge of diabetes, and health behavior when attending shared medical appointments. Group venues may also

be effective because they add an element of peer identification, shared experiences, and motivation for the participants involved (Trento, 2002). Several studies reported a beneficial effect on HbA1c using shared medical appointments, (Trento, et al, 2002; Sadur, et al, 1999; Kirsh, et al, 2007), reduced systolic blood pressure (Kirsh, et al, 2007) and enhanced provider adherence to (ADA) clinical practice guidelines through using group visits in low income, or underinsured patients (Clancy, et al, 2003; Clancy, et al, 2007). Thus, the use of shared medical appointments may provide Americans with a viable health care delivery alternative to managing the complex issues of diabetes and other chronic illnesses.

Jaber et al's integrated literature review (2006) notes that there is wide variation in the content and structure of shared medical appointments, which may account for the mixed results on health behaviors, self-efficacy, and disease specific outcomes. There are still many unanswered questions on how clinical outcomes such as blood pressure, HbA1c, and LDL cholesterol can be improved by using this health care delivery model. For example, it is unknown how many shared medical appointments are needed to affect change in a clinical parameter, or if the presence of a mental health diagnosis reduces a patient's ability to participate in disease self-management. This research study will continue efforts to explore the effectiveness of group visits on clinical parameters and VA DoD diabetes clinical practice guidelines, an important goal in this era of health care reform where controlling costs and managing disease effectively is of utmost importance. It is hypothesized that the group visit, with its interactive, educational format, peer support, and a collaborative, multidisciplinary team will improve both clinical and quality

outcomes for the intervention group. Group visits and shared medical appointments are terms often used interchangeably; for this proposal, the term shared medical appointments will be used to describe this concept.

Theoretical Framework

The theoretical framework that guides the research is the Chronic Care Model (CCM) (Wagner et al, 1998). The CCM was developed as a quality improvement project specifically targeted for chronic disease. The CCM provides a framework for health care providers and organizations to make substantial organizational and systemic changes that support evidence-based practice guidelines and self-management specifically targeted for chronic disease (Wagner, Austin, Davis, Hindmarsh, et al, 2001). It was developed around the Institute of Medicine's (2001) report Crossing the Quality Chasm: "A New Health System for the 21st century", recognizing an increase nationally in chronic disease prevalence, highlights deficiencies in our current poorly designed system, and calls for change in the way healthcare delivery is orchestrated (Institute of Medicine, 2001). The CCM has two overarching realms: the health care organization, which provides the goals, structure, and values for the organization, and the community, with its own policies and resources (Norris, and Olson, 2004; Wagner et al, 2001). Four other components in the model influence health delivery for chronic disease management: 1) self-management support, 2) delivery system design, 3) decision support, and 4) clinical information systems (Wagner, et al, 2001).

The shared medical appointments is part of the 'delivery system design' that allows a team of health care professionals to care for multiple chronic disease patients at the same time in a supportive, educational environment (Wagner, et al, 2001). Working in concert, a multidisciplinary health care team can efficiently disseminate several important diabetes instructions and screening recommendations, which may be cumbersome in a brief 15-minute physician office visit. Elements of good chronic care management requires productive interaction between patients who are engaged in their own care, and a proactive health care team with the expertise, resources, and knowledge to deliver evidence-based practice at the time of the medical encounter (National Diabetes Education Program, 2006). These CCM components in part, or as a whole, can greatly enhance chronic disease care.

"Decision support" refers to evidence- based guidelines that are adopted by the medical practice and ingrained into daily clinical management of the patient (Wagner et al, 1998). "Clinical information systems" involves use of the electronic medical record to develop a registry to track patients with a certain health condition, provide care reminders, supply feedback, and facilitate care planning (NDEP, 2006). The electronic medical record can also be used to track clinical and quality outcomes on the patients in the practice for research purposes. Several electronic medical records have the capability of sharing parts of the medical record with the patient regarding current medications, test results, appointment reminders, or electronic mail so that the patients can interact directly with the medical practice and become an active participant in their own care. Self-management refers to the ability of the patient to engage in health promoting

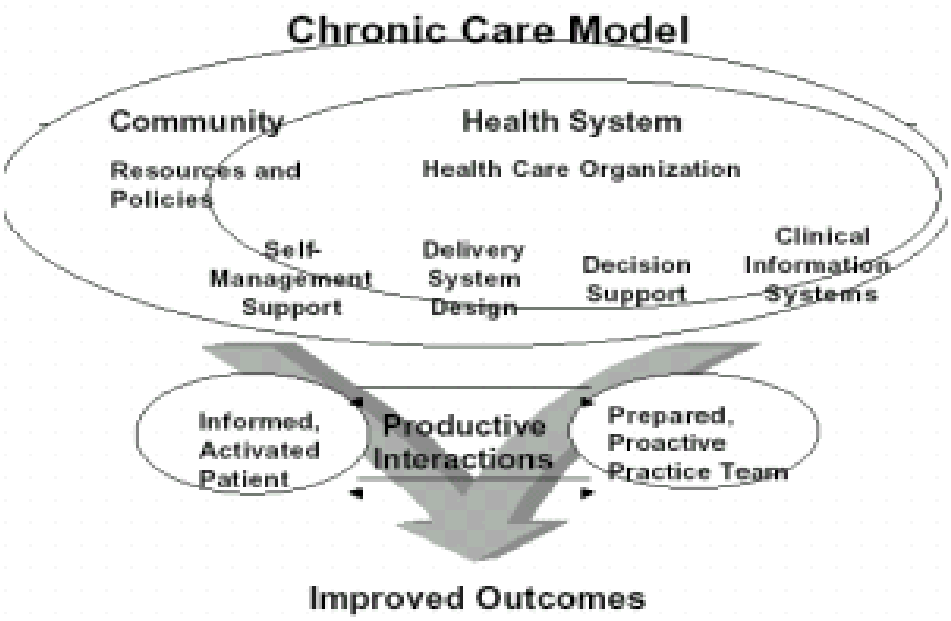
activities to handle his or her own disease (Lorig & Holman, 2003). "Self- management support" involves collaboration between the care team and the patient to provide guidance, skills, and problem solving so the patients can play a fundamental role in managing their own care (NDEP, 2006).

In this study, the "CCM delivery system design" is the group medical visit, defined as the LSCDVAMC as shared medical appointment (SMA) for veterans with type 2 diabetes. The decision support refers to the clinical practice guidelines that are the VA DoD quality measures for patients with type 2 diabetes that include using an angiotensin converting enzyme inhibitors (ACE-I) and angiotension-receptor blockers (ARB's), aspirin, measuring and treating lipids, obtaining regular HbA1c and urine microalbumin to monitor progression of the disease, specific vaccinations such as influenza and pneumovax, and annual referrals for foot and eye exams. Decision support provides a care pathway for the providers to incorporate care planning determined by evidenced-based practice that is integrated into daily practice (NDEP, 2006). Because shared medical appointments utilize an interactive, multidisciplinary team approach, this care delivery format facilitates the dissemination of evidence-based clinical practice guidelines. Forms of decision support also include access to specialist care for consultation, computer based reminders, and use of flowsheets, as well as other decision prompts that direct clinical care (Norris & Olson, 2004).

The clinical information systems for this study are the VISN 10 database warehouse that will provide the information from the Computerized Patient Record System (CPRS) to track the clinical and quality outcome measures. These electronic

databases interface and will allow the researchers access to the patient electronic medical information, medical visit types, and admission information, to track the clinical and quality outcomes. Health care utilization via urgent care or emergency room visits will be gleaned from LSCDVAMC administrative data. Self-management support is the educational component of the shared medical appointments that promulgates patient knowledge, skills, confidence, and assistance so the patient is an active agent in his own health management. As the CCM proposes, productive interaction between the activated, informed patient and the proactive prepared health care team will produce improved clinical and quality outcome measures. Figure 2 below diagrams the CCM.

Figure 2



From "Chronic disease management: What will it take to improve care for chronic illness?" by EH Wagner, 1998, *Effective Clin Pract* 1:2-4. Reprinted with permission:

Bandura's Social Learning Theory provides framework of why social interaction and group dynamics may influence disease self-management. Social Learning Theory posits that people learn through observing others' attitudes and behaviors and assessing the outcomes of those behaviors (Bandura, 1977). Increasing knowledge of type 2 diabetes and modeling others with type 2 diabetes in the shared medical appointment may motivate patients to take control of their disease process, and ultimately change behavior. Having additional support from other patients with like medical conditions, particularly type 2 diabetes, may be advantageous for these individuals.

Setting and Sample

The Louis Stokes Department of Veterans Administration Medical Center (LSCDVAMC) serves approximately 95,000 veterans a year in two inpatient facilities in Cleveland (Wade Park and Brecksville), as well as in 13 community-based health centers in the northeast Ohio (www.cleveland.va.gov). It was the first VA to receive disease specific accreditation from the former Joint Commission on Accreditation of Hospital Organizations (JCAHO) in 2007 for inpatient diabetes management (www.cleveland.va.gov). The sample for the study will contain the medical record findings of veterans with type 2 diabetes that are outpatients of the LSCDVAMC in Wade Park. Type 2 diabetes has been a concern for veterans as highlighted in several publications on insulin therapy based on the Veterans Affairs Cooperative Study in type 2 diabetes (VA CSDM) showing stepped up insulin therapy was feasible to reduce HbA1c levels in veterans and reduce disease related morbidity (Abraira, et al, 1995; Abraira, et al. 1998; Abraira & McGuire, 1999; Azad, et al, 1999). There is mounting evidence that

veterans of the Vietnam War were exposed to dioxin which was a contaminant in the herbicide Agent Orange used to defoliate trees, and exposure to that toxin placed them at risk for the development of type 2 diabetes, as well as several other maladies (www.vba.va.gov). Clearly, the VA medical centers serve millions of veterans nationally, and have a stake in finding management strategies for those afflicted with type 2 diabetes to reduce disease related morbidity and mortality in this cohort.

Significance to nursing practice, education and health policy

The CCM application to nursing include many roles and functions within the model that involve the nurse in direct patient care during the group visit, self-management support via phone encounters, medication management, assessing clinical information systems, scheduling, and providing the patient with community-based resources. Advanced practice nurses, certified diabetes educators, clinical nurse specialists, and registered nurses can all contribute to the group medical visit in various functions. In a recent study testing the elements of the Chronic Care Model, Nutting and colleagues (2007), found that patients with type 2 diabetes who were managed by a nurse practitioner had significantly lower HbA1c levels, and greater clinician use of CCM elements were associated with lower HbA1c, and lipid ratios after adjusting for covariates (Nutting, Dickinson, Dickinson, Nelson, et al, 2007). Nurses with all levels of training, knowledge and expertise related to diabetes, cardiovascular care, as well as other chronic diseases will be needed to effectively implement care, and provide education or patient support at all levels of this model.

The CCM was developed in response to the increasing numbers of Americans who were living longer and/or living with chronic illness (Wagner, et al, 2001). The Institute of Medicine's (2001) report asserts that the current US healthcare system is inefficient, poorly designed, inconsistent, and does not effectively utilize resources to care for individuals with chronic diseases (IOM, 2001). Despite new emerging technology, the US system fails to consistently provide high quality care to all individuals, and at translating new knowledge into practice (IOM, 2001). The CCM was developed as a potential framework to help restructure the current US healthcare delivery system, and serve as a rudimentary template to guide future health policies. While not all-inclusive, the CCM provides an essential guide for stakeholders, policy makers, and industry leaders to explore strategic changes for chronic disease management in all elements of the model. The CCM will need further testing and revision as new innovations in health care delivery emerge.

Summary

Type 2 diabetes continues to be a significant threat to public health, and our current healthcare system has not been effective in changing the trajectory of the disease. Unless burgeoning rates of obesity and sedentary lifestyle cease in this country, we will likely continue to see sobering statistics on rising numbers of Americans afflicted with type 2 diabetes. Several studies on using shared medical appointments have revealed promising, yet mixed results on how this care delivery paradigm may affect chronic disease management. Wagner et al's (1998) Chronic Care Model provides a template on how patients may be better managed living with chronic disease. Persons with type 2

diabetes need additional self-management support, and a team of health professionals to effectively manage their disease, and shared medical appointments provide these patients with additional education, health personnel, and social support that may help keep them on track. Further research on how shared medical appointments may influence clinical and quality outcomes in patients with type 2 diabetes is needed to assess if this health delivery paradigm will make substantial strides in reducing cardiovascular morbidity and mortality for those afflicted with diabetes as well as other chronic diseases.

CHAPTER TWO

Introduction

The burden of chronic disease is enormous with approximately 80% of the annual US health care expenditure allocated for the management of chronic disease (Nuovo, 2007). According to the Center for Disease Control, an estimated 23.6 million Americans have diabetes mellitus, of which 5.7 million are yet to be diagnosed (Center for Disease Control, 2008). Type 2 diabetes and heart disease are two chronic conditions that occur mutually, and type 2 diabetes is a particularly troublesome because adults diagnosed with diabetes have the same mortality risk as those individuals who have an established diagnosis of coronary heart disease (Carnethon, et al, 2010). Traditionally, our current US health care system focuses on the treatment of acute illness, to the detriment of providing strategies for patients needing complex, continuous, multidisciplinary chronic illness care (Wagner, et al, 2004). With an epidemic of obesity in the United States (AHA, 2010), rates of type 2 diabetes and heart disease will continue to mount, therefore, new paradigms of health care delivery need to be explored to control the burden of chronic disease and reduce mortality.

Historical perspective

One of the possible solutions to chronic disease management is to direct patient care in a group venue. Known as shared medical appointments (SMA) or 'group medical care', these shared medical appointments integrate the use of a multidisciplinary team of health care professionals who provide health care services to multiple patients at the same time in a supportive, educational and interactive environment that is often 90-

minutes or longer (Noffsinger & Scott, 2000; Houck, Kilo, & Scott, 2003). Shared medical appointments have been in the literature for several decades, with the first documented reports occurring in the early 1970's when pediatric nurse practitioners used cluster visits" at the Kaiser-Permanente health care system in San Francisco, CA to conduct pediatric well-child visits in an interactive, shared venue (Feldman, 1974). These cluster visits allowed for much of the anticipatory guidance related to child rearing, and pediatric health care to be performed in front of other parents who clearly benefitted from the joint interactions and support of others raising young children (Feldman, 1974).

The concept of a shared medical appointment was expanded to the geriatric population when in 1991, the Cooperative Health Care Clinic (CHCC), developed under a research grant from The Robert Wood Johnson Foundation utilized this health care delivery paradigm to improve quality of care, enhance physician-patient relationships, and reduce healthcare costs for older Americans at Kaiser- Permanente in Colorado (Scott, Gade, McKenzie, & Venohr, 1998). The CHCC, which utilized a team approach to health care delivery, was initially conceived to provide health care services to geriatric patients who had high healthcare utilization rates, but later expanded to meet the needs of high-risk populations with chronic conditions that included diabetes, hypertension, asthma, congestive heart failure, and depression (Noffsinger & Scott, 2000). One of the therapeutic advantages that the groups provided was that the integration of medical care and health education, along with encouragement and social support, reduced the sense of isolation in the group participants, and relieved some of the negative, self-deprecating thinking that can occur when dealing with a lifelong chronic condition (Noffsinger &

Scott, 2000). The more homogeneous groups were also helpful in enhancing specific disease self-management strategies and goal setting that was particularly helpful in maintaining motivation for the participants (Noffsinger, Sawyer, & Scott, 2003). Because family members are often encouraged to attend, caregivers also benefitted from the group experience, by asking questions and gleaning important care information required to help manage the health care needs of their family member (Noffsinger, 2007).

Comparable group care models utilized for care delivery include the Drop-In Group Medical visit or DIGMA's, which is a multidisciplinary, extended, health care visit that utilizes a physician's whole panel of patients to improve access to care, and is generally not disease specific (Noffsinger & Scott, 2000). Developed in 1996 by Edward Noffsinger at Kaiser Permanente in San Jose, CA, the DIGMA allows patients expedited access to their health care provider, which traditionally has been their primary physician, and improves practice productivity by allowing open access scheduling weekly for episodic care needs while efficiently utilizing practice resources (Noffsinger, Sawyer, & Scott, 2003). The DIGMA resembles an informal office visit that is managed in a large conference room usually weekly, for approximately 2-hours with a practice team in place, and could be viewed as a series of individual office visits performed in the presence of others (Noffsinger, 2007; Noffsinger & Scott, 2000). Benefits of the DIGMA model include prompt access to care, high staff and patient satisfaction, increased practice efficiency, increased productivity, and decreased cost (Noffsinger, 2007).

Another care model developed to address difficulties in seeing a primary care physician annually for routine health care, is the Physicals Shared Medical Appointments

(SMA) model (Noffsinger, 2007). Created in 1991 by Noffsinger (2007), this type of group visit streamlines care needed during a routine annual office visit by offloading physician responsibilities to less costly health care providers, and conducting health education in a group, which reduces the constant repetition of health related guidance that physicians repeat daily during a routine patient-physician encounter (Noffsinger, 2007; Noffsinger & Scott, 2000). Practices may opt to construct cohorts for this type of visit, for example, health maintenance visits for females >50 years of age, so that all applicable routine health guidance for perimenopausal females in that age group may be delivered, and discussed amongst participants. Having similar patient populations is practical with this delivery model, because of the similarities in health care needs, and life events for all individuals involved.

Although the taxonomy of the group may vary, the concept of providing shared medical care remains the same regardless of the group's constitution. This speaks to the versatility of using shared medical appointments, and the ability to conform the model to fit the needs of a particular practice or population of patients being served. Other practices that have used group care models for care delivery include pediatric well-care visits (Feldman, 1974; Anderson, 2006), mid-life women, (Thacker, Maxwell, Saporito, & Bronson, 2005), surgical-specialty areas, (Kuiken & Seiffert, 2005; Harris, 2010), type 2 diabetes (Clancy, 2003; Clancy, 2007; Trento, 2002), heart failure (Lin, Cavendish, Boren et al, 2008), and frail elderly (Beck, et al 1997; Coleman, et al, 1999). The paradigm has also been used in obstetrics called Centering Pregnancy, which provides patient-centered prenatal care to pregnant females in a group environment (Reid,

2007; McCartney, et al, 2004). The shared medical appointments must incorporate the delivery of health care by a multidisciplinary team in a group format, and also provide health education and support. Without medical management of the disease during the visit, this encounter would resemble a support group for patients with a particular disease or condition.

Shared Medical Appointments: Team Composition

The health care team composition is highly variable and tailored to meet the needs of the patient population being served. It may include a nurse, certified diabetes educator, nutritionist, nurse practitioner, social worker, physical therapist, pharmacist, and/or physician. The role of the group leader, often called the "behaviorist" according to Noffsinger (2007), is the moderator of the group interactions, and may or may not be involved in direct patient care. The principal health care provider of the group has traditionally been a physician, because of his/her ability to generate the highest reimbursement for services from insurance companies; however, a nurse practitioner, physician assistant, physical therapist, psychologist, and other allied health providers may also be the central care provider for group visits. As health care insurance reimbursement schematics continue to change, more types of providers will likely act as principle providers for group medical visits in the future.

Major Study Concepts

In this study, in addition to the group medical visit, which is considered the intervention, we investigate the concepts of cardiac risk factors, and DoD Diabetes clinical practice guidelines. The clinical outcomes that will be studied include blood

pressure, LDL cholesterol, and HbA1c. These are important cardiovascular risk factors to control in the diabetic population due to the high prevalence of coronary artery disease in this cohort (Beckman, et al 2003). Other outcomes include the clinical practice guidelines, which are evidenced-based quality measures to help clinicians make decisions about important care and screening recommendation in patients with certain diseases (Strano-Paul, et al, 2000). The VA DoD clinical practice guidelines will be utilized because they are similar to the American Diabetes Association guidelines and are accepted by the Louis Stokes Cleveland Department of Veterans Administration Medical Center (LSCDVAMC) and are easily tracked in the VA Diabetes Database. ADA clinical practice guidelines are developed by a panel of experts in diabetology after numerous randomized controlled studies, and systematic reviews are evaluated, and are updated on a regular basis based on new evidence on diabetes management emerges (ADA, 2010).The DoD clinical practice guidelines for this study are: a) HbA1C is measured every 6 months; b) angiotensin converting enzyme inhibitors (ACE-I) are prescribed; c) aspirin is prescribed; d) fasting lipids are reviewed, and treated every 6 months; e) urine microalbumin tested annually f) pneumovax vaccination current, g) annual referrals for foot and eye exams are made.

Integrated Review of the Literature

To date, 25 published studies were found that discussed all, or part of the three key concepts discussed in this research proposal. Because shared medical appointments are often utilized for chronic disease management, the articles were searched via PubMED and CINAHL using the search terms "shared medical appointment" and "group

medical visit" for studies relevant to clinical outcomes and group medical visits in patients with type 2 diabetes or other chronic illnesses. Articles for review were omitted if they did not relate to cardiovascular disease management using group medical care, or were more descriptive in nature with no evaluative component. The current knowledge will be reviewed in relation to clinical and quality outcomes in adult patients with type 2 diabetes and other similar chronic medical conditions only.

Effect of shared medical appointments on cardiac risk factors

Research about the use of shared medical appointments to manage cardiac risk factors such as blood pressure, lipid management, and HbA1c have yielded mixed results. Masley's et al, (2001) dietary intervention study on patients with coronary artery disease showed an increase in fruit and vegetable intake, and cooking with monounsaturated cooking oil at one year in the experimental group versus the control, and reduction of LDL cholesterol in both groups, that met statistical significance in the experimental group at 12 months ($p=.0035$). Sadur et al, (1999) showed reduction in HbA1c by 1.3% in the SMA intervention group, versus only .22% in the control at 6 months, and Gutierrez et al (2011) found a mean reduction HbA1c of 1.19% in the intervention ($p<.01$) and .67% for the control ($p=.02$). Kirsh et al (2007) showed reduction in HbA1c, and systolic blood pressure reduction greater in the SMA intervention group ($p=.0002$) , but LDL reduction although greater for intervention subjects, did not meet statistical significance at 6-months ($p=.29$). Kirsh, et al (2007) also reported that the proportion of veterans with type 2 diabetes meeting targets for HbA1c goal rose from 16.7% pre intervention, to 52.4% post intervention.

In a 2-year longitudinal, randomized controlled trial (RCT) of 112 Italian adults with non-insulin dependent type 2 diabetes, shared medical appointment subjects exhibited significantly lower HbA1c levels, higher HDL levels, lower body mass index (BMI), and triglyceride levels relative to the control at the 2-year follow up (Trento, 2001). Despite randomization with a random numbers table, the control subjects initially had higher levels of education and better knowledge of diabetes prior to the study, and the SMA intervention patients completed an average of 7.9 group visits (range 7-8) and usual care completed 8.2 visits (range 5-11) (Trento, 2001). Regardless of the differences in control and intervention group, at 4-years, Trento, et al's, (2002) longitudinal RCT revealed shared medical appointment intervention subjects continued to show significant improvements relative to HbA1c, HDL, BMI, and diastolic blood pressure. At 5-year follow-up, Trento at al's RCT (2004) found that HbA1c increased significantly in the control group, but not in the intervention group, while levels of HDL, the "helpful" cholesterol, increased, and BMI decreased in the Italian subjects managed in the group medical visit (Trento, 2004).

Other research studies were not able to find significant differences in cardiac risk factors of LDL cholesterol, blood pressure, and HbA1c control over 6 or 12-month intervals (Clancy, et. al, 2003; Clancy, et al, 2007; Wheelock, Savageau, Lee, et al, 2009), and Wagner et al (2001) was unable to report significant differences in HbA1c or cholesterol reduction over a 24 month intention-to-treat analysis. Sanchez (2011) was able to report that Mexican American patients who attended a diabetes self management SMA were able to maintain normal blood pressures, but unable to reduce HbA1c or LDL

cholesterol levels that met statistical significance. However, no published studies to date reported worsening of clinical parameters for cardiac risk factors in patients who received group medical care. Clancy, et al (2003a) also noted that although HbA1c, LDL cholesterol and blood pressure did not meet statistical significance, the authors acknowledged all clinical parameters were trending downward and was considered a positive tendency in the data set. All studies performed by Clancy et al (2003a; 2003b; 2007) included a sample of inadequately insured, low income minority patients with low health literacy from the same South Carolina clinic, and these factors may have severely limited the patient's ability to self- manage their disease and limits generalizability to other populations.

Two studies point out methodological problems related to research on group medical visits. Wagner's et al (2001) study had a small sample size of only 14 intervention and 21 control subjects of which nearly one-half of the intervention patients never attended a shared medical appointment and those who did only attended an average of three group visits instead of the planned 6 over a 2-year period. Wheelock, et al (2009) study of group medical visits with family practice residents had only 25 intervention subjects with a matched controls and lack of randomization may have added selection bias to the subjects inherently motivated to attend and therefore manage their disease. There is still a dearth of research studies to review on group medical care in the literature because the concept is relatively new, and may be difficult to find subjects willing to be randomized to the group intervention in a randomized control trial and continue attendance over time.

The Trento et al study (2004) offers promising, clinically relevant findings that support that group medical visit participants are able to sustain clinical diabetes- related parameters, knowledge on diabetes, problem solving ability, and increase quality of life over 5-years, which was not found to be significant in the control group. Trento et al (2004) is the only 5-year prospective randomized controlled study that addresses shared medical appointments in chronic disease management and speaks to a 'dose effect' that reveals there may be evidence that this care model may bestow clinical and quality of care benefits for disease management over time. No current studies have addressed the use of shared medical appointments for mental health diagnoses other than depression, but Lemke & Schaefer's (2010) recent study on the prevalence of psychiatric diagnoses among VA nursing home residents reveal the prevalence of serious mental illness was present in the oldest birth cohorts at rates of between 19-22%. Since having a mental health diagnosis is widespread in veterans, it is pertinent to evaluate how this variable relates to disease management using group medical care in veterans.

Effect of group medical care on clinical practice guidelines

Clinical practice guidelines are a means for ensuring transparency, scientific rigor, and high standards for accountability in health care (Institute of Medicine, 2008). Health care organizations that measure provider performance are intently looking towards adherence to accepted clinical practice guidelines as a means for evaluation of quality, and reimbursement (IOM, 2008). In three studies, Clancy (2003a; 2003b; 2007) were unsuccessful at finding significant differences in cardiac risk factor reduction, yet all found significant provider adherence on several of the 10-ADA quality standards of care.

Clancy (2007) also found greater screening rates for cancers of the breast, and cervix in participants who attended shared medical appointments. Gutierrez and colleagues (2011) found an increase in aspirin use ($p<.01$), lipid measurement ($p=.02$), pneumococcal vaccination ($p<.05$), eye examination ($p<.01$) and foot examinations ($p<.01$) whereas the controls found significantly significant decreases in influenza injection and foot examinations. Wagner, et al (2001) reported that group participants had higher rates of retinal exams, foot exams, and having medications reviewed, but this was not statistically significant. Lin, Cavendish, Boren, et al (2008) found that after only 6 months there was increased use of recommended heart failure prescriptions namely angiotension-converting enzyme inhibitors (ACE-I), angiotension-receptor blockers (ARB's) and beta blockers in a small pilot study of n=33 heart failure patients that attended shared medical appointments at the Naval Medical Center San Diego. They also found that participants in the heart failure group intervention increased participation in physical therapy directed cardiac rehabilitation from 7% to 42%, and concluded that a multidisciplinary team approach may enhance quality of care (Lin, et al, 2008).

Effect of clinical practice guidelines on cardiac risk factors

According to the Institute of Medicine (IOM), clinical practice guidelines should follow specific characteristics such as objectivity, transparency, efficacy and timeliness, external review, currency, and overlap to ensure that a recommendation is trustworthy and relevant for a particular clinical situation (IOM, 2008). However, the IOM (2008) also pointed out that clinical practice guidelines vary widely in their methodological rigor and protection from partiality, and there are potential sources of bias that may

compromise integrity; for example, when members of the expert panel have a financial interest in instituting a particular guideline. The Department of Health and Human Service (DHHS) and the Agency for Health Care Research and Quality (AHRQ) have hundreds of clinical practice guidelines listed on their website and it is confusing to patients and clinicians alike as to what guideline to follow, and whose professional endorsement to consider (www.guidelines.gov). The American Diabetes Association (ADA, 2009) reviews multiple randomized controlled clinical trials, systematic reviews, and expert opinions, and recommendations are drafted and reviewed by the ADA Executive Committee before being published in *Diabetes Care*. These recommendations are updated regularly and placed on their website for public perusal (ADA, 2009). Because these clinical guidelines are based on multiple randomized controlled trials, systematic reviews, and expert opinion, there is compelling evidence that these particular practice guidelines will positively affect cardiac risk factors.

There are numerous studies that suggest that shared medical appointments may decrease the utilization of specific health care services, namely emergency room visits, specialty care, and repeat hospital admissions (Scott, et al, 2004, Beck et al, 1997, Coleman, Eilertsen, et al, 2001). Miller, Zantop, Hammer, et al (2004) also noted decreased Urgent care visits in low income Latina women who were managed in group care for their chronic illnesses. Wagner et al (2001) noted that group participants had slightly more primary care visits, but fewer specialty care and emergency room visits. High levels of patient satisfaction with shared medical appointments have also been noted

in several studies (Wagner, et al, 2004; Lin, et al 2008, Scott, et al, 2004; Sadur, et al, 1999; Clancy, et al, 2003; Miller, et al, 2004; Beck, et al, 1997, Gutierrez, et al 2011).

In a recent integrated review of the literature on shared medical appointments, Jaber, et al (2006) noted that interpretation of results regarding clinical outcomes and quality measures using group medical care often vary due to the differences in research quality, study design, and description of the intervention. For example, some group medical visits had more educational component, and less disease management (Masley, et al, 2001). The groups also varied widely in the provider make up, group composition, and patient population studied (Jaber, et al 2006). Despite these group differences, Clancy (2003b), noted that group participants reported an increase sense of trust in their physician, better care coordination, improved community orientation, and more culturally competent care.

This review of the current literature indicates that there appears to be compelling evidence that shared medical appointments may positively impact some clinical outcomes, and ADA quality measures. Studies assessing these outcomes are limited, however, by small sample size, lack of adequate time interval for the intervention to take effect, and lack of consistency with group composition and content. The VA Medical Center in Cleveland, Ohio, which has used shared medical appointments for over 8 years, has governmental health care coverage, which may assist in detecting clinical differences using shared medical appointments over past studies in uninsured patients that were not (Clancy, 2007). A recent study involving VA veterans with type 2 diabetes was able to show significant differences in clinical parameters, but did not specifically study the

effect of group visits on ADA clinical practice guidelines (Kirsh, et al, 2007). Studies by Clancy (2003a), Clancy, (2003b) Clancy (2007) found adherence with ADA quality measures, but the clinical outcomes did not meet statistical significance. Increasing knowledge about group care and self- management in patients with type 2 diabetes as well as other chronic diseases may add legitimacy to changing our health care delivery design for certain individuals. The goal of this project is to assess the utility of shared medical appointments in improving chronic illness care, reducing hospital utilization, and appraising adherence of medical providers to quality measures for diabetic patients using a novel health delivery model.

Covariates: Mental Health Diagnosis, Number of clinic visits, other VA Self-management programs

Three additional covariates will be included in this study. These include mental health diagnosis, number of clinical visits, and attendance in other VA self- management programs. The use of the shared medical appointments model has not typically been utilized to treat mental illness, however, a few studies addressed the use of the shared medical appointment with depression screening and physical functioning. In a recent randomized control trial by Taveira, Dooley, Cohen, Khantana, and Wu (2011), patients with type 2 diabetes and comorbid depression who attended a pharmacist-led SMA achieved reduction in HbA1c, systolic BP, LDL cholesterol over the control with no significant change in depressive symptoms. Wagner et al, (2001), was not able to find significance in depression scores between the intervention subjects, and usual care as measured by the CES-D, as well as no improvements on the physical role and physical functioning measured on the SF-36. Coleman et al (1999), found no differences in a

cohort of frail elderly at high risk of hospitalization on depression scores, or physical functioning (SF-36) when compared to the control, and Beck et al (1997), found no differences in functional status measure (ADLs, IADL's and mobility), or depression among chronically ill HMO members. Nonetheless, a recent integrative review of veterans in nursing homes reveal and increase prevalence in depression, post traumatic stress disorder (PTSD), and serious mental health issues in the VA population (Lemke, et al, 2010). Recent studies on PTSD, physical functioning, and quality of life report veterans returning from wars in Iraq and Afghanistan report a relationship between a PTSD diagnosis and impaired physical functioning and quality of life (Schnurr, et al, 2009; Lemke, 2010). The mental health diagnoses of interest for this study include PTSD, depression, bipolar depression, anxiety and alcohol and substance abuse. Other major mental illness including psychosis and schizophrenia will be excluded from this study as veterans with delusional behavior would have difficulty managing both severe mental health issues and chronic disease. Addressing how a mental health diagnosis relates to disease self-management with shared medical appointments for veterans with type 2 diabetes would be useful to ascertain if clinical and quality outcomes improve when controlling this covariate.

Number of shared medical appointments visits over time appears to provide a benefit on clinical and quality outcomes. Trento et al's (2004) 5-year longitudinal study on 112 subjects with type 2 diabetes noted that that HbA1c increased in the control group over time, but not in the intervention group, in whom BMI decreased and HDL, triglycerides, cholesterol and creatinine improved. Knowledge of diabetes, and problem

solving ability improved rapidly over 2-years, but conversely, patient in usual care subjects gradually reduced their knowledge on diabetes related questionnaires (Trento et al, 2004). Although Wagner et al (2001) found no differences in cholesterol and HbA1c between group medical participants and the usual care, frequency of group visit attendance correlated with improvement in cholesterol and reduction in HbA1c. Therefore, tracking number of usual care or shared medical appointments over 2-year observational study will help determine if there is a dose response of the SMA intervention on outcome measures.

The other VA disease self-management programs that will be tracked in this study include PharmD clinic, MOVE! program, Nurse case managers, and Renal Diabetes Clinic. The number and type of visit will be followed during the same time interval to assess if attendance in additional programs to manage chronic disease also improves clinical and quality outcomes since overlap exists in some of the services provided. These VA self-management programs were selected as they afforded an existing matrix for chronic disease management prior to, and during the initiation of the diabetes group medical visits. PharmD clinics have registered VA pharmacists, most with clinical doctorates in pharmacy, who can assist veterans with medication issues, compliance, handling side effects, and questions. They can also assist in learning about drug-drug interactions and obtaining appropriate medications. The MOVE! program is a weight loss program designed by the VA National Center for Health Promotion and Disease Prevention to help veterans increase daily exercise, make healthy dietary choices and track weight loss goals (www.move.va.gov). Palaniappan and colleagues (2011) found

that weight management SMA participants lost an average of 1.0% of their baseline weight whereas patients not managed in group visits gained .8% of baseline weight. Since both the MOVE! program and SMAs are offered to these VA subjects; number of visits to this self-management program will be evaluated. Nurse case managers are used to assess patient adherence to the diabetes management program and provide ongoing support, lifestyle coaching, and assistance. They also may work with a peer mentor or family member to help the veteran stay on track with the diabetes care management goals. The Renal Diabetes Clinic follow diabetics to assess renal functioning using serial laboratory studies and routine follow up, and help with medications that can help the veteran preserve kidney functioning.

Conclusion

There is still much to learn about the use of shared medical appointments, and how they may improve both clinical and quality outcome measures for veterans with type 2 diabetes. Randomized controlled trials (RCT) on the concept for group medical care are scarce, and the few RCTs that are available in the literature currently show mixed results. By assessing veterans with type 2 diabetes retrospectively over a longer study interval, some of the clinical and quality outcome measures may meet statistical significance. Moreover, there is a need to determine what type of patient may benefit from group care, and who would not. Studies may be biased by selection in the sense that patients who would agree to be in a shared medical appointment may be inherently motivated to assist in their own disease self-management. Assessing if a mental health diagnosis, or amount of visits attended will also moderate an outcome measure remains to be determined.

There are no current studies that address how mental health relates to chronic disease self-management using group medical visits. However, this variable is important due to reports that reveal high numbers of veterans with mental health issues. This study anticipates that some of these important questions will be answered for veterans with type 2 diabetes.

CHAPTER THREE

Introduction

This chapter will review the research design and rationale for the study design, methods, sampling, and variables of interest, decision rules, statistical analysis plan, and data management of the abstracted data. Review of the VA Institutional Review Board (IRB) procedures and protection of human subjects will also be discussed.

This observational research study utilized the VA VISN 10 database warehouse, and in collaboration with a VA computer programmer, we abstracted data for over a 5-year period between January 1, 2006- December 31, 2010. We were interested in two groups of subjects with type 2 diabetes who received care via a shared medical appointment (SMA), hereafter known as the SMA group, and those who received usual physician-patient care, hereafter known as the usual care (UC) group. All records for patients with an ICD- 9 code 250.00 for type 2 diabetes who attended 3 years of SMA over a 5-year period with at least 2 consecutive years of SMA visits were considered for the intervention cohort in this study. All records for patients with an ICD- 9 code 250.00 for type 2 diabetes who attended 3 years of usual care over a 5-year period with at least 2 consecutive years of usual care visits were considered for the usual care cohort in this study. Total number of SMAs and UC visits for 3-year study period were abstracted.

In order to maintain the closest temporal relationship between the intervention (type of care delivery) and clinical outcome if interest, the dataset was created from records of veterans who participated in at least 2-consecutive years SMAs or UC visits over 5-years, and had at least one of either UC or SMA visit annually. The research team

desired to abstract all demographic, health-related, and delivery model data from both groups of subjects in SMA and UC cases. Case summaries were run in SPSS to determine how many clinical variables were abstracted in the SMA and UC cases over the 5-year time period. Multiple gaps were noted on the abstraction of clinical parameters, and completeness for both cohorts was desired to assess these outcomes. Several iterations on case summaries revealed that data from the years 2008-2010 had the least amount of missing data on key clinical variables of interest and was subsequently used for analysis.

Study design and rationale

This observational study used a two-group cohort design. The benefit of using an existing database is that research can be conducted relatively inexpensively, because the clinical and quality data are already gathered and readily available (Grady & Hearst, 2007, Boslaugh, 2007). The disadvantage is that the quality and quantity of the data collected are already predetermined (Grady & Hearst, 2007) and the researcher has no ability to substantiate the reliability of the data collection and documentation in the electronic medical record. For this study, some variables of interest in the CPRS electronic medical record were not easily accessible, so the research team needed to make decision rules in regards to handling of missing data, years of analysis, and handling of abstracted data.

Clinical Setting

This study was conducted using databases from the Louis Stokes Cleveland Department of Veterans Administration Medical Center (LSCDVAMC). The sample was drawn from the medical records of veterans with type 2 diabetes. The LSCDVAMC

has been providing inpatient and outpatient health care services for veterans on two campuses which include Cleveland (Wade Park) and Brecksville, along with 13 community-based outpatient clinics within Northeastern Ohio (http://cleveland.va.gov). LSCDVAMC is the 5th largest VA facility in the country serving 95,000 veterans a year (http://cleveland.va.gov). Since 2005, the LSCDVAMC (Wade Park) has been offering shared medical appointments for their veterans with type 2 diabetes as one of several disease management programs offered to control chronic illness. There are other innovative health care programs offered at the LSDCVAMC that include the Renal Diabetes Clinic, MOVE program, PharmD clinic, and nurse case managers. The LSCDVAMC has funded research and development programs accredited by the National Commission for Quality Assurance (NCQA) and a research department that conducts studies in biomedical, clinical, health services, and rehabilitation research (http://cleveland.va.gov).

Veterans with type 2 diabetes receive the diabetes SMA, or usual physician-patient care in the first floor outpatient medical clinics of the LSDCVAMC in Cleveland, Ohio. For veterans with uncontrolled type 2 diabetes who are not at goal levels for blood pressure which is <130/90, HbA1c < 7%, and LDL cholesterol <70, a shared medical appointment is offered as an alternative to usual care. According to Dr. Susan Kirsh, developer and researcher of SMAs for the LSCDVAMC, veterans having difficulty controlling their diabetes are identified through the CPRS electronic medical record or the VA Diabetes Registry, and are encouraged to participate through a VA provider referral. The veterans who attend the diabetes SMA generally have challenges regarding

diabetes self-management and need additional assistance to get these important clinical parameters optimized to reduce the risk of cardiovascular disease.

Shared medical appointments for veterans with type 2 diabetes are scheduled weekly on Thursday for approximately 18 patients per session. They are generally overbooked to account for attrition or “no shows." The LSCDVAMC shared medical appointment is lead by a team of health care providers that may include a physician, nurse practitioner, certified diabetes educator, psychologist, or social worker. The patients are initially taken to a conference room adjacent to the examination rooms, where medications, vital signs, and past laboratory studies are reviewed. The participants in the group are able to ask questions about their disease, review blood work, discuss health related problems, and an interactive discussion ensues. After a 30-45 minute educational session, each veteran is taken to a private exam room where they receive a physical exam, medication adjustment, and further testing if needed. At this juncture, their CPRS medical record is updated with medications, current vital signs, current weight, and medical management plan. Follow up appointments for the veteran in either another SMA, or UC visit would be made at this time.

The VA Databases

The VA VISN 10 database warehouse was used to abstract all data for this study. This database interfaces with CPRS electronic medical record. The CPRS is the United States Department of Veterans Affairs electronic medical record system used for the health care documentation for all veterans. The CPRS electronic record system has been utilized for over a decade. The CPRS medical record interfaces with both the VA

Diabetes registry and VA database warehouse, which receives and permanently stores the clinical updates within approximately 24- hours. The VA Diabetes Registry was created by a VA physician, clinician, and researcher to track important clinical parameters in veterans with type 2 diabetes for quality assurance, and research purposes. The Diabetes Registry was used as a referral source for patients who were selected to attend the SMA. The VA Diabetes database is updated every 24- hours with most recent clinical parameters from the veterans' medical information abstracted from their CPRS record. The VA VISN 10 database warehouse also contains important administrative data including time and date of past medical visits, visit type (SMA versus UC), demographic information, and number of emergency room visits. A numeric sequence or 'stop code' is given to the type of visit attended (SMA or usual care) for the veterans and they were utilized to locate medical visits in the database.

Sample

The sample was composed of the medical records of veterans with type 2 diabetes that receive health care either in a SMA (n=371), or usual care format (n=617) at the LSCDVAMC in Cleveland, Ohio. The sampling procedure included identifying the records of a cohort of veterans with type 2 diabetes in the VA VISN10 database warehouse, male or female, age 51 and over, who attended 3 years of Diabetes SMA over a 5-year period with at least 2 consecutive years of SMA. Table 1 summarizes the inclusion and exclusion criteria for the research.

Table 1

Inclusion and Exclusion Criteria for the Research

Include	*Exclude*
Male or female	Veterans with type 1 Diabetes
Type 2 diabetics*	Schizophrenia/Psychosis/dementia
Age ≥ 51	1-2 yrs SMA or UC
3 yrs of SMA or UC visits/5 yrs	Attendance in other Disease specific SMAs
2 consecutive yrs SMA or UC visits	

SMA=Shared medical appointment
UC=Usual care
yrs=Years
**= with ICD-9 diagnosis code 250.00*

Initial inclusion criteria required that the subject had a HbA1C of at least 8%, LDL cholesterol of >130 mg/dl, a systolic blood pressure of > 140 mmHg at baseline, however, the researchers did not want to limit subjects based on these criteria as it would reduce sample size. Inclusion criteria consisted of having a confirmed diagnosis of type 2 diabetes mellitus (ICD-9 code 250.00) or other similar diabetes related medical codes listed in their electronic record (i.e. diabetes with retinopathy, diabetes with neuropathy, diabetes with nephropathy). Exclusion criteria included subjects' age ≤50, veterans who receive care outside the VA, lack of ability to confirm diagnosis of diabetes, diagnosis of type 1 diabetes, inability to confirm attendance at the SMA. Other clinical exclusion criteria were HbA1C of 6 % or less at baseline, normal blood pressure of < 130/80, and LDL cholesterol of <70, however, these parameters were disregarded due to the limitations it would have on our sample size. Patients with dementia, psychosis, or cognitive impairment were excluded. Veterans with type 2 diabetes who have received

other disease self-management programs at the VA were included and tracked in both the intervention and control groups and includes the Renal Diabetes Clinic, MOVE program, PharmD clinic, or nurse case manager.

Data abstraction for all subjects included clinical outcomes of HbA1c, systolic and diastolic blood pressure, and lipid panel including total cholesterol, HDL, LDL and triglycerides over 5-years. Quality outcomes metrics associated with the management of type 2 diabetes were based on the Department of Defense (DoD) Diabetes clinical practice guidelines. Variables related to diabetes management included using an angiotensin-converting enzyme inhibitors (ACE-I) and angiotension receptor blockers (ARB's) to protect renal functioning, aspirin for its anti-platelet aggregation activity, measuring and treating lipids, obtaining regular HbA1c and urine microalbumin to monitor progression of disease, specific vaccinations such as influenza and pneumovax, and annual referrals for foot and eye exams. Yearly influenza vaccine administration was removed from the variable list because of its difficulty to track, and due to the availability of the vaccine at facilities outside the VA. Additional variables that were measured included the presence of a mental health diagnosis for the veteran, the number of health care visits during the study period (usual care and SMA) and attendance in other VA self-management programs (MOVE program, Renal Diabetes Clinic, RN Case manager, and Pharm D clinic). Using Wagner's et al (1998) Chronic Care Model, this study endeavored to support the premise that redesigning health care delivery utilizing the shared medical appointment model may confer improvement on both clinical and quality outcome measures for veterans with type 2 diabetes.

Shared medical appointment attendance was abstracted from the VA database warehouse using the prescribed VA medical visit stop code 306 and 348. Demographic variables such as age, race, gender, marital status, were compared in both groups. The SMA intervention group may have had other usual care visits attended during the 3-year study period; however, the control group may not have attended any Diabetes SMAs. The control group and SMA subjects also must not have been managed in other disease specific shared medical appointments, for example, Heart Failure SMA. Additional health related variables such as diagnosis of coronary disease, hyperlipidemia, hypertension, obesity and current smoking were extracted from the VA database warehouse for both cohorts in the study using ICD-9 medical diagnosis codes.

Hospital utilization was tracked using the VA visit stop code for Emergency room visit (stop code 130 or 102) also named ED visit for this study. The LSCDVAMC in Cleveland, OH had all episodic visits seen through the Emergency department (ED). The rationale for tracking this variable was to ascertain if shared medical appointment attendance could curtail use of the Emergency room through the use of regular follow up and enhanced disease management education afforded in the group setting. Hospital admission and length of hospital stay was also desired, but was unable to be abstracted by VA IT and was subsequently dropped from this study.

All veterans in this study were assessed for presence or absence of a comorbid mental health diagnosis. Depression, anxiety, PTSD, and substance use including drug, tobacco and alcohol abuse are common medical diagnoses in veterans (Lemke & Schaefer, 2010; Schnurr, Lunney, Bovin, et al, 2009), and was tracked with use of ICD-9

diagnosis codes in the VA database warehouse. This variable was assessed in both groups. The rationale for tracking these additional variables is that it may influence the ability for the veteran to care for themselves, regardless of the intervention. Because of the impact on self-care management, veterans with the diagnosis of a major psychiatric diagnosis i.e. schizophrenia, psychosis, and dementia were excluded from the study. These variables were analyzed along with the other clinical and quality outcome data.

Human Subjects Protection

This observational study was part of an expedited review that was accepted by the Cleveland VA Subcommittee on Research Safety Exemption on 7/18/2011, VA Institutional Review Board on 7/29/2011 the VA Research and Development committee on 10/6/2011. It was also reviewed and accepted January, 2012 by the VA Steering Committee in charge of studies that require use of electronic medical records and large VA database systems. Continuing review of all studies is required by the VA Research Department so that all studies are monitored for adherence to accepted human subject protection protocols.

Once the variables were extracted from the VA database, the subjects name and social security number were removed, and the subject's name replaced with a number to protect confidentiality. All HIPAA mandates regarding use of Protected Health Information (PHI) contained in electronic medical records were adhered to in accordance with state and federal law. The dataset and all supporting documents associated with this project were stored on a VA server and all data analysis were conducted at the VA Wade Park on a password protected computer.

Sample Size Determination

This estimated sample size for the study was based on a randomized controlled trial (Trento, et al, 2002) in which the shared medical appointment yielded a mean difference in HbA1c in the intervention group versus the control at 4-years of 1.6 and the standard deviation was 2.1. The estimated standardized effect size, which is the effect size divided by the standard deviation =.76. Using the Trento (2002) data, the statistical table published in Hulley et al (2007) reveals that if alpha is set at .05 (two-sided) and beta is set at .20 (1-.80), the number of subjects needed in each group is 64 (Hulley, et al, 2007, p.84). The sample size also was calculated using the statistical program G-Power (G*Power 3.2.1, Heinrich-Heine-Universitat-Dusseldorf) and if a medium effect size (.50) is desired, and alpha was set at .05, then 64 subjects in each group, or total n= 128 is desired. The VA database was mined for cases with a diagnosis of type 2 diabetes and yielded a total of 8,145 potential subjects. These were subjects whose medical records were housed in the VA Wade Park, Cleveland, Ohio that had either usual are visits, diabetes SMA visits or a combination of both over a 5-year period. This was the initial dataset obtained by VA Information Technology (IT) department for use in this project, but not all cases met eligibility. Many subjects did not meet the inclusion criteria of 3-years of SMA attendance over 5-years including 2 consecutive years of visits, or had enough clinical or quality outcome recorded over 5-years to be included in the study. After mining the data, decision rules were then formulated by the study team by evaluating recorded numbers of HbA1c, LDL cholesterol and blood pressures contained in the SMA veteran sample over 5-years. Subjects that had all HbA1c's values abstracted,

had 3-years of SMAs including 2 consecutive years, and were seen in a diabetes SMA 2008, 2009 and 2010 were included.

Demographic variables

Demographic variables of interest for this study included age, gender, marital status, race. They were abstracted from the VA database warehouse for the SMA intervention group and compared with a control cohort of similar veterans with type 2 diabetes who have never attended an SMA and only usual care visits over the same 2006-2010 time frame. The SMA and UC subjects were compared on additional covariates using ICD-9 codes, such as a diagnosis of hypertension, dyslipidemia, obesity, coronary artery disease, and other health related factors including tobacco and alcohol use, and hospital emergency room visits. These medical diagnoses and ED utilization was abstracted from the VA database for the study period for both cohorts.

Age was defined as the chronological number on the day of the group medical visit that is recorded in the VA database warehouse based on the date of birth in the year the subject was enrolled into the study. The subjects needed to be age 51 or greater to be included, but there was no upper age limit to the study. Gender is a dichotomous variable that was recorded as male or female as documented in the CPRS medical record. Marital status is a nominal variable and was defined as report of legal living arrangement and included one of the following categories: never married, married, divorced, separated, or widow/widower. The self- reported documented marital status in the CPRS during first SMA or usual care was utilized.

Race categories included African American/black, Hispanic, Pacific Islander/Asian, Caucasian and unknown and was coded using a numerical value for each label for SPSS. There was a category of null or unknown if the racial information was not known in the database. These variables were collapsed to include white, and black.

Major Study Variables

The Shared Medical Appointment

The group visit or shared medical appointment is a type of health care delivery model that allows a team of health care providers to manage multiple patients at the same time, which is usually in a 90- minute or more medical encounter (Noffsinger & Scott, 2000; Noffsinger, 2007) . The SMA has a variety of formats, and may be altered to meet the specific needs of a clinical practice or target population (Barud, Marcy, Armor, et al, 2006; Noffsinger, 2007; Noffsinger & Scott, 2000). At the LSCDVAMC in Cleveland, OH, the SMA is generally moderated by a nutritionist, certified diabetes educator, or PsyD (Doctor of Psychology). An interactive conversation regarding self-management strategies, diet, exercise and symptoms occurs, and may vary weekly depending on the issues brought to the group that day by the participants. After the educational session, the participants are removed individually and taken to an exam room where they receive a private exam time that includes a brief physical exam, weight, and blood pressure by a nurse practitioner, resident, or physician, and for additional management of medications and disease. Health care recommendations are made, BMI, weight and blood pressure recorded, additional laboratory tests ordered if needed, and prescriptions are ordered or refilled. The veteran is scheduled for a 2-3 months follow-up either with an SMA visit, or

individual visit depending on their health status, and individual needs. Confidentiality is maintained by having the participants sign a confidentiality agreement stating that information about patient health status, or clinical parameters are not to be discussed outside the confines of the group.

The attendance was validated by using approved LSDCVAMC visit 'stop codes' 306, and 348 maintained in the VA database warehouse. The numbers of group medical visits, dates, and times, were tracked over 5-years. Participation in shared medical appointments for veterans with type 2 diabetes are completely voluntary, and although most of the veterans are encouraged to try this format of care delivery, the veterans may opt to use the traditional patient-physician care delivery model. This patient-physician format includes a medical visit every 2-3 months with a resident, nurse practitioner, or VA physician where the patient is seen individually. The traditional patient-physician visit would last generally 30-45 minutes, and include a physical examination, health education, laboratory testing, and medical management. Health education would be disseminated throughout the visit, but in the confines of the time allotted. There is generally no other multidisciplinary care provided in the visit, although the veteran may be referred to other disease care management programs offered at LSCDVAMC.

Cardiac Risk Factors

Cardiac risk factors are defined as certain health related predictors that are associated with an increased risk of developing coronary artery disease (AHA, 2009). Cardiac risk factors can be modifiable, for example, body weight, smoking status, blood sugar level, blood pressure, stress level, and cholesterol level, or non-modifiable, such as

heredity including race, gender, and advancing age (AHA, 2009). The three physiological study variables of interest were LDL- cholesterol, HbA1c, and blood pressure; however, the researchers included the entire lipid panel as it was available for this study. The research team was interested predominantly in systolic blood pressure levels, which were measured in mmHg, low density liproprotein cholesterol (LDL) levels in milligrams/dl chiefly for their arthrogenic potential in the intimal layer of the blood vessel (Zipes, et al 2006), and HbA1c in percents which is a marker for diabetes control over a three month period (Treseler,1994). The acceptable normal values for BP control in diabetics and patients with kidney disease according to the Joint National Committee on the Diagnosis and Treatment of Hypertension (JNC-7) is 130/80, the normal values for LDL cholesterol for patients with diabetes is <70 mg/ dl (ADA, 2007) and HbA1c levels is less than 7.0 % of total hemoglobin (ADA, 2009) . The data were recorded as the actual numeric values obtained in the CPRS electronic medical record.

Clinical Practice Guidelines

Clinical practice guidelines are defined by the Institute of Medicine (2008) as "systematically defined statements that are designed to help clinicians and patients make decisions about appropriate health care for specific clinical circumstances." (IOM, 2008). Clinical practice guidelines are tools that are used that can expedite translation of research on a specific topic into clinical practice recommendations for use for clinicians in a certain area (Schmidt, Lindenauer, Fitzgerald, & Benjamin, et al, 2002). According to the Institute of Medicine (IOM, 2008) if well researched and transparent, a clinical practice guideline can be a valid source of clinical information on a certain topic that may

enhance quality of care, while reducing undesirable practice variation that has shown to be of questionable or of little value to a patient. Clinical practice guidelines are developed by panels of experts in a particular field that have access to the current available research and make decisions about the quality of evidence and rigor of the studies, before adopting a certain position (IOM, 2008). The American Diabetes Association position paper (2004) has accepted certain quality care standards that may reduce mortality that include using an angiotensin converting enzyme inhibitors (ACE-I) and angiotension-receptor blockers (ARB's) to protect renal functioning, aspirin for its anti-platelet aggregation activity, measuring and treating lipids, obtaining regular HbA1C and urine microalbumin to monitor progression of disease, specific vaccinations such as influenza and pneumovax, and annual referrals for foot and eye exams. These clinical practice guidelines are also utilized by the VA Department of Defense (DoD) as outlined in Table 2. These quality care measures were abstracted retrospectively from the VA database warehouse in the intervention and control subjects over a 5-year study period in which 2 years would be utilized in the final data analysis.

Table 2

DoD Clinical Practice Guidelines with Indications for the Management of type 2 diabetes:

Clinical Practice Guideline	*Indications for Type 2 Diabetes Management*
Use of ACE-I or ARB medication	Protect renal functioning in patients with type 2 diabetes, and control blood pressure.
Aspirin	Antiplatelet activity, decrease viscosity of the blood to prevent clots
Cholesterol Measured and treated with medication	Prevent the progression of cardiovascular and peripheral vascular disease
HbA1c	To monitor glycemic control over 3 month period and assess self-management compliance
Urine for Microalbumin	Assess for proteinuria; a marker for nephropathy and decline in renal functioning
Pneumovax given and Influenza ordered annually	Protect from respiratory infection in high risk population
Foot examinations annually by podiatrist	Assess for infections, cuts, calluses, nail condition, neuropathy in the foot and extremities
Dilated Eye exam annually by an ophthalmologist	Assess for the presence of diabetic retinopathy and vision loss.

Extracted from the Executive Summary; Standards of Medical Care in Diabetes, Jan, 2010

Reliability and Validity of the Measures

A retrospective observational study design poses difficulty when assessing reliability and validity because the research team relies on data already gathered for another purpose which for this project was from the electronic medical record. Reliability, which refers to the extent that a measure is consistent and predictable (Haber & LoBiondo-Wood, 2006), cannot fully be ascertained as the researchers did not oversee the inputting of the physiologic measurements into CPRS. This is considered a limitation in using this type of study design as the researcher doing the analysis has no control over the data collection process, or the variable's disposition (Boslaugh, 2007). Blood pressure recordings were abstracted by VA IT from results recorded in the CPRS medical record during the time of the usual care or SMA visit. Assumptions were made that the blood pressures in the electronic medical record were accurate as these values were ones that the healthcare providers would base adjustments of medication and base clinical decisions. The systolic and diastolic blood pressures were abstracted during the first half of the year of second half and coded according to whether they were from the first half (6-months) or second half of the year.

Other clinical parameters in the study include HbA1c and cholesterol values which were recorded for the visit. Ways to assure accuracy of cholesterol measurements, and HbA1c is to query the VA laboratory director as to how the lab equipment is calibrated, and what quality standards the VA laboratory maintains. Records could be accessed to determine how the specific machines that process biologic samples are calibrated. The Clinical Laboratory Improvement Amendments (CLIA) is a congressional

bill that was passed in 1988 to establish accuracy, reliability, and quality standards for all clinical testing regardless of where the test was performed (FDA, 2009). The VA laboratory would have to adhere to the same quality standards as all national laboratories, as clinicians rely on the accuracy of clinical laboratory data in order to treat disease.

When abstracting the VA database a variable for the new data set to analyze the clinical and quality measures, there needs to be conformity amongst the researchers on how the variables are abstracted and recorded. Equivalence, which is defined as the agreement when using a measurement tool or between alternate forms of a tool, can be tested using inter-rater reliability (Lo-Biondo-Wood & Haber, 2006). This form of reliability can be ascertained in a retrospective observational study using electronic records, when all involved researchers are trained and oriented to the acceptable procedure of variable abstraction. By cross-referencing the dataset extracted by another researcher, the percentage of agreement between raters can be assessed using a correlation coefficient. Another option would be a that a researcher extracts data from the CPRS using decision rules, and then repeats the process 2 weeks later and assesses consistency between time one, and time two extraction.

The validity of these measures for cardiac risk factors, which refers to whether an instrument or assessment tool accurately measures the construct it is intended to measure (Lo-Biondo- Wood & Haber, 2006), has both content, construct and face validity. These cardiac risk factors are accepted by the American Heart Association and The American Diabetes Association amongst other reputable medical organizations as predictors of cardiovascular disease through decades of thorough research and clinical trials.

According to the National Diabetes Fact Sheet adults with diabetes have heart disease death rates that are 2-4 times higher than those adults who do not have diabetes (ADA, 2007). Reducing cardiovascular risk through cardiac risk factor modification can save millions of lives per year, and researchers continue to delve into other clinical or serologic predictors of cardiovascular morbidity and mortality.

Decision Rules

Guidelines on the abstraction of clinical data, handling of variables, and missing data were conducted using decision rules. The decision rules were guidelines used by the research team for the purpose of clarity, uniformity, and consistency throughout this research project and an indicator of reliability when dealing with electronic medical records. The rules were made by the research team after data mining and cleaning. The initial 8,145 cases with type 2 diabetes abstracted were not all analyzed. In order to obtain the dataset, the sample needed to be systematically reduced to meet IRB specification. Guidelines on the reduction of this dataset was discussed by the research team, and decisions made primarily based on logic, theory, and prior empirical knowledge on use of SMAs. The data was inspected by the study team by running syntax in SPSS prior to the initial dataset to determine which veterans attended the Diabetes SMA intervention, how many Diabetes SMAs were attended over 5-years, and actual years attended. Veterans who did not attend any SMAs from 2006-2010 were identified and considered for the comparison group. However, veterans in the SMA cohort could have attended some usual care visits within the 5-year study period.

After obtaining potential cases for the SMA intervention group, the data was then analyzed for SMA participants who attended 2 consecutive years of SMAs, to ascertain what years of outcomes abstracted could be utilized in the analysis. Because the HbA1c, and lipid panels were time sensitive, the researchers wanted to utilize outcome data that would reflect the SMA model of care on the outcome. The research team also queried the dataset prior to the analysis to determine how many HbA1c values, lipid panels, and blood pressures were abstracted for the SMA participants over the 5-years so important decisions could be made regarding amount of missing data and what years of outcomes were appropriate to use. Subjects who did not have 2-years of consecutive SMAs were then eliminated. Syntax was run in SPSS to determine how many SMA subjects had actual HbA1c values abstracted, and veterans were identified by ID number. The same was determined for LDL, total cholesterol, HDL and triglycerides, and systolic and diastolic blood pressures. Syntax was also run in SPSS to determine if the clinical value has data abstracted for the first half of the year or second half of the year. If no clinical value was available for the first half of the year, the value from the second half of the year was abstracted and placed in SPSS. If biannual values were missing for the variable, the case was removed.

As anticipated, SMA utilization was highly variable over the 5-years. The research team wanted to strictly impose the 3 years of SMA over 5-years with 2-consecutive years of SMA decision rule, but it would mean utilizing different outcome years for each case. Having to use different study years would involve lengthy syntax commands that could introduce error into the study. Using the count command in SPSS,

the dataset was queried for the numbers of HbA1c, and LDL cholesterols abstracted over 5- years, because they were our main clinical dependent outcome variables. A count of 10 HbA1c values over the 5-year period meant that the subject had all the clinical values abstracted for that variable. Through continued analysis, it was determined that the 2008, 2009, and 2010 years had the most complete set of abstracted values for both HbA1c and LDL cholesterol that were very important variables to our study. It was then decided to use 2008- 2010 data for the clinical and quality outcomes for this study.

Data Management

The dataset for this research project was managed using SPSS 20.0 that has the unique identifier code of the participant in the rows, along with the accompanying demographic, administrative, clinical, and quality variables in the columns. The subject's personal information that is protected by the HIPAA privacy rules for example, address, social security number, date of birth, or any additional identifiers was removed from the subject prior to placing them in SPSS.

Coding

The clinical and quality variables, including demographics were given annotated coded names and labels that were produced in a Microsoft Word document. Variables that require numerical values, for example LDL cholesterol level or HbA1c, were kept as continuous variables to preserve the richness of information, and reduce erroneous statistical results that can result from carving up data (Owen & Froman, 2005). The VA DoD clinical practice guidelines were kept as dichotomous variables, and given a number 1 if the quality measure was met, and a 0, if the quality measure was not met. For

example, if the patient was given the pneumovax, or was prescribed an aspirin regimen, that was considered a clinical practice guideline that was met, and coded as a 1. A total of 10 clinical practice quality measures were coded as dichotomous variables for analysis. They include the use of ACE inhibitor, aspirin, and measuring cholesterol annually, treating lipids, obtaining regular HbA1c, checking annual urine microalbumin determinations, vaccination for pneumovax, referrals for podiatry and ophthalmology that are an essential part of quality care for these patients. Variables that were not abstracted in a format useful for analysis in this study were converted. For example, microalbumin was given as a numerical laboratory value, but the study measured whether or not a test was performed, and did not require an actual value, so the variable was converted to a dichotomous variable.

Once the dataset abstracted from the VA diabetes database was reduced to an IRB approved sample size of <1,000 subjects for analysis, the new dataset was evaluated for accuracy by running frequencies, and descriptive statistics including and means, standard deviations, and ranges. All major study variables were checked for outliers or for values on a given variable that does not conform to usual parameters by the coinvestigator. The SPSS descriptive statistics was doubled checked by Dr. Chris Burant, PhD who reviewed all analysis, checked for outliers and reviewed all syntax.

Missing data

Missing data is the most significant problem when performing retrospective data analysis (Smith, 2008). Missing data are pervasive and problematic in longitudinal research (Musil, Warner, Yobas, & Jones, 2002; Patrician, 2002) . Missing data are

particularly challenging because current statistical programs rely on a complete dataset for analysis, analytic power may be reduced, and systematic bias may be entered into the research (Patrician, 2002). Missing data in research can lead to inaccurate conclusions about a population if it is improperly handled (El-Masri, & Fox-Wasylyshyn, 2005). Several techniques exist to handle the missing data that include listwise deletion, pairwise deletion, mean substitution, regression imputation and estimation maximization (El-Masri, & Fox-Wasylyshyn, 2005).

The initial technique used in this study to evaluate for missing data included running syntax to determine how many clinical values were abstracted in both the SMA intervention and control cohort. The goal for this study was to have as many subjects with a complete set of abstracted values as possible to maintain statistical power. For example, we started with HbA1c as it was an important dependent outcome variable for the study. If the SMA subject had 10 clinical values abstracted over 5-years, or 2 values per year, that subject had a full set of values abstracted. If the clinical value was missing for the first half of the year, we imputed the second value for the year. SMA and usual care cases were queried on all clinical outcome measures including LDL, and systolic and diastolic blood pressures to assess for completeness. Multiple queries of the clinical outcomes variables were evaluated in SPSS over the 5-year period to assess for completeness of values on each study subject. We desired to have three consecutive years that had <5% missing data on the key dependent variables that included HbA1c, and LDL-cholesterol which was attained.

Another issue in this study is that it used secondary data, and the datasets using secondary data often are collected for another purpose (Boslaugh, 2007) and not specifically to answer the research questions posed for a specific project. The format in which this data was collected did not necessarily meet the full objectives of the research team. Variables were re-coded, or changed into a format that could be more clinically meaningful for the study. As aforementioned, the microalbumin test was collected as an actual value, which was not needed, and it was converted to a dichotomous outcome for this study as the researchers wanted to know if the quality measure was met, and not the actual numeric value. Other clinical tests including the albumin/creatinine ratio could have been used as a better predictor of renal functioning, but it was not included in this study.

Statistical Analysis

There were three research questions and one hypothesis proposed for this project. The first research question was as follows: Are there differences in two types of clinical outcomes: 1) cardiac risk factors (lipid panel, HbA1c, and blood pressure) and 2) healthcare utilization rates (ED visits) based on healthcare delivery model (SMA versus usual care)?

When comparing means between the intervention and control groups on physiologic measures of lipid panel, HbA1c, and blood pressure, independent samples *t*-test, could be used to compare mean differences between groups. If several means are evaluated over time in two separate groups, the repeated measures analysis of variance (RM-ANOVA) should be used to show variation not only between groups but also within

groups (Whittemore & Grey, 2006). Therefore, since most physiologic measures were present in the VA database warehouse, at baseline 2008, 1- year 2009, and 2-years 2010 post enrollment for all subjects as projected, a RM-ANOVA was better suited to evaluate the mean differences over time on the clinical parameters.

The second research question was: Are there differences in health care provider adherence rates to Veterans' Administration (VA) Department of Defense (DoD) Diabetes clinical practice guidelines based on healthcare delivery model (SMA vs. usual care)? The clinical practice guidelines in this study were treated as dichotomous outcome variables. Attendance in the diabetes SMA versus usual care and the likelihood that the clinical practice guideline was met or not met was analyzed using a chi-square test in SPSS. The chi square test is a nonparametric test used to evaluate nominal level data (Whittemore & Grey, 2006) and is calculated using the crosstabulation command in SPSS. Frequencies were reported based on type of healthcare delivery model attended, and the likelihood that the healthcare provider met the standard of care based on diabetes DoD clinical practice guidelines for the patient.

The third question was: How will moderator variables including number of clinical visits (SMA or usual care) absence or presence of a mental health diagnosis (PTSD, depression, bipolar disorder, anxiety, substance abuse) and participation in other disease self management programs (Renal Diabetes, MOVE! program, Nurse Case manager, PharmD Clinic) modify the relationship of clinical outcome variables in veterans with type 2 diabetes? For analyzing the moderator variables, which were number of SMA or usual care visits, and absence or presence of mental health diagnosis, and

participation in other VA disease self management groups, multiple regression analysis was used. To test for interaction between the moderators and the dependent outcome variables, interaction terms were created in SPSS. There was interaction terms created for each applicable moderator variable. To test the model, the interaction terms were run in a multiple regression analysis utilizing SPSS. If an interaction term met statistical significance, the file was split for that variable, and the multiple regressions were analyzed again to ascertain the amount of influence the moderators had on the dependent outcome variable. The numbers of other disease self-management programs were assessed using frequencies and discovered that for the entire sample, utilization of these programs was not more than 10% for each program per year, so it omitted.

The hypothesis for this study was as follows: For veterans with type 2 diabetes, those who utilize shared medical appointments will have significantly better clinical outcomes and their providers will have higher levels of adherence to accepted VA DoD diabetes clinical practice guidelines compared to veterans who receive usual care. All statistical test as discussed were utilized to answer these research questions and hypothesis to ascertain if statistically significant differences in outcomes were based on model of care delivery.

Dataset Storage

The VA IRB records, master list of subjects, SPSS 20.0 dataset and accompanying documents for this project are the property of the LSCDVAMC Cleveland, OH and will be kept in the GRECC research office computers behind the VA firewall for 6 years in locked offices in the research department. VA research employees

have access to GRECC files at Wade Park, but all research documents are password protected. Passwords are updated every three months to ensure data security. These computer files will be destroyed by secure shredding, and the SPSS file will be erased by the year 2016 per VA research protocols. This research project is currently not funded by any other agency, and no other stipulations have been made on this project in regards to data management.

Conclusion

The combined threat of diabetes and heart disease poses substantial hazard to public health. Novel paradigms to address the deficiencies our current health care system regarding chronic disease management are imperative to start reversing the sobering burden of both conditions. Finding new models of care to enhance delivery, reduce cost, improve quality of care, and increase patient satisfaction are timely in an era where health care expenditure in the United States is the largest percent of the gross domestic product (GDP) of all industrialized nations (Agency for Healthcare Research and Quality, 2002). By tracking clinical and quality outcomes using the VA database warehouse, and CPRS, this study will address how SMA may improve disease management over a 3-year interval, and potentially lead to further longitudinal studies of group care for veterans, as well as other health systems that have utilized this care model. Nurses, physicians and ancillary health care providers are at the vanguard of managing chronic illness, and assessing the utility of a novel care model in veterans with type 2 diabetes will provide knowledge about cardiovascular risk reduction, quality, and feasibility in this cohort.

CHAPTER FOUR

Results

Introduction

This chapter will review the specifics on data analysis, statistical tests, results, and basic conclusions. Because of the observational study design, guidelines and tables were developed by the study team prior to obtaining the sample to ascertain that all abstraction procedures followed accepted protocols.

The dataset was abstracted in June 2012, by the VA Information Technology (IT) department, from the VISN 10 data warehouse, and the CPRS medical records that contains clinical documentation, laboratory data, and medical visit information of the veterans with type 2 diabetes who attend the LSCDVAMC in Cleveland, Ohio for their medical care. After several meetings, a data abstraction template was provided for the VA IT department that included all the demographic variables, health care delivery models (usual care and SMA) clinical outcomes variables, quality outcome variables, medical diagnoses, and moderator variables (number of clinical visits, mental health diagnoses, and additional VA self-management programs).

Five years of data, from January 2006, through December 2010, were mined. This produced 8,145 veteran medical records that included the clinical outcomes (HbA1c, lipid panel, blood pressures) from two separate time periods, approximately six months apart for each year of the study. Data regarding diabetes clinical practice guidelines based on VA Department of Defense (DoD) criteria were abstracted annually, as well as hospital utilization which was annual use of the Emergency room for the SMA and usual

care (UC) cases. Demographic variables of age, race, gender, marital status and medical diagnoses were also included for both groups. The rationale for abstracting 5-years of data was that this was a 3-year retrospective study, and once the subject met enrollment criteria, the following two years of clinical and quality outcome parameters were needed to complete the study. All veteran cases were de-identified by removing names, addresses and social security numbers, and all variables were placed into SPSS 20.0 for analysis.

The Final Sample for analysis: the 988 Dataset

Out of the initial 8,145 eligible veterans, a total of n=371 subjects were identified as the Shared Medical Appointment (SMA) cohort. These were participants who met the criteria of 3 years of SMA attendance over 5-years, with 2 consecutive SMA years. A total of n=617 veterans were in the comparison group; they attended only usual care (UC) visit and no SMAs. A total of 988 cases for analysis adhered to the VA IRB sanctioned number of 1,000 cases approved for this study. Descriptive statistics and frequencies were run on the 988 sample and found that the median age was 68 with a mean age of 70.1 (SD 10.6, range 51-101), and 98% male. Table 3 provides additional sample characteristics for the UC and SMA cohorts.

Table 3

Characteristics by Healthcare Model

	SMA Group n=317		*UC Group* n=617	
Variable	n	%	n	%
Married	185	49.9*	381	61.8
Race (White)	216	65.5*	492	86.2
Alcohol	76	20.5*	50	8.1
Anxiety	108	29.1	146	23.7
Bipolar	11	3	13	2.1
CAD	239	64.4	379	61.4
Depressed	146	39.4*	173	28
HTN	362	97.6	598	96.9
Lipids	331	89.2	534	86.5
PTSD	56	15.1	99	16
Smoker	174	46.9**	239	38.7
Obesity	205	55.3	323	52.4
Substance	145	39.1*	188	30.5

**P<.05 **p<.001*
UC=Usual care
SMA=Shared medical appointment
CAD=coronary artery disease
Marital=marital status
Bipolar=bipolar depression
HTN=hypertension
Lipids=hyperlipidemia
PTSD=post traumatic stress disorder
Substance=substance abuse

Frequencies of other VA self-management programs including MOVE, Renal Diabetes clinic, PharmD and RN case managers were analyzed, and the program attendance was approximately <10% per year, per program. The frequencies of RN case manager program participation revealed that none of the 988 veterans in the sample attended the program over the 3 year study period. Table 4 summarizes the frequency tables as follows.

Table 4

VA Disease Self-Management Programs

		n=988		
Program	Year	Visit #	n	%
MOVE	2008	0	955	96.70%
	2008	1	16	98.30%
MOVE	2009	0	948	96%
	2009	1	10	97%
MOVE	2010	0	947	95.90%
	2010	1	14	97.30%
Renal	2008	0	942	95%
	2008	1	26	98%
Renal	2009	0	932	94%
	2009	1	31	97.50%
Renal	2010	0	923	93.40%
	2010	1	3.8	97.30%
Pharm	2008	0	974	98.60%
	2008	1	13	98.60%
Pharm	2009	0	912	92.80%
	2009	1	28	95.10%
Pharm	2010	0	828	83.80%
	2010	1	100	93.90%
RNCM	2008	0	988	100%
	2009	0	988	100%
	2010	0	988	100%

MOVE=MOVE! Weight loss program
Renal=Renal Diabetes Program
Pharm=PharmD clinic
RNCM=RN case manager

Statistical analyses were run in SPSS 20.0 on the 617 usual care and 371 SMA cases to determine if there were significant differences in the veterans with type 2 diabetes recommended attending the SMA versus usual care (UC). The mean age of the UC cohort was 71.6 years (n=617, SD 9.4) versus 67.6 years in the SMA cohort (n=371, SD 8.9) indicating that the two groups were statistically significant on age (*t* (810.41) =6.65, p=000). Additional analyses revealed statistically significant differences between the groups (SMA vs. UC) on several variables. Table 5 reviews these key differences.

Table 5

Significant differences based on SMA/UC

	SMA group n=317		*UC group* n=617	
Variable	n	%	n	%
Married	185	49.9*	381	61.8
Race(white)	216	65.5*	492	86.2
Alcohol	76	20.5*	50	8.1
Depressed	146	39.4*	173	28
Smoker	174	46.9**	239	38.7
Substance	145	39.1*	188	30.5

**p<.05 **p<.001*

Substance=Substance abuse history

Research Question 1

The first research question was: Are there differences in two types of clinical outcomes: 1) cardiac risk factors (lipid panel, HbA1c, and blood pressures) and 2) healthcare utilization rates (ED visits) based on healthcare delivery model (SMA vs. UC)? To answer this question, a repeated measures ANOVA (RM-ANOVA) was used to evaluate differences in both cohorts over time. The years of analysis were 2008-2010 with 2008 data considered as time one, 2009 data as time two, and 2010 as time three. The variables of interest were the clinical outcomes of HbA1c, LDL, HDL, triglyceride and total cholesterol, systolic and diastolic blood pressure, and Emergency Department visits (ED visits).

The first clinical outcome variable analyzed in the RM-ANOVA was the HbA1c levels between the SMA and UC group over the 2008-2010 study period. A total n=617 were analyzed in the usual care and n=350 were in the SMA group. Table 6 reviews the descriptive statistics for this variable. Prior to running this analysis, descriptive statistics and frequencies were run on all outcome variables to determine if the variables were approximately normally distributed in this large sample size. A few outliers were noted on the histogram produced for triglycerides and LDL cholesterol on the SPSS output for the lipid panel, so the outliers were deleted and the frequencies were run again. There were few differences between the distributions after removal of the outliers for triglyceride and LDL, so it was left in. An alpha level of .05 (two-tailed) was set for the overall significance levels for all tests.

Table 6

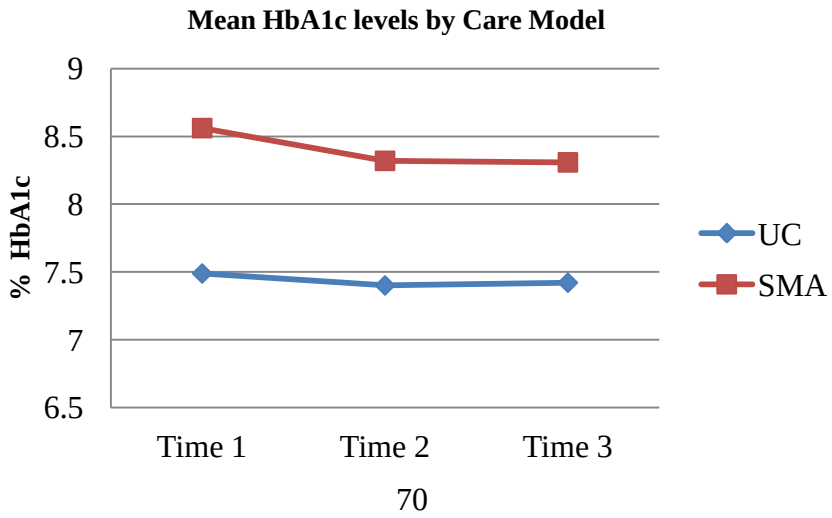
Descriptive Statistics HbA1c

		SMA group n=350		*Usual Care* n=617	
Time	Year	M	SD	M	SD
T1	2008	8.56	1.74	7.48	1.28
T2	2009	8.32	1.65	7.4	1.22
T3	2010	8.3	1.58	7.42	1.16

T=Time

The Mauchley's W test was significant and the Greenhouse-Geisser >.75 (.985) meaning we did not meet the assumption of sphericity. Huynh-Feldt correction was used to report results for HbA1c means between the SMA and UC cohorts. Although the downward slope was greater in the SMA cohort, the within-subjects analysis F(1.977, 1907.5) =2.648 p=.072 did not meet statistical significance for HbA1c. Figure 3 displays these findings.

Figure 3



The next clinical outcome of interest was the LDL-cholesterol. The LDL-cholesterol values were placed in the RM-ANOVA for 2008-2010 years for the UC and SMA cases. Table 7 reviews the descriptive statistics on this variable.

Table 7

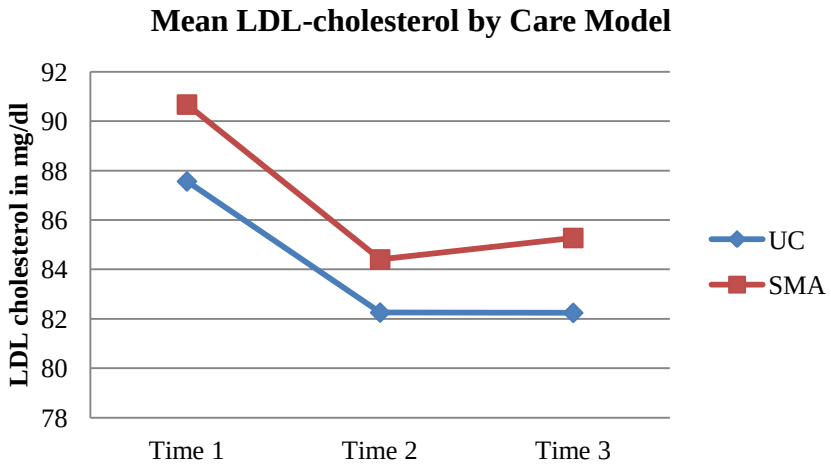
Descriptive Statistics LDL cholesterol

		SMA group n=311		*Usual Care* n=578	
Time	Year	M	SD	M	SD
T1	2008	90.6	33.1	87.5	26.5
T2	2009	84.4	31.4	82.2	24.6
T3	2010	85.2	31.4	82.2	25.3

T=Time

The Mauchley's W test was significant and the Greenhouse-Geisser >.75 (.987) so the Huynh-Feldt correction was used to report results. The tests of within-subjects effect F (1.981, 757.1) =.153, p=.85, did not meet statistical significance. Figure 4 reviews these findings.

Figure 4



HDL-cholesterol levels were then analyzed. The HDL-cholesterol values were placed in the repeated measures ANOVA for 2008-2010 years. A total n=594 were in the usual care and n=326 were analyzed in the SMA group. Table 8 reveals the means and standard deviations for these subjects.

Table 8

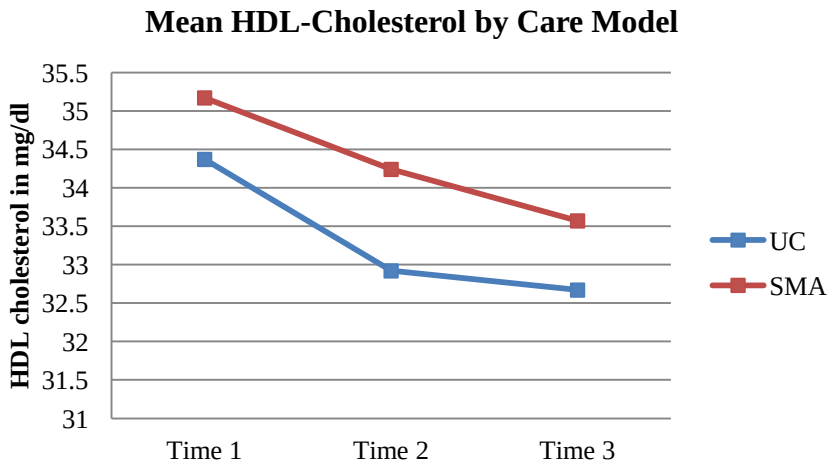
Descriptive Statistics HDL cholesterol

		SMA group n=326		Usual Care n=594	
Time	Year	M	SD	M	SD
T1	2008	35.1	11.2	34.3	9.7
T2	2009	34.2	12.1	32.9	9.9
T3	2010	33.5	11	32.6	10.4

T=Time

The Mauchley's W test was significant and the Greenhouse-Geisser was >.75 (.80) so the Huynh-Feldt correction was used to report results. The tests of within-subjects effect F(1.603, 1,757.18) =.832, p=.412 did not meet statistical significance. Figure 5 reveals the values over the three time points.

Figure 5



The total cholesterol values were placed in the repeated measures ANOVA for 2008-2010 years. A total n=595 cases were analyzed in the usual care (M=152.98, SD 36.41) and n=326 in the SMA group (M=158.05, SD 40.90). Table 9 reviews the descriptive statistics for this variable.

Table 9

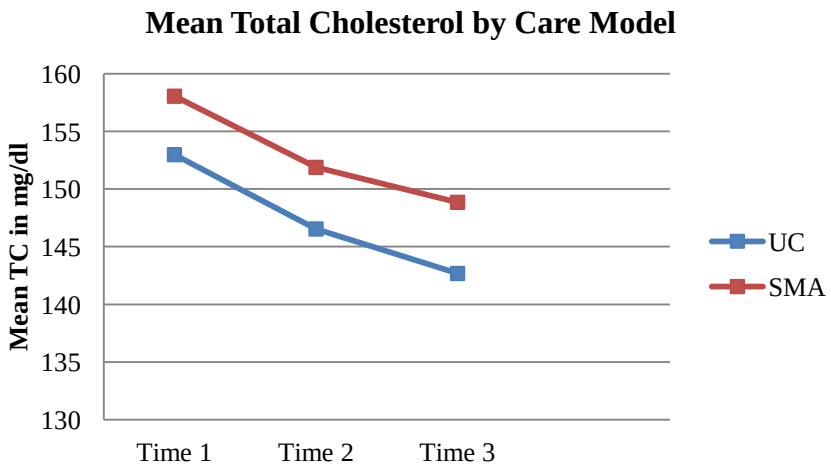
Descriptive Statistics Total Cholesterol

		SMA group n=326		*Usual Care* n=595	
Time	Year	M	SD	M	SD
T1	2008	158.05	40.9	152.9	36.4
T2	2009	151.88	40.5	146.5	34.8
T3	2010	148.8	38.01	142.6	34

T=Time

The Mauchley's W test was not significant (p=.539) so this test met the assumption of sphericity. The sphericity assumed row of the ANOVA was used to report results. The tests of within-subjects effect F(2, 1838) =.111 p=.895 did not meet statistical significance. Figure 6 below reviews these data.

Figure 6



The last value to analyze in the lipid panel was the triglyceride levels for the UC and SMA subjects. Triglyceride values were placed in the repeated measures ANOVA for 2008-2010 years. A total n=594 were in the usual care (M=177.97, SD 130.96) and n=326 (M=194.77, SD 163.27) were analyzed in the SMA group. Table 10 reviews the descriptive statistics for this variable.

Table 10

Descriptive Statistics Triglycerides

		SMA group n= 326		*Usual Care* n=594	
Time	Year	M	SD	M	SD
T1	2008	194.7	163.2	177.9	130.9
T2	2009	171.7	148.5	165.7	170.1
T3	2010	155.1	89.2	150.43	102.1

T=Time

The Mauchley's W test was significant and the Greenhouse-Geisser >.75 (.984) so the Huynh-Feldt correction was used to report results. The tests of within-subjects effect F(1.973, 1811.58) =1.03, p=.354 did not meet statistical significance. Figure 7 reviews the means of the triglyceride values. The RM-ANOVA table 11 below summarizes the between subjects and within subjects effects for variables HbA1c, and lipid panel.

Figure 7

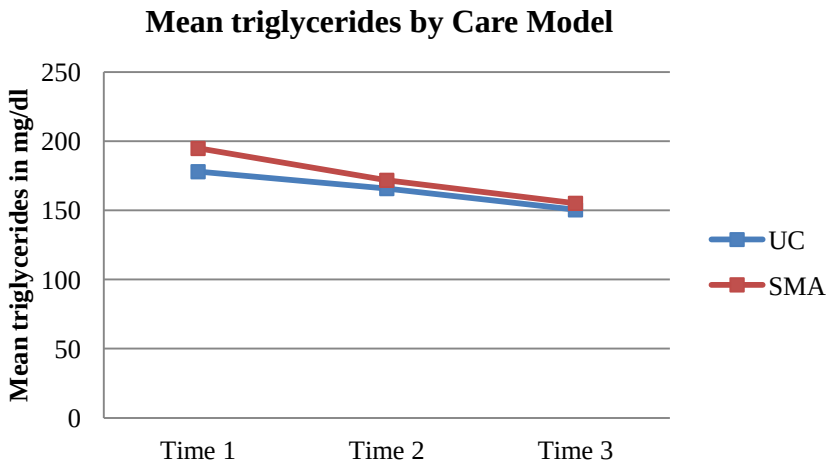

Mean triglycerides by Care Model
Mean triglycerides in mg/dl
250
200
150
100
50
0
Time 1
Time 2
Time 3
UC
SMA

Table 11

RM-ANOVA of Clinical Outcome Variables based on SMA or UC visit

Variable	Source of Variance		SS	df	MS	F	p
HbA1c	*Between-subjects*	UCSMA	616.9	1.0	616.9	146.5	0.00
		Error	40.6	965.0	4.2		
	Within-subjects	Time	15.7	2.0	8.0	9.5	0.00
		TxUCSMA		2.0	2.2	2.6	0.07
		Error	1,597.0	1,907.5	0.8		
LDL	*Between-subjects*	UCSMA	4,620.7	1.0	4,620.7	2.7	0.10
		Error	1,494,110.0	987.0	1,684.5		
	Within-subjects	Time	16,838.7	2.0	8,499.9	25.6	0.00
		TxUCSMA	113.2	2.0	57.1	0.2	0.84
		Error	583,590.0	1,757.1	332.1		
HDL	*Between-subjects*	UCSMA	638.8	1.0	638.8	2.2	0.14
		Error	262,728.0	918.0	286.1		
	Within-subjects	Time	1,226.4	2.0	620.6	24.5	0.00
		TxUCSMA	31.6	2.0	16.0	0.6	0.53
		Error	45,929.0	1,814.0	25.3		
Total Chol	*Between-subjects*	UCSMA	19,203.0	1.0	19,203.0	6.6	0.01
		Error	2,677,580.0	919.0	2,913.6		
	Within-subjects	Time	41,352.0	2.0	20,676.0	36.1	0.00
		TxUCSMA	127.5	2.0	63.7	0.1	0.90
		Error	1,052,638.0	1,838.0	572.7		
Trigs	*Between-subjects*	UCSMA	53,104.0	1.0	53,104.0	1.4	0.24
		Error	3,456,806.0	918.0	37,610.0		
	Within-subjects	Time	474,794.0	1.9	245,340.0	25.0	0.00
		TxUCSMA	18,575.0	1.9	9,598.0	1.0	0.37
		Error	17,431,731.0	1,776.0	9,812.1		

UCSMA=Mode of care delivery Usual or SMA
TxUCSMA=Time x visit type

Systolic blood pressures during our study years 2008-2010 for the SMA and UC cases were analyzed in a RM-ANOVA. A total of n=617 were evaluated in the usual care (M=127.53, SD 14.81) and n=371 (M=130.77, SD 18.27) for the SMA cohort. Table 12 reviews the descriptive statistics for this variable.

Table 12

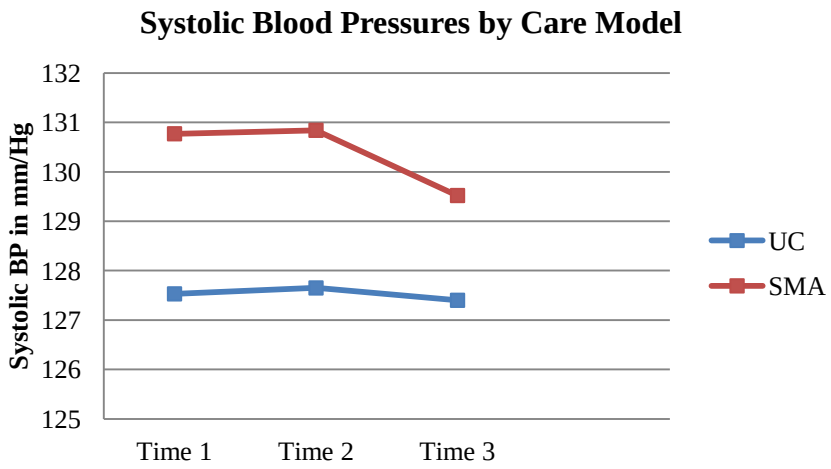
Descriptive Statistics Systolic Blood Pressure

		SMA group n=371		*Usual Care* n=617	
Time	Year	M	SD	M	SD
T1	2008	130.77	18.27	127.5	14.8
T2	2009	130.8	19.26	127.6	13.8
T3	2010	129.5	18.12	127.4	14.6

T=Time

The Mauchley's W test was not significant at p=.439 which means that the assumption of sphericity was met. The tests of within-subjects effect F (2.0, 1,972) =.532, p=.588 for systolic blood pressure did not meet statistical significance over three time periods, or within groups as shown in Figure 8.

Figure 8



Diastolic blood pressures during our study years 2008-2010 for the two study groups were analyzed. A total of n=617 were evaluated in the usual care (M=71.49, SD, 9.554) and n=371 (M=71.66, SD 11.27) for the SMA cohort. Table 13 reviews the descriptive statistics for this variable

Table 13

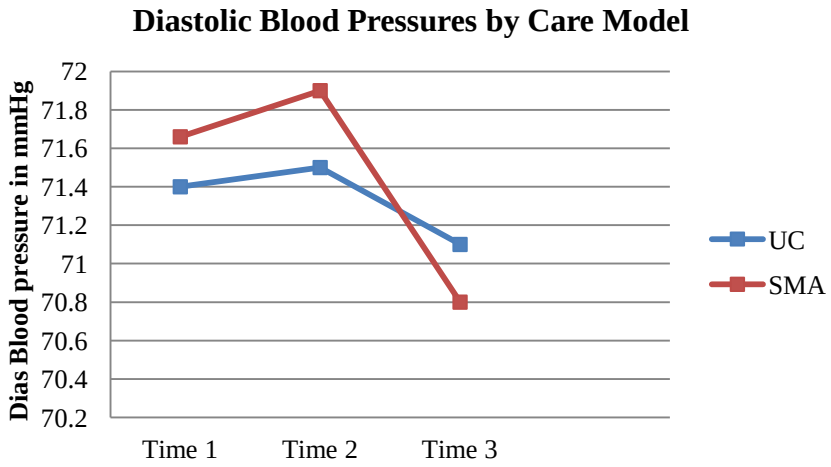
Descriptive Statistics Diastolic Blood Pressure

		SMA group n=371		*Usual Care* n=371	
Time	Year	M	SD	M	SD
T1	2008	71.66	11.2	71.4	9.55
T2	2009	71.9	12.1	71.5	8.95
T3	2010	70.8	11.2	71.1	8.99

T=Time

The Mauchley's W test was not significant p=.447 which means that the assumption of sphericity was met. The tests of within-subjects effect F(2.0,1,972) =.405, p=.667 did not meet statistical significance over three time periods. Figure 9 reviews the mean diastolic blood pressure between the SMA and UC cohorts over 3 time periods.

Figure 9



The last clinical outcome measured was Emergency department (ED) visits of the subjects in usual care and SMA over the 2008-2010 study periods. Descriptive statistics revealed that the mean ED visit number for UC at baseline (M=.51, SD 2.702, n=617) and SMA cohort (M=1.09, SD 1.905, n=317). Table 14 reveals the descriptive statistics for this variable.

Table 14

Descriptive Statistics ED visits

		SMA group n=371		*Usual Care* n=617	
Time	Year	M	SD	M	SD
T1	2008	1.09	1.9	0.51	2.7
T2	2009	1.15	2	0.41	1.02
T3	2010	1.18	2.21	0.45	1.02

T=Time

The Mauchley's W test was significant p=.000 which means that the assumption of sphericity was not met. The Greenhouse- Geisser was >.75 (.80) so the Huynh-Feldt correction was again used to report results. The tests of within-subjects effect showed F (1.603, 1580.48) =.832 p=.412. There was not a reduction in ED utilization in SMA group over the UC subjects, and mean ED visits were higher in the SMA cohort as reviewed in figure 10. Table 15 summarizes the findings of the RM-ANOVA for the clinical outcome variables of blood pressure and ED visits listed below.

Figure 10

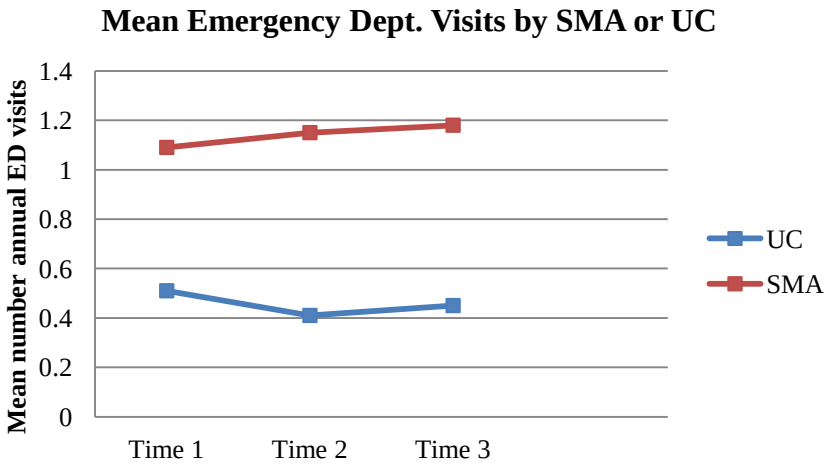


Table 15

RM-ANOVA of Clinical Variables based on SMA or UC visit

Variable	Source of Variance		SS	df	MS	F	p
BP sys	*Between-subjects*	UCSMA	5,630.0	1.0	5,630.0	12.9	0.00
		Error	439,015.0	986.0	434.1		
	Within-subjects	Time	344.8	2.0	172.4	1.0	0.37
		TxUCSMA	183.0	2.0	91.7	0.5	0.59
		Error	340,220.0	1,972.0	172.5		
BP dias	Between-subjects	UCSMA	5.5	1.0	5.5	0.0	0.86
		Error	181,235.0	986.0	183.8		
	Within-subjects	Time	304.0	2.0	25.2	0.4	0.67
		TxUCSMA	50.6	2.0	25.2	0.4	0.67
		Error	123,100.0	1,972.0	62.4		
ED visit	*Between-subjects*	UCSMA	327.4	1.0	327.4	55.2	0.00
		Error	5,844.2	986.0	5.9		
	Within-subjects	Time	0.7	1.6	0.4	0.2	0.81
		TxUCSMA	3.9	1.6	2.4	0.8	0.41
		Error	4,610.0	1,580.4	2.9		

UCSMA=Mode of care delivery
TxUCSMA=Time x visit type
BP sys=Systolic BP
BP dias=Diastolic BP
ED=Emergency dept visit

Research Question 2

Research question 2 asked, are there differences in health care provider adherence rates to Veterans' Administration (VA) Department of Defense (DoD) Diabetes clinical practice guidelines based on healthcare delivery model (SMA vs. UC)? In order to answer this question, chi-square analyses (X^2) were calculated on all quality outcome measures derived from accepted VA DoD clinical practice guidelines. The adherence rate for Pneumonia vaccine in the LSCDVAMC was at 100% for the whole sample of veterans over 3 years so it was not included in the analysis. The influenza vaccine was omitted from the study, because of the availability of influenza vaccine at drugstores, community centers, and outside VA facilities could make this variable inaccurate for the analysis in this study.

The first clinical guideline analyzed was testing for urine microalbumin. This is an important clinical practice guideline to assess for kidney functioning in patients with type 2 diabetes at risk for proteinuria and diabetic nephropathy. Because this clinical practice guideline was placed in the dataset as an actual laboratory value, the variable was transformed to a dichotomous yes/no variable if the value was recorded for the first or second half of the year in 2008-2010, and was placed in a X^2 analysis. There were no statistically significant differences in provider adherence to this guideline between SMA and UC cases over the study period 2008-2010. Average annual provider adherence rates were 58.5% in UC versus 56.2% in SMA in 2008, 54.9% in UC versus 55.4% in SMA in 2009, and 55.2% in UC versus 49.5% in the SMA participants. The chi-square values

comparing provider adherence to testing microalbumin in SMA and UC cases are listed in the table 16 below. The Veterans Administration (VA) healthcare system may be using other surrogate markers for kidney functioning such as albumin/creatinine ratios or estimated glomerular filtration rates that were not abstracted or analyzed for the purposes of this study.

Table 16

Microalbumin tests

SMA n=371 UC n=617

	Group	Year	n	%	X^2	df	p
2008	SMA	1st half	211	56.9	1.85	1	0.17
	SMA	2nd half	206	55.5	0.005	1	0.94
	UC	1st half	378	61.3	1.85	1	0.17
	UC	2nd half	344	55.8	0.005	1	0.94
2009	SMA	1st half	216	58.2	0.73	1	0.39
	SMA	2nd half	195	52.6	0.33	1	0.56
	UC	1st half	342	55.4	0.73	1	0.39
	UC	2nd half	336	54.5	0.33	1	0.56
2010	SMA	1st half	193	52	3.02	1	0.08
	SMA	2nd half	177	47.7	2.28	1	0.13
	UC	1st half	356	57.7	3.02	1	0.08
	UC	2nd half	325	52.7	2.28	1	0.13

SMA=Shared medical appointment
UC=Usual care
1st half=First half of the year
2nd half=Second half of the year

The next statistical analyses were run on health care provider adherence to prescribing angiotension converting enzyme inhibitors/angiotension receptor blocker (ACE/ARB) medication in the SMA and usual care cohorts. Rates of healthcare provider

prescribing of ACE/ARB medications were not different between the SMA and usual care cohorts in 2008, but values did meet statistical significance in 2009, X^2(1, n=988)=6.57, p=.010, and 2010 X^2(1, n=988)=4.44, p=.035 . Table 17 below reviews these salient findings.

Table 17

ACE/ARB Prescribing by Group Model

SMA n=371 UC n=617 N=988

	Group	n	%	X^2	df	p
2008	SMA	237	63.9	2.96	1	0.08
	UC	360	58.3			
2009	SMA	230	62	6.57	1	0.01
	UC	331	53.6			
2010	SMA	218	58.8	4.44	1	0.03
	UC	320	51.9			

**p=<.05*
SMA=Shared medical appointment
UC=Usual care

The provider adherence to prescribing statin medication to control lipid levels in the diabetic was not significantly different based on group: SMA or usual care. The results over the study period were X^2(1, n=988)=3.26, p=.071 in 2008, X^2(1, n=988)=.119, p=.73 in 2009, and X^2(1, n=988)=.87, p=.76 are reviewed on table 18.

Table 18

Provider Adherence to Statin Use

SMA n=371 UC n=617 N=988

	Group	n	%	X^2	df	p
2008	SMA	290	78.2	3.3	1	0.07
	UC	511	82.8			
2009	SMA	311	83.8	0.1	1	0.73
	UC	512	83			
2010	SMA	307	82.7	0.9	1	0.76
	UC	506	82			

SMA=Shared medical appointment
UC=Usual care

Provider adherence to prescribing aspirin met statistical significance for SMA participants in 2008 X^2(1, n=988)=19.7, p=000, in 2009 X^2(1, n=988)=40.5 p=000), and 2010 X^2(1, n=988)=32.0, p=000 respectively and is summarized on table 19.

Table 19

Provider Adherence to Aspirin RX

SMA n=371 UC=617

	Group	n	%	X^2	df	p
2008	SMA	229	61.7	19.7	1	*
	UC	291	47.2			
2009	SMA	247	66.6	40.5	1	*
	UC	282	45.7			
2010	SMA	239	64.4	32	1	*
	UC	283	45.9			

**p=<.001*
SMA=Shared medical appointment
UC=Usual care

Besides treating lipid level with statins in patients with type 2 diabetes, measuring a fasting lipid panel bi-annually is an important quality measure in this patient population. Actual LDL cholesterol values were transformed into dichotomous variables (0=absent, 1=present) in the dataset and were analyzed in a Pearson X^2 to ascertain the percentage of subjects that had bi-annual LDL cholesterol values drawn. SMA and UC subjects were analyzed from 2008-2010 and revealed that for 6 time points, the UC providers had a higher percentage of subjects that had lipid panels drawn over the SMA care providers. Table 20 outlines these findings.

Table 20

Provider Adherence to obtaining biannual Lipids (LDL)

SMA n=371 UC =617

	Group	Year	n	%	X^2	df	p
2008	SMA	1st half	230	62	10.2	1	
	SMA	2nd half	289	77.9	12.4	1	
	UC	1st half	443	71.8	10.2	1	*
	UC	2nd half	534	86.5	12.4	1	*
2009	SMA	1st half	286	77.1	10	1	
	SMA	2nd half	260	70.1	24.5	1	
	UC	1st half	525	85.1	10	1	*
	UC	2nd half	515	83.5	24.5	1	*
2010	SMA	1st half	279	75.2	18.4	1	
	SMA	2nd half	251	67.7	41.7	1	
	UC	1st half	531	86.1	18.4	1	*
	UC	2nd half	525	85.1	41.7	1	*

**p<.001*

SMA=Shared medical appointment

UC=Usual care

1st half=First half of the year

2nd half=Second half of the year

Similar findings were noted for having bi-annual HbA1c levels drawn. SMA and UC subjects were analyzed from 2008-2010 and revealed that for 6 time points, the UC providers had a 100% of subjects that obtained a bi-annual HbA1c measurements. SMA providers did not have 100% adherence. Table 21 reviews these data.

Table 21

Provider Adherence to obtaining bi-annual HbA1c

SMA n=371 UC n=617

	Group	Year	n	%	X^2	df	p
2008	SMA	1st half	308	83.0	111.9	1	
	SMA	2nd half	337	90.8	58.5	1	
	UC	1st half	617	100.0	111.9	1	*
	UC	2nd half	617	100.0	58.5	1	*
2009	SMA	1st half	335	90.3	62.1	1	
	SMA	2nd half	330	88.9	71.1	1	
	UC	1st half	617	100.0	62.1	1	*
	UC	2nd half	617	100.0	71.1	1	*
2010	SMA	1st half	338	91.1	56.7	1	
	SMA	2nd half	314	84.6	100.5	1	
	UC	1st half	617	100.0	56.7	1	*
	UC	2nd half	617	100.0	100.5	1	*

**p<.001*
SMA=Shared medical appointment
UC=Usual care
1st half=First half of the year
2nd half=Second half of the year

Annual Podiatric exams are an important clinical practice guideline to ensure quality of care for persons with diabetes at substantial risk of amputation of the lower extremities due to diabetic neuropathy and infection. Statistically significant adherence

to this clinical practice guidelines were noted in the SMA providers over UC providers over the three year study period. Table 22 summarizes these findings.

Table 22

Provider Adherence to ordering Annual Podiatry Exams

SMA n=371 UC n=617

Group	n	%	X^2	df	p
SMA	245	66	21.1	1	*
UC	315	51.1			
SMA	257	69.3	26.8	1	*
UC	324	52.5			
SMA	264	71.2	29.6	1	*
UC	331	53.6			

**p< .001*

Annual Ophthalmology exams were another clinical practice guidelines that also met statistical significance for the SMA cohort over UC in the Chi-square analysis. The table 23 below summarizes these findings.

Table 23

Provider Adherence to ordering Annual Opthalmology Exam

SMA n=371 UC n=617

Group	n	%	X^2	df	p
SMA	245	66	21.1	1	*
UC	315	51.1		1	
SMA	257	69.3	26.8	1	*
UC	324	52.5		1	
SMA	264	71.2	29.6	1	*
UC	331	53.6		1	

**p<.001*

Research Question 3

How will moderator variables including number of clinical visits (SMA or usual care) absence or presence of a mental health diagnosis (PTSD, depression, bipolar disorder, anxiety, substance abuse) and participation in other disease self management programs (Renal Diabetes, MOVE program, Nurse Case manager, PharmD Clinic) modify the relationship of clinical outcome variables in veterans with type 2 diabetes?

To answer this research question, we ran multiple regression analyses using the clinical parameters of HbA1c, LDL cholesterol, systolic blood pressure, and ED visits as dependent outcome variables. Multiple regressions are often used to evaluate how multiple independent predictor variables influence the dependent outcome variable. This question sought to answer if dose effect of the SMA or usual care (UC) visit, presence of a mental health diagnosis, or participation in other disease-self management programs influenced the clinical outcome variables. If the initial regression model showed high correlation with the predictor variables on the outcome, interaction terms could be formulated and placed back into the regression model for analysis.

Initially, descriptive statistics and frequencies were run on all regression variables to ascertain the prevalence of mental health in our sample, frequency of visit attendance (SMA or UC), and the utilization of other VA disease self- management programs. Running initial statistics help determine if any assumptions of regression had been violated. The three primary assumptions of multiple regression are that the variables have adequate variance, that there is an absence of influential cases, and linearity (Field, 2005). By evaluating means and standard deviations, checking for skewness and kurtosis,

and assessing for outliers, these assumptions were met. Secondary assumptions of regression include having constant error variance, and normally distributed error variance (Field, 2005). These are evaluated by using scatterplots from the studentized deleted residuals found on the SPSS output, and applying a line of best fit for loess, cubic or quadratic functions onto the graph to assess spread of residuals around the line.

Mental health diagnoses queried from our 988 dataset revealed that 15.7% had PTSD, 25.7% had anxiety, 32.3 % were depressed, 2.4% were bipolar, 34% had a substance abuse history, and 12.8% had a diagnosis of alcohol abuse. Based on frequencies, the attendance in other disease self-management programs, the utilization by our subjects showed < 10% in the Renal Diabetes, MOVE! program, and PharmD clinics per program per year from 2008-2010. The nurse case manager program was not attended at all over the 3 years, so all of the VA disease self-management programs were removed from the regression analysis.

The first clinical outcome run in the regression model was HbA1c in 2010. The first regression sought to answer if the mental health and other medical diagnoses could predict HbA1c level in the subject with type 2 diabetes. All mental health diagnoses and comorbid medical diagnoses such as CAD, hyperlipidemia, hypertension were added to the model. Age, race and marital status of the subject as well as SMA/UC visits were also added. The regression model summary showed a correlation R=.346 and R^2=.12, which was significant at p=.000. After reviewing the unstandardized, and standardized betas, a diagnosis of hyperlipidemia (β=.061, p<.05), age (β=.12, p=.001) and attendance

in UC/SMA visits (β=.28,p <.001) predicted HbA1c in this model. Table 24 reviews these findings.

Table 24

Regression Model: predictors of HbA1c 2010

n=980

Variables	B	SE	β	t	p
(constant)	8.391	0.461		18.29	0
Alcohol	-0.214	0.151	-0.051	-1.414	0.158
Anxiety	0.058	0.11	0.018	0.53	0.596
Bipolar	-0.327	0.279	-0.036	-1.171	0.242
CAD	0.084	0.089	0.029	0.946	0.344
Depressed	-0.005	0.105	-0.002	-0.045	0.964
HTN	-0.005	0.256	-0.001	-0.018	0.986
Lipids	0.258	0.129	0.061	2.002	0.046
PTSD	0.173	0.126	0.045	1.378	0.169
Substance	0.098	0.103	0.033	0.947	0.344
Age	-0.018	0.005	-0.12	-3.48	0.001
UCSMA	0.831	0.091	0.287	9.171	0

**=p=000.*
HTN=Hypertension
Lipids=Hyperlipidemia
UCSMA=Is flag for either UC or SMA veteran
PTSD=Post traumatic stress disorder

The next multiple regression was run using the dependent outcome variable of LDL cholesterol in 2010. The model summary for the regression revealed an R=.176, R^2 = .031 and adjusted R^2= .019 p=.004 which showed that very few predictors were able to explain the variance in this model. Reviewing the coefficients and unstandardized and standardized beta, age, visit type, mental health diagnosis, and race were not significant. Predictably, the variables diagnosis of CAD (β=-.07, p=.036) and diagnosis of hyperlipidemia (β=.08, p=.01) were significant to predict LDL-cholesterol. Table 25 shows the regression results.

Table 25

Regression Model: predictors of LDL cholesterol 2010

n=877

Variable	B	SE	β	t	p
(constant)	90.4	9.2		9.8	0.00
Alcohol	4.4	3.3	0.1	1.3	0.18
Anxiety	-0.4	2.4	0.0	-0.2	0.86
CAD	-4.1	1.9	-0.1	-2.1	0.04
Depressed	-1.0	2.3	0.0	-0.4	0.67
Lipids	7.3	2.9	0.1	2.5	0.01
PTSD	2.3	2.7	0.0	0.9	0.39
Substance	2.5	2.2	0.0	1.1	0.27
Age	-0.2	0.1	-0.1	-1.8	0.08
UCSMA	1.3	2.0	0.0	0.6	0.53
Marital	-0.1	0.6	0.0	-0.1	0.93
Race	2.2	2.4	0.0	0.8	0.37

**=p=000.*
UCSMA=Is flag for either UC or SMA veteran
HTN=Hypertension
Lipids=Hyperlipidemia
PTSD=Post traumatic stress disorder

We ran the next multiple regression on the dependent variable systolic blood pressure in outcome year 2010. The model summary for the regression showed that R=.197, and R^2= .027 p=000. Reviewing the coefficients and unstandardized and standardized beta, none of the predictor variables of mental health diagnoses, age, medical visit type, or marital status were significant. However, the only predictor that did influence this model was race, which was highly significant (β=-.180, p=000). Hypertension disproportionally affects African Americans and our sample had almost 30% of the subjects were reported as Black/African American. Table 26 reviews these data.

Table 26

Regression Model: predictors of Systolic Blood pressures 2010

n=901

Variable	B	SE	β	t	p
(constant)	131.5	5.2		25.3	0.00
Alcohol	0.6	1.8	0.0	0.3	0.74
Anxiety	1.9	1.4	0.1	1.4	0.17
CAD	-1.1	1.1	0.0	-1.0	0.31
Depressed	0.5	1.3	0.0	0.4	0.73
Lipids	2.2	1.6	0.0	1.3	0.21
PTSD	0.7	1.5	0.0	0.5	0.64
Substance	-1.3	1.3	0.0	-1.0	0.32
Age	0.0	0.1	0.0	0.2	0.84
UCSMA	-0.2	1.2	0.0	-0.2	0.86
Marital	-0.2	0.3	0.0	-0.5	0.61
Race	-7.0	1.4	-0.2	-5.9	0.00

**=p=000.*
UCSMA=Is flag for either UC or SMA veteran
HTN=Hypertension
Lipids=Hyperlipidemia
PTSD=Post traumatic stress disorder

Multiple regression analysis was run with the dependent outcome ED visits in 2010 to assess if mental health could predict use of the Emergency room in 2010. The regression model summary showed a correlation R=.34 and an R^2=.121, which was significant at p=000. After reviewing the unstandardized, and standardized betas, the only mental health diagnoses met statistical significance was depression (β=.08, p<.05). Other variables that met significance in predicting ED visits in 2010 was race (β= -.183, p<.001), UC or SMA visits (β=.153, p<.001), substance abuse (β=.08, p<.05), and history of coronary artery disease (β=.09, p=.004). Table 27 reviews the results of this regression.

Table 27

Regression Model: predictors of ED visits in 2010

n=901

Variable	B	SE	β	t	p
(constant)	0.962	0.52		1.852	0.064
Alcohol	0	0.185	0	-0.003	0.998
Anxiety	-0.016	0.135	-0.004	-0.117	0.907
CAD	0.318	0.11	0.092	2.884	0.004
Depressed	0.286	0.13	0.081	2.207	0.028
Lipids	0.186	0.161	0.037	1.157	0.248
PTSD	-0.121	0.154	-0.027	-0.791	0.429
Substance	0.294	0.128	0.084	2.297	0.022
Age	0.006	0.007	-0.036	-0.961	0.337
UCSMA	0.528	0.115	0.153	4.583	0
Marital	0.035	0.033	0.034	1.057	0.291
Race	-0.742	0.137	-0.183	-5.407	0

**=p=000.*
HTN=Hypertension
Lipids=Hyperlipidemia
UCSMA=Is flag for either UC or SMA veteran
PTSD=Post traumatic stress disorder

Significant differences were found in health care utilization when frequencies were run on total number of health care visits based on UC and SMA. The usual care group mean visits/3years (M=18.62, SD 13.53, p=.000) vs. SMA participants visits/3 years (M=27.97, SD 14.00, p=.000) was statistically significant. The mean age of the SMA veterans was younger (M=67.77, SD=8.91, p=.000) than the usual care (M=71.64, SD 9.377, p=.000).

Our last regression used total ED visits over three years from 2008-2010 as our dependent outcome variable. The model summary for the regression showed that *R*=.419, and R^2= .176, F(14,886)=13.47, p=000 which showed that some of the predictor variables influenced this model, and approximately 18% of the variance was explained. Reviewing the coefficients and unstandardized and standardized beta, 6 variables met significance in the model. SMA or UC visit type (β=-.123, , p=000), Race (β=-.181, p=000), diagnosis of coronary artery disease (β=.102, p=001), substance use history (β=-.102, p=.038), smoking (β=.191, p=000), and total UC and SMA visits (β=.100, p=003). Use of SMA care model did not reduce the use of ED visits, and contained a cohort of vulnerable veterans that appeared to be high consumers of healthcare resources. Table 28 reveals these findings.

Table 28

Regression of ED utilization over 3-years

n=901

Variables	B	SE	β	t	p
(constant)	3.36			2.403	0.016
TotalUC/SMA	0.031	0.01	0.1	2.972	0.003
Obesity	0.077	0.281	-0.009	-0.275	0.783
Smoker	1.732	0.419	0.191	4.131	*
Substance	-0.961	0.463	-0.102	-2.077	0.038
Age	-0.03	0.017	-0.063	-1.768	0.077
Depressed	0.648	0.342	0.068	1.895	0.058
Anxiety	-0.035	0.355	-0.003	-1	0.921
PTSD	0.036	0.405	0.003	0.088	0.93
CAD	0.951	0.29	0.102	3.284	0.001
Lipids	0.487	0.422	0.036	1.155	0.248
Married	-0.395	-0.395	-0.044	-1.329	0.184
Race	-1.984	-1.98	-0.181	-5.424	*
Alcohol	0.262	0.262	0.02	0.535	0.593
UCSMA	1.148	0.312	0.123	3.676.	*

**=p=000.*

TotalUC/SMA=Total SMA or UC visits over 3 years

UCSMA=Is flag for either UC or SMA veteran

Interaction terms

To answer the research question, the multiple regressions were reviewed to assess if certain variables including mental health and number of health visits would be appropriate to create interaction terms to test for moderation. An interaction effect refers to the combined effect of two or more predictor variables on a dependent outcome variable (Field, 2005). Three interaction terms were created from the variable medical visit type (UCSMA). The variables depression, substance abuse and total combined UC or SMA visits were combined to create three new variables named UCSMAxdepressed, UCSMAxsubstanceabuse and UCSMAxtotalUCSMA. The dependent outcome variables for the regression included ED visits in 2010 and total ED visits over 3 years. The regressions were re-run with these interaction terms and found that none of them were significant predictors of total ED visits over 3 years. However, reviewing the unstandardized betas for the regressions, the only interaction term UCSMAxsubstanceabuse was a significant predictor of ED visits in 2010 ($p<.023$). Table 29 reviewed this interaction term.

Table 29

Regression Model: interaction predictors of ED visits in 2010

Variables	B	SE	β	t	p
(constant)	0.06	0.53		1.08	0.27
UCSMAxdepressed	0.16	0.23	0.03	0.69	0.49
UCSMAxsubstanceab	0.53	0.23	0.11	2.29	0.02

Hypothesis

The hypothesis for this study was as follows: For veterans with type 2 diabetes, those who utilize shared medical appointments will have significantly better clinical outcomes and their providers will have higher levels of adherence to accepted VA DoD diabetes clinical practice guidelines compared to veterans who receive usual care. The clinical outcomes variables of HbA1c, lipid levels, and blood pressures did not show statistically significant differences or improvement based on healthcare delivery model (SMA vs. usual care) in this observational case study. However, some of the DoD clinical practice guidelines did meet statistical significance in that veterans with type 2 diabetes who utilized SMAs who were more likely to have aspirin prescribed, ACE/ARB prescribed, and annual Ophthalmology and Podiatry exams. . The multiple regressions run on the outcomes of HbA1c, LDL-cholesterol, systolic blood pressure and ED visits, did provide some interesting information on how the covariates of mental health and medical diagnoses could partially predict clinical outcomes. For example, substance abuse history, diagnosis of CAD, medical visit type, depression, and race, all predicted use of the Emergency room.

One of the most revealing findings was that healthcare utilization based on overall health visits was higher in the SMA veterans than in UC over 3-years (usual care M=18.62, SD 13.53, vs. SMA M=27.97, SD 14.00) $t(758.8)=-10.2$, p=.000). Perhaps this is related to the fact that the cohort in the SMA group had clinical parameters of HbA1c, blood pressure and LDL that were higher than UC at baseline and were at an increased

risk of morbidity and mortality. They also were more likely to be single, minority, depressed, smokers, and have a substance abuse history. These veterans were recommended for the SMA group by their VA care providers because their glycemic control and other parameters such lipid and blood pressures were not yet optimized. However, based on the SMA cohort's high utilization of healthcare resources, additional interventions would need to be developed to mitigate hospital utilization.

Conclusion

The clinical outcomes measures of HbA1c, lipid panel and blood pressures did not meet statistical significance annually in the repeated measures (RM-ANOVA) over 3-time points in 2008-2010. Some of the DoD diabetes clinical practice guidelines in this study including prescribing ACE/ARB, aspirin, and podiatry and ophthalmology exams annually met significance in Pearson X^2 analyses. Perhaps if this study was a prospective, 2-year randomized controlled trial, the clinical outcomes would have met statistical significance. Having data abstracted from medical records by a computer programmer, or non clinical resource may have influenced the rigor in which data was abstracted. Regardless, it is understood that changing patient behavior is indeed difficult, and that the SMA cases posed some unique challenges in regards to their baseline characteristics, clinical care, and healthcare utilization. Perhaps another intervention, for example, a nurse case manager or social worker in addition to the use of the shared medical appointment is warranted in this high risk VA cohort to ascertain that both clinical and quality diabetes metrics are met. The RN case manager was a program provided by the VA that was not utilized during any of the study years, and could have provided another

resource for disease management. PharmD clinic, Renal Diabetes clinic and the MOVE! weight loss program were also LSCDVAMC sponsored programs that were vastly underutilized by these subjects. Additional studies on the shared medical appointment and other clinical outcome measures would be useful in high risk patients to determine utility of this care model.

CHAPTER FIVE

Discussion

Introduction

Over 2 decades have passed since the development of group medical visits or shared medical appointments (SMA), and the body of knowledge regarding clinical and quality outcomes related to this care delivery model, albeit sparse, continues to grow as additional hospitals and healthcare systems adopt this model as an alternative to traditional or usual medical care for chronic disease management. The purpose of this observational 3-year retrospective study was to determine if compared to usual care, SMAs supported positive improvements in diabetes management for veterans with type 2 diabetes. Study findings are from the medical record data of veterans who received care at the Louis Stokes Cleveland Veterans Affairs Medical Center during the years of 2008-2010. The VISN 10 database warehouse at the VA Medical Center provided a wealth of information about the clinical and quality outcomes needed for this project. This project may not have been able to be completed in other healthcare systems that may not enjoy such longevity in the use of this healthcare delivery model.

Clinical Outcomes: HbA1c, lipid panel, and blood pressure

Despite some positive trends, this study's analyses did not show statistically significant reductions in HbA1c, lipids and blood pressure by repeated measures analysis of variance (RM-ANOVA) over the three year study period 2008-2010. Mean HbA1c levels in the SMA group (M=8.56, SD1.74 n=350) was a whole percentage point higher at time one than the usual care (UC) group (M=7.48, SD, 1.28 n=617). All clinical

parameters including HbA1c, lipid panel, blood pressure and ED visits were higher in the SMA cohort at baseline, than in the UC cases. Baseline parameters of LDL-cholesterol for SMA cohort (M=90.6, SD=33.1, n=311 vs. M=87.56, SD 26.5 n=578) systolic blood pressure (M=130.77, SD=18.27, n=371, vs. M=127.53, SD 14.8, n=617) and diastolic blood pressure (M=71.66, SD 11.27, n=371, vs. M=71.4, SD=9.55, n=617) revealed similar trends for SMA cases over UC. However, other current VA related studies reported improvement in clinical parameters for diabetes management. For example, in a recent prospective study by Taviera, Dooley, Cohen, et al, (2011) conducted at the Veterans Administration Medical Center (VAMC) in Providence, Rhode Island, veterans with comorbid depression and type 2 diabetes who attended a Pharmacist-led SMA along with usual care (VA-MEDIC-D) revealed a greater proportion of participants who achieved a HbA1c <7% (29.6 vs. 11.9%) than those in usual care only without a change in depression symptoms in either arm. The veterans in the VA-MEDIC-D study also achieved reductions in systolic blood pressure, LDL, and non-HDL cholesterol, whereas the usual care subjects only reported significant reduction in non-HDL cholesterol (Taviera, et al, 2011). Unlike our study, the VA-MEDIC-D trial was a randomized controlled trial of veterans with type 1 or 2 diabetes, who were similar in terms of cardiovascular risk factors, and psychiatric comorbidity at baseline (Taviera, et al, 2011). Our SMA participants were dissimilar to UC in terms of psychiatric comordibity and had a higher proportion of SMA veterans who had substance abuse history (39.1% vs. 30.5%) depression (39.4% vs. 28%), and alcohol abuse (20.5% vs. 8.15) that was highly statistically significant (p=000).

A 6-month randomized controlled study at the VAMC in Providence, Rhode Island by Cohen, Taviera, Khatana, Dooley et al (2011) revealed that the intervention group in the (VA-MEDIC-E) trial achieved goal HbA1c over usual care (40.8% vs. 20.4% p=.028) and systolic blood pressure reduction (58% vs. 32.7% p=.015) in a pharmacist-led SMA, while LDL reduction although improving (82% vs. 65.3% p=.059) did not meet statistical significance. Compared to the usual care, the VA-MEDIC-E intervention subjects had lower baseline, LDL-cholesterol and total cholesterol but were similar to the control group in all other characteristics (Cohen, et al, 2011). As aforementioned, our study was observational and non-randomized, and SMA cases were dissimilar in terms of psychiatric comorbidity and demographic features. The SMA group in our VA study had a lower proportion of veterans who were married (49.9% vs. 61.8%) and higher percentage reported as minority (34.5% vs. 13.8%) that was statistically significant p=000. According to Healthy People 2020, factors such as race or ethnicity, sex, sexual identity, age, disability, socioeconomic status, and geographic location all may contribute to an individual's ability to achieve good health. Several social determinants including but not limited to race have influenced health outcomes of specific populations (www.healthypeople.gov). The effect of marriage on health has become an increasingly important topic in academic and policy research (www.aspe.hhs.gov). A burgeoning body of literature suggests that marriage may have a wide range of benefits, including improvements in individuals' economic well-being, mental and physical health, as well as the well-being of their children (www.aspe.hhs.gov).

Kirsh et al's (2007) non randomized quasi-experimental study on veterans with type 2 diabetes at the LSCDVAMC in Cleveland, Ohio found similar results on reduction in HbA1c and systolic blood pressure in the SMA intervention group versus the control group at 6-months, but LDL cholesterol although improving in the SMA intervention group, failed to meet statistical significance. However, this study reported that there were no significant differences in baseline parameters in terms of age, clinical outcomes metrics and medication use between the intervention and control groups. Our retrospective observational study found significant differences in terms of age as the SMA cohort tended to be younger than UC (M=67.6, SD 8.91, n=371) vs. (M=71.64, SD=9.3, n=617) *t*(810.4)=6.65,p=000. It is unclear why the younger, single, veterans participated in the SMA cohort, but would warrant further exploration of certain demographic and clinical features, that pertain to SMA utilization at the LSCDVAMC. Perhaps this high risk cohort needs additional support, and intervention to optimize glycemic, lipid and blood pressure control.

Clinical Outcome: ED visits

Results from this study did not show improvement in Emergency Room (ED) utilization from the veterans who attended the shared medical appointment. Mean ED visits were higher at time one for the SMA participants over usual care (M=1.09, SD, 1.9, n=371) vs. (M=.51, SD 2.701, n=617) and persisted over the study period. There was significantly higher utilization of healthcare resources in SMA over UC cohort in regards to number of total clinical visits over 3-years (*t* (758.8)=-10.9, p=000). However, several studies reported that there were significant reductions in Emergency room visits

in participants attending SMAs (Coleman, Eilertsen, Kramer, Magid, et al, 2001; Wagner, et al, 2001; Beck, Scott, Williams, Robertson, et al, 1997). Coleman et al's (2001) 2-year randomized controlled trial revealed that the average SMA attendance was 10.6 visits over 2-years, and the SMA participants averaged fewer ED visits (0.65% vs.1.08, p=.005) and less likely to have any ED visits (34.9% vs. 52.4%, p=.003) over the control subjects and remained significant when controlling for demographic factors, comorbid conditions, functional status and prior utilization. Scott et al (2004), was able to find that chronically ill participants in Cooperative Health Care Clinics (CHCC) had fewer hospital admissions (p=.012) and ED visits (p=.008) over the control group.

Because we were unable to abstract data regarding hospital admissions and length of hospital stay for this study, we did not have data related to inpatient hospital utilization in both groups. However, other studies do support that hospital admission and utilization decreases in participants attending shared medical appointments (Miller, et al, 2004; Lin, et al, 2008; Beck, et al, 1997; Wagner, et al, 2001; Scott, Conner, Venohr, Gade, et al, 2004; Sadur, et al 1999). Most studies that have reported improvement in hospital utilization were prospective and randomized-controlled, except for a 6-month pilot study by Lin, et al (2008) who was able to show reduction in hospital admission for Heart Failure patients who utilized SMA. Clancy, Dismuke, Magruder, Simpson, et al, (2008) also reported reduction in Emergency room charges and total outpatient charges when comparing shared medical appointment patients over usual care and concluded that it may be related to a reduction in specialty care visits. If use of SMA can reduce hospital admission and ED utilization, it may be a viable care delivery option for patients with

chronic disease that are persistent users of Emergency services for non-urgent matters. This would be an important implication for VA subjects attending SMAs, as this study supports that this care model did not reduce ED utilization over 2-years. Perhaps these subjects would need to be monitored more closely for utilization of healthcare service over time.

DoD Diabetes Clinical Practice Guidelines

Our trial did not show statistically significant improvement in our clinical outcomes of HbA1c, lipid levels, blood pressures, and ED visits, but did have some of the DoD diabetes clinical practice guidelines that met significance. Other studies have confirmed positive trends in HbA1c and lipid control in diabetic patients that were not statistically significant, but validated that clinical practice guideline adherence improved in patients seen in shared medical appointments (Clancy, et al 2003a; Clancy, et al, 2003b; Clancy et al 2007). Our study found that some of these quality care metrics were able to meet statistical significance in the SMA included prescribing ACE/ARB medication, prescribing aspirin, and annual podiatry and ophthalmology exams. Adherence to accepted quality metrics for diabetes will continue to be an important factor in chronic disease management as doctors and other healthcare providers will be penalized for not meeting prescribed quality measures in certain groups of patients with diseases such as heart failure or diabetes (http://www.ahrq.gov/professionals/quality-patient-safety). According to Mc Namara (2006) "pay for performance refers to financial incentives that reward providers for the achievement of a range of payer objectives, including delivery efficiencies, submission of data and measures to payer, and improved

quality and patient safety." Meeting and documenting accepted clinical practice guidelines may be the difference between being reimbursed or not for services rendered which may have sweeping financial implications for healthcare providers and systems. It also provides consistency, quality, transparency and clarity for chronic disease management and reduce undesirable practice variation that is not evidence-based.

Lin, et al (2008) found that beta blocker use, and use of angiotension-converting enzyme inhibitors increased by 19% and 20% respectively in a 6-month pilot study of SMAs in Heart Failure patients at the Naval Medical Center in San Diego, California, which supports that the SMA may increase provider adherence to clinical practice guidelines. Clancy, et al (2007) also found better adherence to United States Preventive Services Task Force (USPSTF) recommendations for screening of the breast (80 vs. 60%, p=.006) and cervix (80 vs. 68%, p=.019) in low income subjects who attended SMAs. Wagner, et al (2001) found that chronic care clinics for diabetics at 24-months had statistically significant improvement in preventive procedures and having microalbumin tested, plus improved rates of foot exams, retinal exams and medication review, but these measures did not meet statistical significance. Our three year observational study did not report that microalbumin screening to detect kidney disease, or prescribing statins to control lipid levels was significantly different in either the SMA or UC cohorts. However, having bi-annual HbA1c and lipid panels drawn were statistically significant for the UC cohort, and not the SMA. Perhaps the usual care subjects were more compliant overall with obtaining regular blood work, and the subjects recommended to attend the diabetes SMA were not. Several of the veterans recommended for the SMA

may have been referred because of issues of compliance on obtaining and monitoring lab values and evaluating disease progression.

Moderator Variables: Number of clinical visits SMA or UC, mental health diagnosis or other VA-self management programs

Our key moderators that were tested via a linear regression included number of clinical visits (UC or SMA), presence of a mental health diagnoses, and attendance in other VA-disease self management programs. It was posited that attending additional VA self- management programs would enhance the effects of the diabetes SMA. However, when we ran frequencies on number of MOVE, PharmD, RN case manager, or Renal DM clinics, the utilization was <10%/year per program so it was omitted from the regression. Number of clinical visits and mental health diagnoses did not explain much variance in the linear regression model with the major clinical dependent outcomes of HcA1c, blood pressure, ED visits and LDL-cholesterol as was hypothesized. SMAs are not specifically utilized for patients with mental illness, rather, it is used as an adjunct healthcare model for chronic disease management. However, there are a significant proportions of veterans that have mental illness including, substance abuse, depression and anxiety, which may impact how the veterans is able to self-management their disease. This would support conducting additional research with depression and anxiety scales to assess the level of mental illness in VA participants to compare degree of mental illness with clinical outcome metrics. Based on frequencies, numbers of overall clinical visits were significantly higher in the SMA participants in our study over UC at baseline. This finding did not support our hypothesis that the SMA would mitigate usage of the ED. However, the SMA cohort had higher levels of substance abuse, alcoholism,

depression and anxiety, that may have confounded this study, and there were differences on several baseline clinical parameters for the SMA participants.

Mechanism of Action for SMA

Several authors have hypothesized the mechanism of action that may influence some improvement in outcomes in the management of type 2 diabetes in subjects who attend SMAs. Possible explanations include the improved communication among patients and care providers (Scott, et al, 2004; Clancy, et al, 2007; Gutierrez, et al, 2011; Trento, et al, 2002, Jaber, et al, 2006) peer support developed in the group (Gutierrez, et al, 2011; Trento, et al, 2004; Jaber, et al, 2006) greater amounts of time spent with the healthcare team over a traditional medical visit (Bronson & Maxwell, 2004; Noffsinger, 2007) improved problem solving or knowledge of diabetes management (Trento, et al, 2001; Trento, et al, 2004; Bronson & Maxwell, 2004). Perhaps these relevant factors were why some of our DoD clinical practice guidelines met statistical significance. SMA healthcare providers may be more astute as to the importance of reviewing and documenting these quality care metrics, or have more time in the group to evaluate pertinent clinical practice guidelines.

Several studies report improved patient satisfaction in subjects that use shared medical appointments (Beck, et al, 1997; Wagner, et al, 2001; Sadur, et al 1999) which may translate to subjects being more engaged in their health care, and satisfied with their treatment plans. Prior studies that included knowledge of the management of diabetes, and quality of life (Trento, et al, 2001; Trento, et al 2004) and heart failure education and self-care (Yehle, Sands, Rhynders, & Newton, 2009; Lin, et al, 2008) showed

significant improvements in test scores which may correlate to an improved understanding of the disease, disease self-management, and clinical measures over time. Because changing clinical health parameters including blood pressure, cholesterol levels, weight and HbA1c are difficult to achieve even in non-diabetic patients, improving disease management knowledge may be the first step in helping patients take control of their health.

Studies that addressed depression scales in shared medical appointment participants, showed mixed results in depression scores in subjects who attended a shared medical appointment for chronic disease management. For example, Lin et al (2008) was able to show improvement in depression scores for hope for the future, interest in sex, and feelings of sadness, in a 6-month follow up in Heart Failure patients managed in SMA . Patients who were diagnosed with, and treated for depression also increased from 23% to 52% (p=.01) for subjects in the SMA intervention group over 6-months (Lin et, al , 2008) However, Taviera, et al (2011) was unable to ascertain significant differences in depression scores in veterans attending a diabetes SMA, but did achieve significant reductions in blood pressure and lipid levels. Improving depression scores may or may not improve diabetes disease self-management, but Taviera et al's (2011) study saw improvement in clinical parameters regardless of depression scores. This is a positive finding in a sample of veterans who are prone to mental health issues. In our sample of 988 cases, 32.3% or generally a third had depression, 15.7% had PTSD, and 25.7% had anxiety, and knowing that reduction in clinical parameters is possible despite these comorbidities is useful.

In the LSCDVAMC, providers routinely recommend individuals for SMA model of care because of poor compliance to diabetes regimen, worsening clinical parameters through surveillance within the Diabetes Registry, or inability to control essential clinical metrics for example, HbA1c, blood pressure of lipid levels (Dr. Kirsh personal communication, 3/6/2013). The findings from this observational study indicate the results of this practice: the veterans were recommended by their VA provider to attend a diabetes SMA were clearly different than the subjects who were seen in the usual patient-physician model based on baseline characteristics. SMA participants were more likely to be single males, with depression, substance abuse, alcoholism and a smoking history. Clearly, these individuals would present challenges in terms of disease self-management regardless of what health care model they used.

Limitations

Limitations of this study include that this was an observational study of veterans who attended a single, VA facility in Cleveland, Ohio were predominately male, so the ability to generalize these findings to other non-veteran populations, females, ethnic backgrounds or healthcare settings is limited. Working with preexisting records for a retrospective observational study design posed some difficulties, as the dataset used was derived from electronic medical record cases of actual patients and reflected real world challenges in regards to medical visit variability, missing data, and variables that were not formatted or easily retrievable to answer the research questions. For example, hospital admission, length of hospital stay, and discharge data were desired variables for this study. This information was difficult to abstract for the VA Information Technology (IT)

team, so the only hospital utilization variable abstracted was Emergency Room visits using stop codes. Had admission data and length of hospital stay been easily retrievable, it would have been included. Because this study was not randomized or prospective, the subjects' utilization of the SMA visit varied widely, and decision rules were developed for inclusion criteria based on quantity of medical visits, and consecutive years of SMA attended, to ascertain that the SMA visit truly reflected the years of the clinical outcomes that were abstracted.

Additional Analysis Plans

Other potential statistical analysis plans for this dataset could be to analyze the clinical and quality outcomes measures over 5-years from 2006-2010 to track trends in parameters used in this study. The diabetes SMA model commenced around 2005 and there would be more SMA naive subjects prior to that date that were not exposed to the SMA care model that could be evaluated in the study. Multiple data points could have be used for each year for 5-years, for example bi-annually or quarterly blood pressure and lipid panels to ascertain how the veterans' clinical and quality outcomes fared over a longer period of time. Because 2008-2010 data was utilized, some subjects who attended the SMA had some exposure to the SMA prior to 2008, which may have biased the study. The dataset was queried for SMA attendance in 2007 to ascertain if the majority of SMA subjects also had visits in 2007, the year prior to the start of the data used for the outcome analysis. The data revealed that 39.6% of the SMA cohort did not have any exposure to SMAs in 2007, but 60.4%, or almost two-thirds of the SMA cohort did.

Future Directions

As escalating rates of type 2 diabetes, and the obesity epidemic intensifies in the United States, healthcare delivery systems will need to address the heightened cardiovascular and stroke risk associated with these common medical maladies. Rising costs of healthcare delivery as well as medications used to treat chronic disease stymies the United States healthcare system and presents a challenge in the way the health care team can deliver care. Using a shared medical appointment with multiple specialties involved is one way to get the shared knowledge and experiences of many disciplines to care for the complexity of the diabetic patient. Having more time with the patient, and the support from peers appears to garner some benefit in disease self-management based on the current body of knowledge. Much of the literature reviewed has showed multiple ways in which this care model can be utilized and restructured to facilitate the needs of a particular practice. Physicians, nurses, nurse practitioners, certified diabetes educators, nutritionists, pharmacists, psychologist, social workers, and other allied health providers all can be key members of the SMA team depending on the targeted patient population, goals of the group visit, and desired outcome.

Research on the cost-benefit analysis of this model may also be an avenue of exploration for healthcare systems. Because SMAs are resource and time intensive, what may work for one practice, may not be feasible for another. For example, a large urban multispecialty health maintenance organization with a capitated plan structure may find value to this model to reduce costs for plan members, whereas another rural health center with more limited resources may not find this model pragmatic. Moreover, there may be

other cultural, demographic, and socioeconomic factors that could provide barriers to implementing a successful SMA in some geographic locations. If a preceding cost benefit analysis does not show an improvement on a clinical or quality metrics using an SMA for a healthcare system, but increases labor costs, it may not be a viable solution. Piloting a group visit for a chronic disease entity may be a good first step for a medical practice or healthcare system to see if logistically, the SMA is an option.

Hospital utilization is another variable that may be assist practices and providers with the decision to use a SMA. With Medicare reimbursement rubrics changing to reduce remuneration to hospitals for patient readmission within 30-days of discharge (http://www.ahrq.gov/news 3/7/2012) , a shared appointment after surgery or hospitalization may prevent readmission or Emergency room utilization by reviewing important discharge instruction, monitoring blood pressure or weights, ordering appropriate diagnostics, assuring medication compliance, and assisting with follow up. Because this study supported that the high risk SMA cohort of veterans used more healthcare resources and ED visits, identifying these patients, and providing additional nurse case manager intervention would be helpful. The VA provides a nurse case manager, but based on our frequency analysis this service was not utilized. More research in this area would help hospital administrators determine if this type of care could salvage Medicare reimbursement to the hospital and reduce crowded and unnecessary use of the Emergency room.

A body of evidence is continuing to mount on clinical and quality metrics on participants who attend SMAs, however much is still unknown. Further prospective,

randomized controlled trials are still needed on larger cohorts of patients with varied medical diagnoses. Addressing this model in myriad clinical settings and over longer periods of time is needed to fill in the gaps in the literature. Adding knowledge of diabetes scales, patient satisfaction, quality of life, self-care management and depression scales, may also add to the richness of knowledge associated with shared medical appointments. However, longitudinal research on chronic disease SMAs can prove problematic because of recruitment issues, attrition of subjects, feasibility, patient relocation, and difficulty controlling for some variables such as medication compliance, and disease self-management. Composition of group medical providers, patient populations, and medical diagnoses can be challenging to evaluate, as there are several iterations and variability of this care model that can make analyzing outcomes complicated.

Implications to Nursing practice, healthcare policy and education

Nurses with all levels of experience and scope of practice are an integral part of the SMA experience for the patient. Nurse practitioners, clinical diabetes educators (CDE), clinical nurse specialists and staff nurses all have a role and are utilized at the LSCDVAMC to facilitate this care model. The VA has used the diabetes shared medical appointment as a system redesign and process improvement project based on Wagner's Chronic Care Model targeting veterans at high cardiovascular risk (Kirsh, et al 2007). The SMA provides a compelling venue for multidisciplinary collaboration, education and support between physicians, nursing, pharmacy, psychiatry as well as other ancillary providers that is not feasible in our current traditional healthcare model. Promoting

disease specific clinical practice guidelines in the SMA provides standards of uniformity, transparency, safety and quality that is relevant in an era of healthcare cost containment. As the nation looks towards value based purchasing and providing quality chronic disease care, the shared medical appointment may become an adjunct for other difficult to control disease entities.

Conclusion

Our retrospective, observational study did not show significant differences in clinical outcomes, but some of the DoD diabetes clinical practice guidelines measuring quality of diabetes care did meet statistical significance in subjects attending the shared medical appointment. The participants selected for the SMAs were high risk, comorbid subjects who had different baseline characteristics, and tended to have HbA1c, blood pressures, and lipid levels that were higher than the usual care subjects. The statistical analysis here supported that SMA cases were a group of veterans that were not optimized in their glycemic, lipid, and blood pressure control prior to SMA attendance and hence, needed additional intervention to control their chronic disease. The peer support, additional education, interactive environment and time with the healthcare team may prove advantageous over time in these high risk subjects. Perhaps if this was a longitudinal, prospective, randomized control trial, more clinical and quality measures would have met statistical significance. Further research should continue in this domain to clearly establish the benefits, and disadvantages of shared medical appointments in the management of type 2 diabetes.

Appendix A

Louis Stokes Cleveland Department of

Veterans Affairs Medical Center

10701 East Boulevard

Cleveland, OH 44106

Date

Dear ,

I want to invite you to participate in a new way of delivering medical care. This program is designed specifically for veterans with Diabetes. By choosing to participate you will be asked to:

- Become a member of a small group of patients with Diabetes. This group will meet every week with me to address medical and other issues of concern to you.
- Help evaluate the success of the program in meeting your needs.

Most of the time when you come in to the clinic, you are ill or have a specific problem that we need to talk about. Discussions about managing or improving your health are often hard to fit into these short visits. The purpose of this group is improved health. In the group we will discuss ways

you can maintain or improve your health and make sure you are up-to-date with care recommended for you.

The first group visit will be held _____ (day and date) from _____ (am or pm). These group visits will be held at _____. We encourage you to bring a family member with you. Since this visit includes a medical evaluation, a co-pay will be collected if you usually pay for medical care.

If you are interested, please RSVP by _____ (date) to _____ (name) at _____ (phone number). If you are not interested, you will continue to receive usual health care. Remember to bring a record of your blood sugar readings to each visit. Remember to bring a bag of all the medicines you take now.

Dr. Susan R. Kirsh Director of Primary Care Wade Park

Appendix B

A retrospective study comparing SMA with usual health care on clinical outcomes and quality measures in veterans with type 2 diabetes

Marianne D. Harris- dissertation proposal

Susan Kirsh MD-PI

Inclusion Criteria to obtain dataset:

All veterans who meet ALL of the following criteria during a 3 year period, 01/01/2006 to 12/31/2008:

1. Veterans ages 51 and older
2. > 1 clinic primary care visits (323) or Diabetes SMA (306,348) visits at Wade Park or Brecksville.
3. Must have ICD-9 code for type 2 diabetes 250.00-250.09, Exclude type 1 Diabetics

Variables and data set location table:

Pull data for all variables below for veterans at Wade Park or Brecksville meeting the above criteria annually during the **5 year period of 01/01/2006 up to 12/31/2010**

Variable Name	*VAMC Dataset*	*Database location*
Age	Demographic profile	Demographic profile, age, DOB
Gender	Demographic profile	Demographic profile, gender
Marital Status	Demographic profile	maritalstatus
Race	Demographic profile	Race
ICD-9 codes	CPRS, or database warehouse	ICD-9 codes
Obesity	CPRS, or database warehouse	lastweightdate, lastwt, value
Smoker	CPRS, or database warehouse	CKD profile under, tobaccohealthfactor
Substance Abuse	CPRS, or database warehouse	ICD-9 303, 304, 305
Alcohol	CPRS, or database warehouse	ICD-9 303, 304, 305
All UC visits	CPRS, or database warehouse	use stop codes 323
All Diabetes SMAs	CPRS, or database warehouse	use stop codes 306, 348
All HbA1c results	CPRS, or database warehouse	CKD registry, lastA1cdate, value
All BPs	CPRS, or database warehouse	lastsystolic, last. diastolic values
Lipid panels	CPRS, or database warehouse	lastldlsite, value, lipidpanel
ACE/ARB use	CPRS, or database warehouse	AceArbRX group, Aceinhibitorallergy
Aspirin use	CPRS, or database warehouse	pharmacy records
All meds	CPRS, or database warehouse	pharmacy record
Statins	CPRS, or database warehouse	statinuse, lipiduse, statinallergy
Microalbumin	CPRS, or database warehouse	lastmicroalbuminvalue
ED visits	CPRS, or database warehouse	Stop codes 130, 102
Admissions	CPRS, or database warehouse	sourceofadmission
Length of stay	CPRS, or database warehouse	admissiondate, 102, dischargedate
VA self-management	CPRS, or database warehouse	Use stop codes
annual visits	CPRS, or database warehouse	
Renal DM	CPRS, or database warehouse	313
MOVE	CPRS, or database warehouse	372373
RN Case Manager	CPRS, or database warehouse	184
PharmD clinic	CPRS, or database warehouse	160
Pneumovax	CPRS, or database warehouse	pneumovaxhealth, factor, V03.82
Diabetic foot exam (all annual)	CPRS, or database warehouse	lastfootexam, stop code 411
Eye Exam (all annual)	CPRS, or database warehouse	lasteyeexamdate, stop codes 407, 408

Appendix C

Cleveland VA Quality Improvement and Research Database

Research Proposal Instructions

The Cleveland VA Quality Improvement and Clinical Research Database has been developed to improve management of patients with chronic diseases and to enable clinical outcomes research. The database facilitates research by providing rapid access to nearly all objective data within CPRS (e.g., demographic data, vital signs, laboratory data, outpatient medications filled, inpatient medications dispensed, note titles, note authors, surgical procedures, radiology tests performed, microbiology results, and ICD-9 codes for inpatient and outpatient encounters).

Applications for use of the database for research should be submitted to Cameron Carter (Cameron.Carter@va.gov). Applications are reviewed by the Database steering committee. If approved, investigators will work with individuals with knowledge of the database to design and conduct the research project.

Applications should be approximately 1 page (single spaced) in length and include:

Principal investigator

1. VA investigator (if PI is not paid by VA)
2. Mentee (it is preferred that projects include a trainee, e.g., student, resident)
3. Background
4. Methods
    a. Patients – Inclusion and exclusion criteria
        i. Anticipated sample size(s)
    b. Exposure(s) of interest
    c. Covariates
    d. Outcomes
    e. Statistical support person/funding source
5. Timeline
6. Anticipated conference where results will be presented

Appendix D

SPSS Variable Labels

ID ‘VA identification number is the veteran's study ID number

/Patients’ ‘ the veteran' s social security number’

/Age ‘age of patient’

/Gender ‘gender of veteran’

/MaritalStatus ‘marital status on enrollment into the study’

/Race ‘race of veterans’

/Zipcode ‘zip code of veteran's residence’

/Obesity ‘veteran has a diagnosis code for obesity’

/ Smoker ‘subject is a reported cigarette smoker’

/Substanceabuse ‘reported illicit recreational drug use of study veteran’

/UCVisits2006 ‘number of usual care visits in 2006 (physician-patient dyad)’

/UCVisits2007 ‘number of usual care visits in 2007 (physician-patient dyad)’

/UCVisits2008 ‘number of usual care visits in 2008 (physician-patient dyad)’

/UCVisits2009 ‘number of usual care visits in 2009 (physician-patient dyad)’

/UCVisits2010 ‘number of usual care visits in 2010 (physician-patient dyad)’

/SMAVisits2006 ‘number of SMA visits attended in 2006 (Diabetes SMA)’

/SMAVisits2007 ‘number of SMA visits attended in 2007 (Diabetes SMA)’

/SMAVisits2008 ‘number of SMA visits attended in 2008 (Diabetes SMA)’

/SMAVisits2009 ‘ number of SMA visits attended in 2009 (Diabetes SMA)’

/SMAVisits2010 ‘number of SMA visits attended in 2010 (Diabetes SMA)’

/Hba1c20061 ‘Hba1c value first half of 2006’

/Hba1c20062 ‘Hba1c value second half of 2006’

/Hba1c20071 ‘Hba1c value first half of 2007’

/Hba1c20072 ‘Hba1c value second half of 2007’

/Hba1c20081 ‘Hba1c value first half of 2008’

/Hba1c20082 ‘Hba1c value second half of 2008’

/Hba1c20091 ‘Hba1c value first half of 2009’

/Hba1c20092 ‘ Hba1c value second half of 2009’

/Hba1c20101 ‘Hba1c value first half of 2010’

/Hba1c20102 ‘Hba1c value second half of 2010’

/LDLchol20061 ‘LDL cholesterol value first half of 2006’

/LDLchol20062 ‘LDL cholesterol value second half of 2006’

/LDLchol20071 ‘LDL cholesterol value first half of 2007’

/LDLchol20072 ‘LDL cholesterol value second half of 2007’

/LDLchol20081 ‘LDL cholesterol value first half of 2008’

/LDLchol20082 ‘LDL cholesterol value second half of 2008’

/LDLchol20091 ‘LDL cholesterol value first half of 2009’

/LDLchol20092 ‘LDL cholesterol value second half of 2009’

/LDLchol20101 ‘LDL cholesterol value first half of 2010’

/LDLchol20102 ‘LDL cholesterol value second half of 2010’

/HDLchol20061 ‘HDL cholesterol value first half of 2006’

/HDLchol20062 ‘HDL cholesterol value second half of 2006’

/HDLchol20071 ‘HDL cholesterol value first half of 2007’

/HDLchol20072 ‘HDL cholesterol value second half of 2007’

/HDLchol20081 ‘HDL cholesterol value first half of 2008’

/HDLchol20082 ‘HDL cholesterol value second half of 2008’

/HDLchol20091 ‘HDL cholesterol value first half of 2009’

/HDLchol20092 ‘HDL cholesterol value second half of 2009’

/HDLchol20101 ‘HDL cholesterol value first half of 20010’

/HDLchol20102 ‘HDL cholesterol value second half of 2010’

/TC20061 ‘Total cholesterol value first half of 2006’

/TC20062 ‘Total cholesterol value second half of 2006’

/TC20071 ‘Total cholesterol value first half of 2007’

/TC20072 ‘Total cholesterol value second half of 2007’

/TC20081 ‘Total cholesterol value first half of 2008’

/TC20082 ‘Total cholesterol value second half of 2008’

/TC20091 ‘Total cholesterol value first half of 2009’

/TC20092 ‘Total cholesterol value second half of 2009’

/TC20101 ‘Total cholesterol value first half of 2010’

/TC20102 ‘Total cholesterol value second half of 2010’

/Triglyceride20061 ‘Triglyceride level first half of 2006’

/Triglyceride20062 ‘Triglyceride level second half of 2006’

/Triglyceride20071 ‘Triglyceride level first half of 2007’

/Triglyceride20072 ‘Triglyceride level second half of 2007’

/Triglyceride20081 ‘Triglyceride level first half of 2008’

/Triglyceride20082 ‘Triglyceride level second half of 2008’

/Triglyceride20091 ‘Triglyceride level first half of 2009’

/Triglyceride20092 ‘Triglyceride level second half of 2009’

/Triglyceride20101 ‘Triglyceride level first half of 2010’

/Triglyceride20102 ‘Triglyceride level second half of 2010’

/microalbumin20061 ‘vet had urine microalbumin test first half of 2006’

/microalbumin20062 ‘vet had urine microalbumin test second half of 2006’

/microalbumin20071 ‘vet had urine microalbumin test first half of 2007’

/microalbumin20072 ‘vet had urine microalbumin test second half of 2007’

/microalbumin20081 ‘vet had urine microalbumin test first half of 2008’

/microalbumin20082 ‘vet had urine microalbumin test second half of 2008’

/microalbummin20091 ‘vet had urine microalbumin test first half of 2009’

/microalbumin20092 ‘vet had urine microalbumin test second half of 2009’

/microalbumin20101 ‘vet had urine microalbumin test first half of 2010’

/microalbumin20102 ‘vet had urine microalbumin test second half of 2010’

/AceArb2006 ‘vet was prescribed ACE/ARB medication in 2006’

/AceArb2007 ‘vet was prescribed ACE/ARB medication in 2007’

/AceArb2008 ‘vet was prescribed ACE/ARB medication in 2008’

/AceArb 2009 ‘vet was prescribed ACE/ARB medication in 2009’

/AceArb2010 ‘vet was prescribed ACE/ARB medication in 2010’

/Aspirin2006 ‘vet was prescribed aspirin in 2006’

/Aspirin2007 ‘vet was prescribed aspirin in 2007’

/Aspirin2008 ‘vet was prescribed aspirin in 2008’

/Aspirin2009 ‘vet was prescribed aspirin in 2009’

/Aspirin2010 ‘vet was prescribed aspirin in 2010’

/Statinuse2006 ‘vet was prescribed a statin in 2006’

/Statinuse2007 ‘vet was prescribed a statin in 2007’

/Statinuse2008 ‘vet was prescribed a statin in 2008’

/Statinuse2009 ‘vet was prescribed a statin in 2009’

/Statinuse2010 ‘vet was prescribed a statin in 2010’

/Pneumovax ‘veteran has one pneumovax recorded during study period’

/Footexam2006 ‘diabetic foot exam recorded in 2006’

/Footexam2007 ‘diabetic foot exam recorded in 2007’

/Footexam2008 ‘diabetic foot exam recorded in 2008’

/Footexam2009 ‘diabetic foot exam recorded in 2009’

/Footexam2010 ‘diabetic foot exam recorded in 2010’

/Eyeexam2006 ‘vet had one ophthalmology visit in 2006’

/Eyeexam2007 ‘vet had one ophthalmology visit in 2007’

/Eyeexam2008 ‘vet had one ophthalmology visit in 2008’

/Eyeexam2009 ‘vet had one ophthalmology visit in 2009’

/Eyeexam2010 ‘vet had one ophthalmology visit in 2010’

/EDvisit2006 ‘number of ED visits by veteran in 2006’

/EDvisit2007 ‘number of ED visits by veteran in 2007’

/EDvisit2008 ‘number of ED visits by veteran in 2008’

/EDvisit2009 ‘number of ED visits by veteran in 2009’

/EDvisit2010 ‘number of ED visits by veteran in 2010’

/PharmD2006 ‘number of visits to PharmD clinic program in 2006’

/PharmD2007 ‘number of visits to PharmD clinic program in 2007’

/PharmD2008 ‘number of visits to PharmD clinic program in 2008’

/PharmD2009 ‘number of visits to PharmD clinic program in 2009’

/PharmD2010 ‘number of visits to PharmD clinic program in 2010’

/RenalDM2006 ‘number of visits to Renal Diabetes clinic in 2006’

/RenalDM2007 ‘number of visits to Renal Diabetes clinic in 2007’

/RenalDM2008 ‘number of visits to Renal Diabetes clinic in 2008’

/RenalDM2009 ‘number of visits to Renal Diabetes clinic in 2009’

/RenalDM2010 ‘number of visits to Renal Diabetes clinic in 2010’

/MOVE2006 ‘number of visits to the MOVE program in 2006’

/MOVE2007 ‘number of visits to the MOVE program in 2007’

/MOVE2008 ‘number of visits to the MOVE program in 2008’

/MOVE2009 ‘number of visits to the MOVE program in 2009’

/MOVE2010 ‘number of visits to the MOVE program in 2010’

/RNCM2006 ‘number of Nurse Case Manager visits in 2006’

/RNCM2007 ‘number of Nurse Case Manager visits in 2007’

/RNCM2008 ‘number of Nurse Case Manager visits in 2008’

/RNCM2009 ‘number of Nurse Case Manager visits in 2009’

/RNCM2010 ‘number of Nurse Case Manager visits in 2010’

/BP20061 ‘BP value first half of 2006’

/BP20062 ‘BP value second half of 2006’

/BP20071 ‘BP value number first half of 2007’

/BP20072 ‘BP value second half of 2007’

/BP20081 ‘BP value first half of 2008’

/BP20082 ‘BP value second half of 2008’

/BP20091 ‘BP value first half of 2009’

/BP20092 ‘BP value second half of 2009’

/BP20101 ‘BP value first half of 2010’

/BP20102 ‘BP value second half of 2010’

/DxCAD ‘vet had a diagnosis of coronary artery disease’

/Dxlipids ‘vet had a diagnosis of hyperlipidemia’

/DxHTN ‘vet had a diagnosis of hypertension’

/DxPTSD ‘vet had a diagnosis of PTSD’

/DxDepressed ‘vet had a diagnosis of depression’

/DxAnxiety ‘vet had a diagnosis of anxiety’

/DxBipolar ‘vet had a diagnosis of bipolar depressive disorder’

/DXalcohol ‘vet had diagnosis of alcohol abuse’.

Variable Labels:

(1)=yes (0)=no var8, var9, var10, var81, var82, var83, var84, var85, var86, var87, var88, var89, var90, var91, var92, var93, var94, var95, var96, var97, var98, var99, var100, var101, var102, var103, var104, var105, var106, var142, var143, var144, var145, var146, var147, var148, var149

Rename Gender=Gender old

if Gender old=‘male’ Gender=0

if Gender old=‘female’ Gender=1

Rename MaritalStatus= MaritalStatus old

if MaritalStatus old= ‘single’ single=1

if MaritalStatus old =‘married’ married =2

if MaritalStatus old =‘divorced’ divorced=3

if MaritalStatus old =‘separated’ separated =4

if MaritalStatus old =‘widowed’ widowed=5

Rename Race= race old

if race old =‘African American’ African American=1

if race old =‘White’ White=2

if race old =‘Asian/Pacific Islander’ Asian/Pacific Islander=3

if race old= ‘Latino’ Latino=4

if race old ‘Unknown’ unknown=5

Appendix E

Louis Stokes Cleveland VAMC
Study Approval Tracking Sheet

10/6/2011

Dr. Kirsh,

Congratulations, your study entitled **"A Retrospective study comparing group medical care with usual care on clinical outcomes and quality measures in veterans with type 2 diabetes"** has obtained the following Louis Stokes Cleveland VAMC approvals:

- ☒ Final Research & Development Committee Approval on: 10/6/2011
- ☒ Institutional Review Board Approval on: 7/29/2011
- ☒ Subcommittee on Research Safety Exemption: 7/18/2011

Now that you have obtained approval from all applicable subcommittees you may begin your project. Please remember that within 1 year, or sooner if required by specific subcommittee(s), of the approval dates, you must submit continuing renewals. If you should need anything in the interim, please do not hesitate to contact the Research Office.

Best Regards,

Neal S. Peachey, Ph.D.
Associate Chief of Staff for Research (ACOS/R)

George Jaskiw MD

George Jaskiw, M.D.
Chairperson, Research & Development Committee

Rev09082006
CY11-036

REFERENCES

Abraira, C., Colwell, J. A., Nuttall, F. Q., Sawin, C. T., Nagel, N. J., Comstock, J. P., et al. (1995). Veterans affairs cooperative study on glycemic control and complications in type II diabetes (VA CSDM). results of the feasibility trial. veterans affairs cooperative study in type II diabetes. *Diabetes Care, 18*(8), 1113-1123.

Abraira, C., Duckworth, W., McCarren, M., Emanuele, N., Arca, D., Reda, D., et al. (2003). Design of the cooperative study on glycemic control and complications in diabetes mellitus type 2: Veterans affairs diabetes trial. *Journal of Diabetes and its Complications, 17*(6), 314-322.

Abraira, C., Henderson, W. G., Colwell, J. A., Nuttall, F. Q., Comstock, J. P., Emanuele, N. V., et al. (1998). Response to intensive therapy steps and to glipizide dose in combination with insulin in type 2 diabetes. VA feasibility study on glycemic control and complications (VA CSDM). *Diabetes Care, 21*(4), 574-579.

Abraira, C., & McGuire, D. K. (1999). Intensive insulin therapy in patients with type 2 diabetes: Implications of the veterans affairs (VA CSDM) feasibility trial. *American Heart Journal, 138*(5 Pt 1), S360-5.

Agency for Healthcare Research and Quality: on Medicare reimbursement accessed on 3/7/2012 at http://www.ahrq.gov/news, Dr. Carolyn Clancy on Navigating the Health Care system, January 21, 2009, accessed at httl://ahrq.gov/cosumer/cc/cc012109.htm

Altman, D. E., Clancy, C., & Blendon, R. J. (2004). Improving patient safety -- five years after the IOM report. *New England Journal of Medicine, 351*(20), 2041-2043.

American Diabetes Association. (2010). ADA's 2010 clinical practice recommendations. *Diabetes Care, 33* (Supplement 1)

American Diabetes Association, Executive Summary: Standards of Diabetes Care (2010). http://care.diabetesjournals.org/content/33/Supplement_1/S4.extract

American Heart Association. (2010 Update). Retrieved 0ctober 25, 2010, from http://www.americanheart.org/downloadable/heart/1265665152970DS-3241%20HeartStrokeUpdate_2010.pdf

Azad, N., Emanuele, N. V., Abraira, C., Henderson, W. G., Colwell, J., Levin, S. R., et al. (1999). The effects of intensive glycemic control on neuropathy in the VA cooperative study on type II diabetes mellitus (VA CSDM). *Journal of Diabetes and its Complications, 13*(5-6), 307-313.

Bandura, A.(1977). Social Learning Theory, New York. General Learning Press.

BARI 2D Study Group, Frye, R. L., August, P., Brooks, M. M., Hardison, R. M., Kelsey, S. F., et al. (2009). A randomized trial of therapies for type 2 diabetes and coronary artery disease. *The New England Journal of Medicine, 360*(24), 2503-2515.

Barr, V. J., Robinson, S., Marin-Link, B., Underhill, L., Dotts, A., Ravensdale, D., et al. (2003). The expanded chronic care model: An integration of concepts and strategies from population health promotion and the chronic care model. *Hospital Quarterly, 7*(1), 73-82.

Barud, S., Marcy, T., Armor, B., Chonlahan, J., & Beach, P. (2006). Development and implementation of group medical visits at a family medicine center. *American Journal of Health-System Pharmacy : AJHP : Official Journal of the American Society of Health-System Pharmacists, 63*(15), 1448-1452.

Beck, A., Scott, J., Williams, P., Robertson, B., Jackson, D., Gade, G., et al. (1997). A randomized trial of group outpatient visits for chronically ill older HMO members: The cooperative health care clinic. *Journal of the American Geriatrics Society, 45*(5), 543-549.

Beck, A., Gade, G., McKenzie, M., Venhor, I. (1998). Cooperative Health Care Clinics: a group approach to individualized care, *Geriatrics*, 53(5), p. 68-78

Beckman, J. A., Libby, P., & Creager, M. A. (2006). Diabetes mellitus, the metabolic syndrome, and atherosclerotic vascular disease in Braunwald's heart disease: A textbook of cardiovascular medicine. In D. Zipes, P. Libby, R. Bonow & E. Braunwald (Eds.), (7th edition ed.,). Philadelphia, PA: Elsevier.

Beckman, J. A. (2002). Cardiology patient page. diseases of the veins. *Circulation, 106*(17), 2170-2172.

Beckman, J. A. (2003). Diabetes and atherosclerosis: The deadliest duo. *Patient Care, 37*(2), 61.

Beckman, J. A. (2010). Aspirin for prevention of cardiovascular events in individuals with low ankle brachial index. *JAMA: Journal of the American Medical Association, 303*(21), 2136-2136.

Beckman, J. A., Creager, M. A., & Libby, P. (2002). Diabetes and atherosclerosis: Epidemiology, pathophysiology, and management. *JAMA: Journal of the American Medical Association, 287*(19), 2570.

Beckman, J. A., Goldfine, A. B., Dunaif, A., Gerhard-Herman, M., & Creager, M. A. (2007). Endothelial function varies according to insulin resistance disease type. *Diabetes Care, 30*(5), 1226-1232.

Blakely, T. J., & Dziadosz, G. M. (2008). The chronic care model for behavioral health care. *Population Health Management, 11*(6), 341-346.

Bodenheimer, T., Wagner, E. H., & Grumbach, K. (2002). Innovations in primary care. improving primary care for patients with chronic illness. *JAMA: Journal of the American Medical Association, 288*(14), 1775-1779.

Boslaugh, S. (2007). *Secondary data sources for public health : A practical guide*. Cambridge ; New York: Cambridge University Press.

Bronson, D.L. & Maxwell, R.A (2005). Shared Medical Appointments: increasing patient access without increasing physician hours, *Cleve Clinic J Med,* 72(4), p. 277-280.

Brunzell, J. D., & Ayyobi, A. F. (2003). Dyslipidemia in the metabolic syndrome and type 2 diabetes mellitus. *The American Journal of Medicine, 115 Suppl 8A*, 24S-28S.

Carnethon, M. R., Biggs, M. L., Barzilay, J., Kuller, L. H., Mozaffarian, D., Mukamal, K., et al. (2010). Diabetes and coronary heart disease as risk factors for mortality in older adults. *The American Journal of Medicine, 123*(6), 556.e1-556.e9.

Carr, M. C., & Brunzell, J. D. (2004). Abdominal obesity and dyslipidemia in the metabolic syndrome: Importance of type 2 diabetes and familial combined hyperlipidemia in coronary artery disease risk. *The Journal of Clinical Endocrinology and Metabolism, 89*(6), 2601-2607.

Carroll, J. G. (2002). Crossing the quality chasm: A new health system for the 21st century. *Quality Management in Health Care, 10*(4), 60-60.

Center for Disease Control. (2009). *Center for disease control, Atlanta, GA, chronic disease prevention and health promotion; chronic disease statistics.* Retrieved October 25, 2010, from http://www.cdc.gov/chronicdisease/overview/index.htm

Center for Disease Control- National Center for Chronic Disease Prevention and Health Promotion. (2009). *Diabetes successes and opportunities for population-based prevention and control at a glance 2009.* Retrieved 1/15/2010, 2010, from http://www.cdc.gov/diabetes

Center for Disease Control- US Department of Health and Human Service. Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011.

Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.

Clancy, C. (2007). Safer and better are achievable. *Health Progress, 88*(4), 58-61.

Clancy, C. (2008). Improving care quality and reducing disparities: Physicians' roles. *Archives of Internal Medicine, 168*(11), 1135-1136.

Clancy, C. (2009). Building the path to high-quality care. *Health Services Research, 44*(1), 1-4.

Clancy, C., Stryer, D., & Eisenberg, J. M. (2002). From publication to public action: Agency for healthcare research and quality: (AHRQ) perspectives on ethnicity and race-related outcomes research. *Ethnicity & Health, 7*(4), 287-287.

Clancy, D. E., Brown, S. B., Magruder, K. M., & Huang, P. (2003). Group visits in medically and economically disadvantaged patients with type 2 diabetes and their relationships to clinical outcomes. *Topics in Health Information Management, 24*(1), 8-14.

Clinical Laboratory Improvement Amendment (CLIA) information accessed from the FDA http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm

Crossing the quality chasm: A new Health System for the 21st century(2001) IOM report accessed online 3/4/2010 from http://www.iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx

Culhane-Pera, K., Peterson, K. A., Crain, A. L., Center, B. A., Lee, M., Her, B., et al. (2005). Group visits for hmong adults with type 2 diabetes mellitus: A pre-post analysis. *Journal of Health Care for the Poor and Underserved, 16*(2), 315-327.

Davis, K. S., Magruder, K. M., Lin, Y., Powell, C. K., & Clancy, D. E. (2006). Brief report: Trainee provider perceptions of group visits. *Journal of General Internal Medicine, 21*(4), 357-359.

Durso, S. C. (2006). Using clinical guidelines designed for older adults with diabetes mellitus and complex health status. *JAMA : The Journal of the American Medical Association, 295*(16), 1935-1940.

Eder, C., Fullerton, J., Benroth, R., & Lindsay, S. P. (2005). Pragmatic strategies that enhance the reliability of data abstracted from medical records. *Applied Nursing Research : ANR, 18*(1), 50-54.

El-Masri, M. M., & Fox-Wasylyshyn, S. M. (2005). Missing data: An introductory conceptual overview for the novice researcher. *The Canadian Journal of Nursing Research = Revue Canadienne De Recherche En Sciences Infirmieres, 37*(4), 156-171.

Epping-Jordan, J., Pruitt, S. D., Bengoa, R., & Wagner, E. H. (2004). Improving the quality of health care for chronic conditions. *Quality & Safety in Health Care, 13*(4), 299-305.

Field, A. (2005) Discovering Statistics Using SPPS, 2nd ed, Sage Publications, Thousand Oaks, CA

Feinstein, S. B. (2007). Diabetes mellitus and noninvasive imaging of atherosclerosis. *The American Journal of Cardiology, 99*(4A), 89B-95B.

Feldman, M. (1974). Care of the well child. cluster visits... part 6. *American Journal of Nursing, 74*, 1485-1488.

Felix-Aaron, K., Moy, E., Kang, M., Patel, M., Chesley, F. D., & Clancy, C. (2005). Variation in quality of men's health care by race/ethnicity and social class. *Medical Care, 43*(3), I-72-81.

Fleisher, L. A., Beckman, J. A., Brown, K. A., Calkins, H., Chaikof, E., Fleischmann, K. E., et al. (2007). ACC/AHA 2007 guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery: Executive summary. *Journal of the American College of Cardiology, 50*(17), 1707-1732.

Garratt, K. N., & Bailey, S. R. (2009). Therapies for type 2 diabetes and coronary artery disease. *The New England Journal of Medicine, 361*(14), 1407-8; author reply 1409-10.

G-Power G*Power 3.2.1 general power analysis program E. Erdfelder, F. Faul and A. Buchner, accessed http://www.psycho.uniduesseldorf.de/aap/projects/gpower

Gutierrez, N., Gimpel, N.E., Dalio, F.J., Foster, B.M., et al (2011). Shared medical appointments in a residency clinic: An exploratory study among Hispanics with Diabetes, *Am J Managed Care*, 17(6) p, e212-e214.

Haffner, S. M., Lehto, S., Ronnemaa, T., Pyorala, K., & Laakso, M. (1998). Mortality from coronary heart disease in subjects with type 2 diabetes and in nondiabetic subjects with and without prior myocardial infarction. *The New England Journal of Medicine, 339*(4), 229-234.

Hahn, K. A., Ferrante, J. M., Crosson, J. C., Hudson, S. V., & Crabtree, B. F. (2008). Diabetes flow sheet use associated with guideline adherence. *Annals of Family Medicine, 6*(3), 235-238.

Harris, M.D (2010). Shared Medical Appointments after Cardiac Surgery, The process of implementing a novel pilot paradigm to enhance post discharge care, *J Cardiovasc Nursing*, 25(2) p. 124-129.

HealthyPeople 2020 references accessed at www.healthypeople.gov.

Hepner, D. L., Correll, D. J., Beckman, J. A., Klickovich, R. J., Park, K. H., Govindarajulu, U., et al. (2008). Needs analysis for the development of a preoperative clinic protocol for perioperative beta-blocker therapy. *Journal of Clinical Anesthesia, 20*(8), 580-588.

Hickman, L. D., Rolley, J. X., & Davidson, P. M. (2010). Can principles of the chronic care model be used to improve care of the older person in the acute care sector? *Collegian, 17*(2), 63-69.

Hofer, T. P., Hayward, R. A., Greenfield, S., Wagner, E. H., Kaplan, S. H., & Manning, W. G. (1999). The unreliability of individual physician "report cards" for assessing the costs and quality of care of a chronic disease. *JAMA: Journal of the American Medical Association, 281*(22), 2098-2105.

Hoge, C. W., Auchterlonie, J. L., & Milliken, C. S. (2006). Mental health problems, use of mental health services, and attrition from military service after returning from deployment to iraq or afghanistan. *JAMA : The Journal of the American Medical Association, 295*(9), 1023-1032.

Houck, S., & Kilo, C., Scott, J.C (2003). Improving patient care. group visits 101. *Family Practice Management, 10*(5), 66.

Hroscikoski, M. C., Solberg, L. I., Sperl-Hillen, J., Harper, P. G., McGrail, M. P., & Crabtree, B. F. (2006). Challenges of change: A qualitative study of chronic care model implementation. *Annals of Family Medicine, 4*(4), 317-326.

Hulley, S. B., Cummings, S., R., Browner, W. S., Grady, D., G., & Newman, T., B. (2007). *Designing clinical research* (3rd ed.). Philadelphia, PA: Lippincott, Williams, & Wilkins.

Hung, D. Y., Glasgow, R. E., Dickinson, L. M., Froshaug, D. B., Fernald, D. H., Balasubramanian, B. A., et al. (2008). The chronic care model and relationships to patient health status and health-related quality of life. *American Journal of Preventive Medicine, 35*(5), S398-406.

Jaber, R., Braksmajer, A., & Trilling, J. S. (2006). Group visits: A qualitative review of current research. *Journal of the American Board of Family Medicine : JABFM, 19*(3), 276-290.

Jackson, G. L., & Weinberger, M. (2009). A decade with the chronic care model: Some progress and opportunity for more. *Medical Care, 47*(9), 929-931.

Jakupcak, M., Luterek, J., Hunt, S., Conybeare, D., & McFall, M. (2008). Posttraumatic stress and its relationship to physical health functioning in a sample of Iraq and Afghanistan war veterans seeking post deployment VA health care. *The Journal of Nervous and Mental Disease, 196*(5), 425-428.

Joint Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) accessed from National Heart, Lung, and Blood Institute at http://www.nhlbi.nih.gov/guidelines/hypertension/

Katzelnick, D. J., von Korff, M., Chung, H., Provost, L. P., & Wagner, E. H. (2005). Applying depression-specific change concepts in a collaborative breakthrough series. *Joint Commission Journal on Quality & Patient Safety, 31*(7), 386-397.

Kawasaki, L., Muntner, P., Hyre, A. D., Hampton, K., & DeSalvo, K. N. (2007). Willingness to attend group visits for hypertension treatment. *The American Journal of Managed Care, 13*(5), 257-262.

Kirsh, S., Watts, S., Pascuzzi, K., O'Day, M., Davidson, D., Strauss, G., et al. (2007). Shared medical appointments based on the chronic care model: A quality improvement project to address the challenges of patients with diabetes with high cardiovascular risk. *Quality & Safety in Health Care, 16*(5), 349-353.

Kirsh, S. R., & Aron, D. C. (2008). Integrating the chronic-care model and the ACGME competencies: Using shared medical appointments to focus on systems-based practice... accreditation council for graduate medical education. *Quality & Safety in Health Care, 17*(1), 15-19.

Kirsh, S. R., Schaub, K., & Aron, D. C. (2009). Shared medical appointments: A potential venue for education in interprofessional care. *Quality Management in Health Care, 18*(3), 217-224.

Kuiken, S., Seiffert, D. (2005). Thinking Outside the Box! Enhance patient education by using Shared Medical Appointments, 25(4), p.191-195.

Leeman, J., & Mark, B. (2006). The chronic care model versus disease management programs: A transaction cost analysis approach. *Health Care Management Review, 31*(1), 18-25.

Lemke, S. P., & Schaefer, J. A. (2010). Recent changes in the prevalence of psychiatric disorders among VA nursing home residents. *Psychiatric Services (Washington, D.C.), 61*(4), 356-363.

Lessig, M., Farrell, J., Madhavan, E., Famy, C., Vath, B., Holder, T., et al. (2006). Cooperative dementia care clinics: A new model for managing cognitively impaired patients. *Journal of the American Geriatrics Society, 54*(12), 1937-1942.

Lin, A., Cavendish, J., Boren, D., Ofstad, T. et al (2008). A Pilot Study: Reports of Benefits from a 6-Month Multidisciplinary Shared Medical Appointment Approach for Heart Failure Patients, 173 (12), p.1210.

Lo, B. (2007). Addressing ethical issues. In S. B. Hulley, S. R. Cummings, W. S. Browner, D. G. Grady & T. B. Newman (Eds.), *Designing clinical research* (3rd edition ed., pp. 225). Philadelphia, PA: Lippincott, Williams, & Wilkins.

LoBiondo-Wood, G., & Haber, J. (2006). Nursing Research: Methods and critical appraisal for evidence-based practice. (6th edition ed.,). St. Louis, Missouri: Mosby.

Louis Stokes Cleveland Department of VAMC information accessed from http://www.cleveland.va.gov.

Lorig, K.R. & Holman, H.R.(2003). Self-management education: History, definition, outcomes, and mechanism, *Ann Behav Med*, 26(1), 1-7

Lotufo, P. A., Gaziano, J. M., Chae, C. U., Ajani, U. A., Moreno-John, G., Buring, J. E., et al. (2001). Diabetes and all-cause and coronary heart disease mortality among US male physicians. *Archives of Internal Medicine, 161*(2), 242-247.

Luck, J., Peabody, J. W., Dresselhaus, T. R., Lee, M., & Glassman, P. (2000). How well does chart abstraction measure quality? A prospective comparison of standardized patients with the medical record. *The American Journal of Medicine, 108*(8), 642-649.

Lüscher, T., Creager, M. A., Beckman, J. A., & Cosentino, F. (2003). Diabetes and vascular disease: Pathophysiology, clinical consequences, and medical therapy: Part II. *Circulation, 108*(13), 1655-1661.

Mangione-Smith, R., Schonlau, M., Chan, K. S., Keesey, J., Rosen, M., Louis, T. A., et al. (2005). Measuring the effectiveness of a collaborative for quality improvement in pediatric asthma care: Does implementing the chronic care model improve processes and outcomes of care? *Ambulatory Pediatrics, 5*(2), 75-82.

Masharani, U., & Karam, J. H. (2002). Diabetes mellitus & hypoglycemia. In L. M. Tierney, S. J. McPhee & M. A. Papadakis (Eds.), *2002 Current Medical Diagnosis and Treatment: Adult ambulatory and inpatient management* (41st ed., pp. 1203-1220). New York: McGraw-Hill.

Masley, S., Phillips, S., & Copeland, J. R. (2001). Group office visits change dietary habits of patients with coronary artery disease-the dietary intervention and evaluation trial (D.I.E.T.). *The Journal of Family Practice, 50*(3), 235-239.

Mathura, K. C., Vaidya, B., & Gurbacharya, D. L. (2005). Study of serum lipid profile in type 2 diabetic patients attending KMCTH. *Nepal Medical College Journal : NMCJ, 7*(2), 97-100.

McCartney, P. R. (2004). The new networking. centering pregnancy: A renaissance in prenatal care? *MCN: The American Journal of Maternal Child Nursing, 29*(4), 261-261.

McCulloch, D. K., Davis, C., Austin, B. T., & Wagner, E. H. (2004). Constructing a bridge across the quality chasm: A practical way to get healthier, happier patients, providers, and health care delivery systems. *Diabetes Spectrum, 17*(2), 92-96.

McEvoy, P., & Barnes, P. (2007). Using the chronic care model to tackle depression among older adults who have long-term physical conditions. *Journal of Psychiatric & Mental Health Nursing, 14*(3), 233-238.

McNamara, P (2006) "Foreword: Payment Matters? The Next Chapter" *Medical Care Research and Review*, February;63(1Suppl):5S-10S

Miller, D., Zantop, V., Hammer, H., Faust, S., Grumbach, K. (2004). Group Medical Visits for low income Women with Chronic Disease: A Feasibility Study, *J Women's Health*, 13(2). p.217-225.

Moore, K. D., & Coddington, D. C. (2002). Models of care that meet the standards of crossing the quality chasm: A new health system for the 21st century. *Journal of Ambulatory Care Management, 25*(1), 12-21.

Musil, C. M., Warner, C. B., Yobas, P. K., & Jones, S. L. (2002). A comparison of imputation techniques for handling missing data. *Western Journal of Nursing Research, 24*(7), 815-829.

Nagy, E., Watine, J., Bunting, P. S., Onody, R., Oosterhuis, W. P., Rogic, D., et al. (2008). Do guidelines for the diagnosis and monitoring of diabetes mellitus fulfill the criteria of evidence-based guideline development? *Clinical Chemistry, 54*(11), 1872-1882.

National Diabetes Education Program (NDEP) in partnership with NIH and CDC accessed at http//: ndep.nih.gov/diabetes/diabetes.htm

Noffsinger, E.B. (2003) Working Smarter: Group visits save time*:* accessed at *PhysiciansPractice. Business web site for physicians* at http://www.physicianspractice.com/

Noffsinger, E.B, (2007) Use of group visits for the care of the chronically ill, in Nuovo, J, *Chronic disease management*. New York, NY: Springer.

Noffsinger, E. B. (2009). *Running group visits in your practice*. Dordrecht ; New York: Springer.

Noffsinger, E.B., Sawyer, D.R., & Scott, J.C. (2003). Group Medical Visits: a glimpse into the future? *Patient care nurse pract*, 14.

Noffsinger, E. B., & Scott, J.C.(2000). Understanding Today's Group Visit Models, *Group Pract J*, 68(2), p. 56-58.

Norris, S. L., & Olson, D. E. (2004). Implementing evidence-based diabetes care in geriatric populations: The chronic care model. *Geriatrics, 59*(6), 35-40.

Nuovo, J. (2007). *Chronic disease management*. New York, NY: Springer.

Nutting, P. A., Dickinson, W. P., Dickinson, L. M., Nelson, C. C., King, D. K., Crabtree, B. F., et al. (2007). Use of chronic care model elements is associated with higher-quality care for diabetes. *Annals of Family Medicine, 5*(1), 14-20.

Oprea, L., Braunack-Mayer, A., Rogers, W. A., & Stocks, N. (2010). An ethical justification for the chronic care model (CCM). *Health Expectations, 13*(1), 55-64.

O'Rourke, R. A. (2005). Should patients with type 2 diabetes asymptomatic for coronary artery disease undergo testing for myocardial ischemia? *Nature Clinical Practice.Cardiovascular Medicine, 2*(10), 492-493.

Pan, L., Fergusson, D., Schweitzer, I., & Hebert, P. C. (2005). Ensuring high accuracy of data abstracted from patient charts: The use of a standardized medical record as a training tool. *Journal of Clinical Epidemiology, 58*(9), 918-923.

Palaniappan, L.P., Muzaffar, A.L., Wang, E.J., et al (2011). Shared Medical Appointments: Promoting Weight loss in a Clinical Setting, *J Am Board Fam Med* , 24(3) p.326-328.

Papaioannou, G. I., Seip, R. L., Grey, N. J., Katten, D., Taylor, A., Inzucchi, S. E., et al. (2004). Brachial artery reactivity in asymptomatic patients with type 2 diabetes mellitus and microalbuminuria (from the detection of ischemia in asymptomatic diabetics-brachial artery reactivity study). *The American Journal of Cardiology, 94*(3), 294-299.

Parchman, M., & Kaissi, A. A. (2009). Are elements of the chronic care model associated with cardiovascular risk factor control in type 2 diabetes? *Joint Commission Journal on Quality & Patient Safety, 35*(3), 133-138.

Parchman, M. L., Zeber, J. E., Romero, R. R., & Pugh, J. A. (2007). Risk of coronary artery disease in type 2 diabetes and the delivery of care consistent with the chronic care model in primary care settings: A STARNet study. *Medical Care, 45*(12), 1129-1134.

Patients with diabetes have better glucose control when they receive care at primary care clinics that adhere to the chronic care model.(2008). *AHRQ Research Activities,* (333), 17-19.

Patrician, P. A. (2002). Multiple imputation for missing data. *Research in Nursing & Health, 25*(1), 76-84.

Pearson, M. L., Wu, S., Schaefer, J., Bonomi, A. E., Shortell, S. M., Mendel, P. J., et al. (2005). Assessing the implementation of the chronic care model in quality improvement collaboratives. *Health Services Research, 40*(4), 978-996.

Peeples, M. M. (2006). From the president. AADE board adopts chronic care model. *Diabetes Educator, 32*(1), 35-36.

Piatt, G. A., Orchard, T. J., Emerson, S., Simmons, D., Songer, T. J., Brooks, M. M., et al. (2006). Translating the chronic care model into the community: Results from a randomized controlled trial of a multifaceted diabetes care intervention. *Diabetes Care, 29*(4), 811-817.

Plutzky, J. (2003). The vascular biology of atherosclerosis. *The American Journal of Medicine, 115 Suppl 8A*, 55S-61S.

Psaty, B. M., Heckbert, S. R., Koepsell, T. D., Siscovick, D. S., Raghunathan, T. E., Weiss, N. S., et al. (1995). The risk of myocardial infarction associated with antihypertensive drug therapies. *JAMA: Journal of the American Medical Association, 274*(8), 620-625.

Reid, J. (2007): Centering Pregancy: A model for group prenatal care. *Nursing for Women's Health, 11*(4), 382-388.

Rijswijk, C., Zantinge, E., Seesing, F., Raats, I., & van Dulmen, S. (2010). Shared and individual medical appointments for children and adolescents with type 1 diabetes; differences in topics discussed? *Patient Education & Counseling, 79*(3), 351-355.

Rondeau, K. V., & Bell, N. R. (2009). The chronic care model: Which physician practice organizations adapt best? *Healthcare Management Forum, 22*(4), 31-39.

Rothe, U., Muller, G., Schwarz, P. E., Seifert, M., Kunath, H., Koch, R., et al. (2008). Evaluation of a diabetes management system based on practice guidelines, integrated care, and continuous quality management in a federal state of Germany: A population-based approach to health care research. *Diabetes Care, 31*(5), 863-868.

Sadur, C. N., Moline, N., Costa, M., Michalik, D., Mendlowitz, D., & Roller, S. (1999). Diabetes management in a health maintenance organization: Efficacy of care using cluster visits. *Diabetes Care, 22*(12), 2011-2017.

Saltiki, K., Cimponeriu, A., Lili, K., Peppa, M., Anastasiou, E., & Alevizaki, M. (2008). Severity of coronary artery disease in postmenopausal diabetic women. *Hormones (Athens, Greece), 7*(2), 148-155.

Sanchez, I. (2011). Implementation of a diabetes self-management education program in primary care for adults using Shared Medical Appointments, *Diab Educ*, 37(3), 381-391.

Sasso, F. C., Torella, D., Carbonara, O., Ellison, G. M., Torella, M., Scardone, M., et al. (2005). Increased vascular endothelial growth factor expression but impaired vascular endothelial growth factor receptor signaling in the myocardium of type 2 diabetic patients with chronic coronary heart disease. *Journal of the American College of Cardiology, 46*(5), 827-834.

Schmidt, M. Lindenauer, P.K., Fitzgerald, J.L & Benjamin, E.M. (2002). Forecasting the impact of a Clinical Practice Guidelines for Perioperative beta-blockers to reduce Cardiovascular Risk, *Arch Intern Med*. 162: 63-69.

Schnurr, P. P., Lunney, C. A., Bovin, M. J., & Marx, B. P. (2009). Posttraumatic stress disorder and quality of life: Extension of findings to veterans of the wars in Iraq and Afghanistan. *Clinical Psychology Review, 29*(8), 727-735.

Scott, J., Connor, D., Venohr, I., Gade, G., McKenzie, M., Kramer, AM., Bryant, L., & Beck, A. (2004). Effectiveness of a group outpatient visit model for chronically ill older health maintenence organization members: A 2-year randomized trial of the cooperative care clinic. *JAGS, 52*(9), 1463-1470.

Scott, J. C., Conner, D. A., Venohr, I., Gade, G., McKenzie, M., Kramer, A. M., et al. (2004). Effectiveness of a group outpatient visit model for chronically ill older health maintenance organization members: A 2-year randomized trial of the cooperative health care clinic. *Journal of the American Geriatrics Society, 52*(9), 1463-1470.

Seal, K. H., Bertenthal, D., Miner, C. R., Sen, S., & Marmar, C. (2007). Bringing the war back home: Mental health disorders among 103,788 US veterans returning from Iraq and Afghanistan seen at department of veterans affairs facilities. *Archives of Internal Medicine, 167*(5), 476-482.

Simons, M. (2005). Angiogenesis, arteriogenesis, and diabetes: Paradigm reassessed? *Journal of the American College of Cardiology, 46*(5), 835-837.

Smith, E. (2006). Using Secondary Data in Educational and Social Research. New York: McGraw-Hill

Solberg, L. I., Crain, A. L., Sperl-Hillen, J., Hroscikoski, M. C., Engebretson, K. I., & O'Connor, P. (2006). Care quality and implementation of the chronic care model: A quantitative study. *Annals of Family Medicine, 4*(4), 310-316.

Stolar, M. W., & Chilton, R. J. (2003). Type 2 diabetes, cardiovascular risk, and the link to insulin resistance. *Clinical Therapeutics, 25 Suppl B*, B4-31.

Strano-Paul, L., & Phanumas, D. (2000). Diabetes management. analysis of the American diabetes association's clinical practice recommendations. *Geriatrics, 55*(4), 57-62; quiz 65.

Strickland, P. A., Hudson, S. V., Piasecki, A., Hahn, K., Cohen, D., Orzano, A. J., et al. (2010). Features of the chronic care model (CCM) associated with behavioral counseling and diabetes care in community primary care. *Journal of the American Board of Family Medicine, 23*(3), 295-305.

Stroebel, R. J., Broers, J. K., Houle, S. K., Scott, C. G., & Naessens, J. M. (2000). Improving hypertension control: A team approach in a primary care setting. *The Joint Commission Journal on Quality Improvement, 26*(11), 623-632.

Stroebel, R. J., Gloor, B., Freytag, S., Riegert-Johnson, D., Smith, S. A., Huschka, T., et al. (2005). Adapting the chronic care model to treat chronic illness at a free medical clinic. *Journal of Health Care for the Poor & Underserved, 16*(2), 286-296.

Stryer, D., & Clancy, C. (2005). Patients' safety: Progress is elusive because culture in health care has not changed. *BMJ: British Medical Journal, 330*(7491), 553-554.

Taviera, T.H., Dooley, A.G., Cohen, L.B, Khantana, S.A. (2011). Pharmacist-led Group Medical Appointments for the management of Type 2 Diabetes with Comorbid Depression in Older adults, *The Annals of Pharmacotherapy*, 45, p. 1346-1355.

Thacker, H. L., Maxwell, R., Saporito, J., & Bronson, D. (2005). Innovations in clinical care. shared medical appointments: Facilitating interdisciplinary care for midlife women. *Journal of Women's Health (15409996), 14*(9), 867-870.

Transforming healthcare: IOM panel discusses vision and reality after crossing the quality chasm... institute of medicine.(2004). *Quality Letter for Healthcare Leaders*, *16*(3), 9-12.

Trento, M., Passera, P., Bajardi, M., Tomalino, M., Grassi, G., Donnola. C., et al. (2002). Lifestyle intervention by group care prevents deterioration of type II diabetes: A 4-year controlled clinical trial. *Diabetologia*, *45*, 1231-1239.

Trento, M., Passera, P., Borgo, E., Tomalino, M., Bajardi, M., Cavallo, F., et al. (2004). A 5-year randomized controlled study of learning, problem solving ability, and quality of life modifications in people with type 2 diabetes managed by group care. *Diabetes Care, 27*(3), 670-675.

Trento, M., Passera, P., Bajardi, M., Tomalino, M., Grassi, G. Borgo, E., & Donnola, C., Cavallo, F., et al. (2002). Lifestyle intervention by group care prevents deterioration of type II diabetes: A 4-year randomized controlled clinical trial. *Diabetologia, 45*, 1231-1239.

Trento, M., Borgo, E., Kucich, C., Passera, P., Trinetta, A., Charrier, L., et al. (2009). Quality of life, coping ability, and metabolic control in patients with type 1 diabetes managed by group care and a carbohydrate counting program. *Diabetes Care*, *32*(11), e134-e134.

Trento, M., Passera, P., Borgo, E., Tomalino, M., Bajardi, M., Cavallo, F., et al. (2004). A 5-year randomized controlled study of learning, problem solving ability, and quality of life modifications in people with type 2 diabetes managed by group care. *Diabetes Care, 27*(3), 670-675.

Trento, M., Passera, P., Tomalino, M., Bajardi, M., Pomero, F., Allione, A., et al. (2001). Group visits improve metabolic control in type 2 diabetes: A 2-year follow-up. *Diabetes Care, 24*(6), 995-1000.

Trento, M., Tomelini, M., Basile, M., Borgo, E., Passera, P., Miselli, V., et al. (2008). The locus of control in patients with type 1 and type 2 diabetes managed by individual and group care. *Diabetic Medicine*, 25(1), 86-90.

Treseler, K.M (1994). Clinical Laboratory and Diagnostics Tests: Significance and Nursing Implications: 3rd Ed. Prentice Hall, Englewood Cliffs, NJ.

Type 2 diabetes mellitus. (2000). In H. David Humes (Ed.), *Kelley's textbook of internal medicine* (4th edition ed.,). Philadelphia, PA: Lippincott, Williams & Wilkins.

Von Korff, M., Gruman, J., Schaefer, J., Curry, S. J., & Wagner, E. H. (1997). Perspective. collaborative management of chronic illness. *Annals of Internal Medicine, 127*(12), 1097-1102.

Wagner, E. H. (1998). Chronic Disease Management: what will it take to improve care for chronic illness. *Eff Clin Pract, 1,* p 2-4

Wagner, E. H. (2000). The role of patient care teams in chronic disease management. *BMJ: British Medical Journal, 320*(7234), 569-572.

Wagner, E. H. (2001). Meeting the needs of chronically ill people: Socioeconomic factors, disabilities, and comorbid conditions are obstacles. *BMJ: British Medical Journal, 323*(7319), 945-946.

Wagner, E. H. (2004). Chronic disease care. *BMJ: British Medical Journal, 328*(7433), 177-178.

Wagner, E. H. (2004). Deconstructing heart failure disease management. *Annals of Internal Medicine, 141*(8), 644-646.

Wagner, E. H. (2007). Diversifying the options for interacting with patients. *Quality & Safety in Health Care, 16*(5), 322-323.

Wagner, E. H., Austin, B. T., Davis, C., Hindmarsh, M., Schaefer, J., & Bonomi, A. (2001). Improving chronic illness care: Translating evidence into action: Interventions that encourage people to acquire self-management skills are essential in chronic illness care. *Health Affairs, 20*(6), 64-78.

Wagner, E. H., Grothaus, L. C., Sandhu, N., Galvin, M. S., McGregor, M., Artz, K., et al. (2001). Chronic care clinics for diabetes in primary care: A system-wide randomized trial. *Diabetes Care, 24*(4), 695-700.

Wagner, E. H., & Groves, T. (2002). Care for chronic diseases: The efficacy of coordinated and patient centered care is established, but now is the time to test its effectiveness. *BMJ: British Medical Journal, 325*(7370), 913-914.

Wagner, E. H., Sandhu, N., Newton, K. M., McCullocj, D. K., Ramsey, S. D., & Grothaus, L. C. (2001). Effect of improved glycemic control on health care costs

and utilization. *JAMA: Journal of the American Medical Association, 285*(2), 182-189.

Watson, K. E., Peters Harmel, A. L., & Matson, G. (2003). Atherosclerosis in type 2 diabetes mellitus: The role of insulin resistance. *Journal of Cardiovascular Pharmacology and Therapeutics, 8*(4), 253-260.

Watts, S. A., Gee, J., O'Day, M. E., Schaub, K., Lawrence, R., Aron, D., et al. (2009). Nurse practitioner-led multidisciplinary teams to improve chronic illness care: The unique strengths of nurse practitioners applied to shared medical appointments/group visits. *Journal of the American Academy of Nurse Practitioners, 21*(3), 167-172.

Wheelock, C., Savageau, J. A., Silk, H., & Lee, S. (2009). Improving the health of diabetic patients through resident-initiated group visits. *Family Medicine, 41*(2), 116-119.

Whittemore, R & Grey, M. (2006). Experimental and Quasiexperimental Designs. In LoBiondo-Wood, G., & Haber, J. Eds. Nursing Research: Methods and critical appraisal for evidence-based practice. (6th edition ed.,). St. Louis, Missouri: Mosby.

Whittemore, R & Grey, M. (2006). Data Collection Methods. In LoBiondo-Wood, G., & Haber, J. Eds. Nursing Research: Methods and critical appraisal for evidence-based practice. (6th edition ed.,). St. Louis, Missouri: Mosby.

Wolfe, A. (2001). Policy highlight. institute of medicine report: Crossing the quality chasm: A new health care system for the 21st century, part 2. *Policy, Politics, & Nursing Practice, 2*(3), 233-235.

Yehle, K.S., Sands, L.P., Rhynders, P.A., Newton, G.A. (2009). The effect of shared medical visits on knowledge and self-care in patients with heart failure: *Heart and Lung*, 38(1), p. 25-33.