ADHERENCE, GOAL-SETTING, AND CARDIOVASCULAR RISK REDUCTION AMONG THE VETERAN POPULATION

A DISSERTATION SUBMITTED TO THE GRADUATE DIVISION OF THE UNIVERSITY OF HAWAI'I IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY

IN

NURSING

DECEMBER 2009

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DEDICATION PAGE

This dissertation is dedicated to my sons Jeremy and Matthew.

Hold fast to your dreams (Hughes, 1965)

ACKNOWLEDGEMENTS

I am very grateful to Dr. Merle Kataoka-Yahiro for her expert guidance throughout this process. I would like to thank Dr. Francisco Conde, Dr. Debra Mark, Dr. Victoria Niederhauser, and Dr. John Grove who served on my committee. I would like to thank the administration and staff at the Department of Veterans Affairs Medical Center and recognize Dr. David Buyck who served on my committee and helped me navigate the research process. A special thank you to Marla Acosta, James Callahan, Aeza Hafalia, and Wanda Takayama for their assistance and the library staff at the University of Hawai'i for their prompt replies to my requests for articles. I would like to thank my family and friends for their encouragement. I would like to acknowledge the financial support of the Nurses Educational Funds, Inc. and Sigma Theta Tau. Finally I would like to express my gratitude for the love and support of my sons Jeremy and Matthew who I hold most dear.

The Department of Veterans Affairs Medical Center provided no research funding for this study. The views expressed in this dissertation are those of the author and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government. Portions of chapter one and two have been published as a result of this work with the knowledge and agreement of the journal publishers and this committee. Wiley and Blackwell publishers (Nursing Forum) allow pre-peer review publication of manuscripts in institutional repositories with appropriate acknowledgement to the journal and state that authors are free to reuse all of their tables, data, and figures without any restrictions. Lippincott publishers (The Journal of Cardiovascular Nursing) have likewise agreed to publication in ProQuest as the work is substantially changed following the journal's peer review process.

ABSTRACT

Purpose: Determine the prevalence of cardiovascular risk factors and to examine the influence of patient adherence and patient-provider goal-setting and decision support on factors related to cardiovascular disease risk among veterans receiving outpatient care.
Design: Secondary data analysis of de-identified medical records of 1,865 veterans, aged 18-89 years old, who received outpatient primary care services at least twice over a two-year time period between 2003-2007 at a Department of Veterans Affairs Medical Center. Descriptive statistics were used to describe the prevalence of cardiovascular risk factors. The association among patient adherence and patient-provider goal setting and decision support on body mass index, HbA1c, and LDL cholesterol was examined using generalized estimating equations with exponential regression.
Findings: 1,579 (84.7%) veterans were 50 years or older in 2007, 22.9% had an existing diagnosis of cardiovascular disease, 26.2% had diabetes, and 6.6% had both cardiovascular disease and diabetes. Nearly 40% of the sample was considered obese with a BMI $\geq$30. Twenty-eight percent had an LDL higher than recommended but risk levels declined from 42.9% high risk cases in 2003 to 24.2% high risk cases in 2007. Over three-quarters of the sample reported a smoking history. Patient-provider goal setting was not a predictor of BMI, however, cholesterol medication prescribed, age, and number of visits was significant. Patient-provider goal setting was a significant predictor of HbA1c and LDL along with educational class attendance, cholesterol medication prescribed, age, and type of health care provider.
Conclusions: Veterans in this study were at high risk for cardiovascular disease. Patient-provider goal setting, educational class attendance, cholesterol medication prescribed, age, and type of health care provider were significant predictors of HbA1c and LDL. BMI levels remained steady as weight loss requires a great deal more effort. The gap between behavioral intention and action is a challenge in obesity management. Future prospective studies are needed to further define the relationship between patient adherence and patient-provider goal-setting and decision support and develop culturally sensitive and innovative programs among this population.

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LIST OF ABBREVIATIONS AND SYMBOLS

ADA	American Diabetes Association
AHA	American Heart Association
AR1	autoregressive model
ATP III	adult treatment panel III
BMI	body mass index
CAD	coronary artery disease
CDC	Center for Disease Control and Prevention
CHF	congestive heart failure
COACH	coaching patients on achieving cardiovascular health
CPRS	computerized patient record system
CVD	cardiovascular disease
DM	diabetes mellitus
GEE	generalized estimating equations
HbA1c	glycosylated hemoglobin
HBM	health belief model
LDL	low-density lipoprotein
MD	medical doctor (physician)
MOVE!	managing overweight and obesity in veterans *e*verywhere
NCEP	national cholesterol education program
NP	nurse practitioner
PA	physician assistant
QUERI	quality enhancement research initiative

RCT	randomized controlled trial
RISKO	American Heart Association health risk appraisal
SCT	social cognitive theory
TPB	theory of planned behavior
TRA	theory of reasoned action
TTM	transtheoretical model
VHA	Veterans Health Administration
VAMC	Department of Veterans Affairs Medical Center
WHO	World Health Organization

CHAPTER 1. INTRODUCTION

Background

Nurses have been in the forefront of health promotion efforts since the establishment of formal public health initiatives in the United States in the early 1900's. Nursing leaders guided the development of outpatient care and preventive health services which has continued to this day. The current focus in medical care is moving toward patient self-management, promotion of patient adherence, and collaboration in practice to prevent and delay the progression of cardiovascular disease.

Cardiovascular Disease: Public Health Significance

Cardiovascular disease is the number one cause of death in the United States and claims the lives of over 700,000 people annually (Center for Disease Control and Prevention, 2004). The direct and indirect costs of cardiovascular disease are estimated at $156 billion a year (American Heart Association, 2008). Cardiovascular disease is believed to affect 70 million Americans and is the leading cause of disability with two thirds of those experiencing a myocardial infarction never returning to their previous level of functioning (AHA, 2008).

Cardiovascular disease is caused by fatty deposits which build up and narrow the coronary arteries; this condition is called atherosclerosis. When the arteries narrow, the heart receives less oxygen and nutrients leading to angina pectoris (chest pain), acute myocardial infarction, congestive heart failure, and/or sudden death (Campione, 2005). Low density lipoprotein (LDL) cholesterol levels are the primary target of prevention through medication and dietary change to reduce cardiovascular disease risk (ATP, 2004). See Figure one for a review of costs associated with cardiovascular disease.

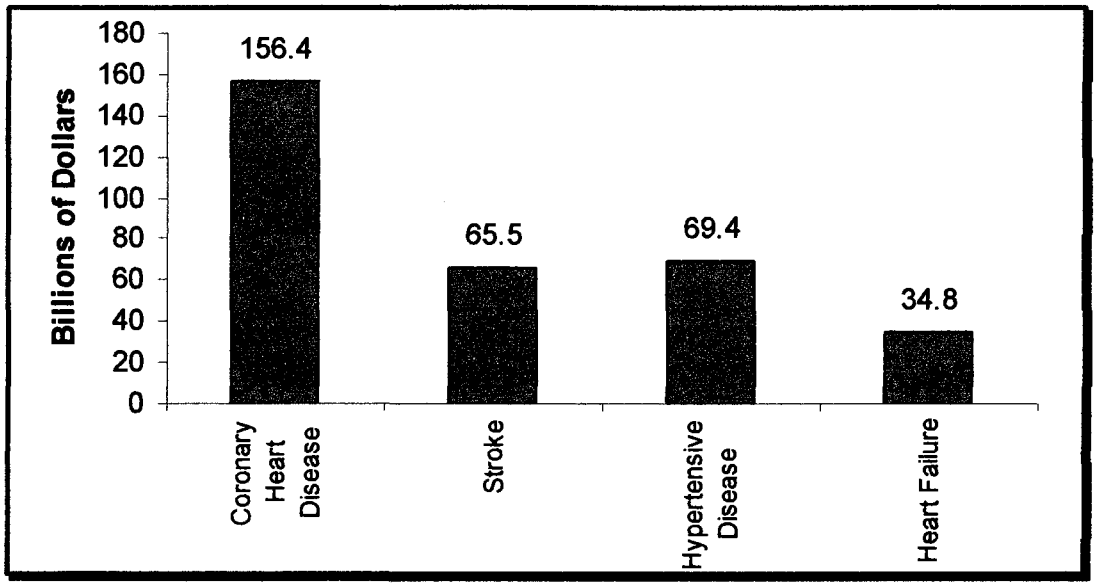


Figure 1. Estimated direct and indirect costs of major cardiovascular diseases and stroke (AHA, 2008, p.37).

Risk Factors for Cardiovascular Disease

Cardiovascular disease risk can be reduced through changes in health behavior and patient adherence to lifestyle recommendations (CDC, 2004). Modifiable risk factors for cardiovascular disease include obesity, hypertension, hyperlipidemia, and diabetes (Kirk, Poirier, Mattox, Thomas, & Michielutte, 2002). Diabetes is considered a cardiovascular disease risk equivalent; rates of coronary events in patients with diabetes are as high as those with established heart disease (Johnson, Pietz, Battleman, & Beyth, 2006). Major risk factors for cardiovascular disease include (ATP, 2004):

a. Age (men $\geq$ 50 years, women $\geq$ 55 years)

b. Family history of premature CVD (CVD in a male first-degree relative < 55 years; CVD in a female first-degree relative < 65 years)

c. Current cigarette smoking

d. Hypertension (BP ≥ 140/90 mm Hg or on antihypertensive medication)

e. Low HDL cholesterol < 40 mg/dL

f. Elevated LDL cholesterol >130 mg/dl (LDL<100 mg/dl is optimal)

g. Diabetes mellitus

h. Obesity and physical inactivity

Overall nonadherence to health recommendations are estimated between 50%-80% for chronic disease management, medication, and lifestyle changes (Delamater, 2006; Karner, Goransson, & Bergdahl, 2002; World Health Organization, 2003). National surveys show that only 38% of patients meet their cholesterol goals, 65% are obese or overweight, 21% smoke, and only 30% exercise regularly (Andal, 2006). Nonadherence costs in the United States are estimated at over $100 billion annually with another $52 billion in lost earnings and productivity (Peterson, Takiya, & Finley, 2003).

Cardiovascular Disease Risk among Veteran and Active Military Populations

One out of every five deaths in the United States is due to cardiovascular disease with rates among veterans at least as high as the general population (Damschroder, 2008). Elevated cholesterol, diabetes, tobacco use, and hypertension are risk factors for cardiovascular disease (Fonarow, 2007). The prevalence of overweight veterans is estimated at 73% and those categorized as obese (BMI>30) is 33% (Damschroder, 2008; Kinsinger, 2006). Eighty percent of veterans have more than two risk factors for heart disease, one being elevated LDL cholesterol (Voils, 2008). One in six veterans have diabetes with many more having metabolic syndrome (Aron, 2008). Seven percent of veterans have hypertension and veterans have a 43% higher smoking rate than nonveterans (Farmer-Coste, 2006; Natarajan, 2008). An estimated 500,000 veterans have

a diagnosis of ischemic heart disease based on computer generated diagnosis codes (McDonnell, 2008).

Active military personnel are also at risk for cardiovascular disease. The military consists of primarily young men under age 34 who are more likely to take risks with their health and use tobacco, alcohol, and prescription drugs than the general population (Bray, Olmsted, Williams, Sanchez, & Hartzell, 2006; Harada, et al., 2002). Several Healthy People 2000 objectives related to cardiovascular risk were reviewed by Bray et al. In that study, active duty men and women completed surveys (n= 46,213) in the years 1995, 1998, and 2002 and reported high rates of cigarette smoking, elevated blood pressure, high cholesterol, and obesity. Bray et al. found that 53% of active military personnel were overweight per NHLB1 guidelines (2000) which was higher than civilian estimates but reflects the trends of the general U.S. population.

Patient decision-making and patient adherence to health recommendations are influenced by military socialization, combat trauma, issues of control, and expectation of self reliance (Alcaras & Roper, 2006). Military personnel, especially combat veterans and prisoners of war, are exposed to high levels of stress and are at risk for depression and posttraumatic stress disorder, which affect their lifestyle and health decisions (Jakupcak, Osborne, Michael, Cook, & McFall, 2006). Soldiers are exposed to the constant threat of death and injury in combat as well as other potentially dangerous occupational exposures (Helmer et al., 2007). Military service is very demanding physically and the impact of physical disability and the sick role can profoundly affect their career (Alcaras & Roper, 2006). They are also more likely to suffer gender role stress (hyper-masculine norms),

have difficulty coping with anger and fear expressing emotions, do not seek out social support, and are more likely to engage in high risk behaviors (Jakupcak et al., 2006).

Adult Treatment Panel III Guidelines for Cardiovascular Disease Risk Reduction

This section provides a brief overview of the clinical guidelines for cardiovascular disease risk reduction and management. Cardiovascular disease risk reduction includes screening patients for risk factors and diagnosing disease, initiating medications as appropriate, providing education about healthy lifestyle, and performing appropriate monitoring and follow up. An integral part of cardiovascular disease risk reduction is health care provider and patient collaboration to meet therapeutic goals derived from evidence based practice guidelines. The National Cholesterol Education Program (NCEP) developed by the National Heart, Lung, and Blood Institute periodically releases updated evidence based guidelines for reduction of cardiovascular risk and management of patients with existing disease.

The most recent guidelines published in 2004, the Adult Treatment Panel III (ATP III), reviews the results of five major clinical trials and sets a standard of care for clinical practice related to cardiovascular disease. The guidelines emphasize patient-provider adherence, screening/detection, and treatment with therapeutic lifestyle changes and medications. Lifestyle changes include weight control, physical activity, tobacco cessation, and reduction in cholesterol. See Table 1 for a summary of the ATP III standards.

Table 1

ATP III Guideline Summary (2004)

LDL Cholesterol - Primary Target of Therapy	LDL <100 mg/dl optimal
Identify presence of clinical atherosclerotic disease that confers high risk for cardiovascular disease events	History CVD
	Symptomatic carotid artery disease
	Peripheral arterial disease
	Abdominal aortic aneurysm
Determine presence of major risk factors (other than LDL)	Cigarette smoking
	Hypertension (BP ≥140/90 mmHg or on antihypertensive medication)
	Low HDL cholesterol (<40 mg/dl)
	Family history of premature CVD (CVD in male first degree relative <55 years; CVD in female first degree relative <65 years)
	Age (men ≥50 years; women ≥55 years)
	Diabetes mellitus
Determine risk category/ Framingham tables	Establish LDL goal of therapy
	Determine need for therapeutic lifestyle changes
	Determine level for medication consideration
Initiate therapeutic lifestyle changes/ medications	Offer education, nutrition referral
Identify and treat metabolic syndrome (elevated glucose and triglycerides, hypertension, obesity, increased waist circumference)	Intensify weight management
	Increase physical activity
	Treat hypertension and hyperlipidemia
	Use aspirin for CVD patients to reduce prothrombotic state

Veterans as a Vulnerable Population

Veterans are a vulnerable group and are aging rapidly with high rates of mental health issues, substance abuse, and homelessness; 30% of the homeless in this country are veterans (National Coalition for Homeless Veterans, 2005). Veterans often utilize the VA health system when they are unable to afford or access care thus placing them in the category of a captive population (Mather, 2008). If dissatisfied with their care, it is difficult for them to transfer to another facility, as the system is set up to encourage veterans to go to the center nearest to their home.

On return from combat, many veterans are hesitant to receive services for post traumatic stress disorder, depression, and anxiety thus affecting their family life, employment, and health care decisions (Jakupcak et al., 2006). Veterans who seek care at VA facilities are more likely to be diagnosed with multiple chronic diseases, have a lower income, and are less able to afford their medications (Hynes et al., 2007; Mather, 2008).

Veterans express conflicting views of participation in research studies. Many feel it is their patriotic duty and obligation to serve as a research participant (Mather, 2008). Other veterans have expressed fear of "being tested on... being a guinea pig" (S.M. Cohen, personal communication, October 2, 2007). Veterans also express concern that they will lose their medical care access if they do not participate in studies, despite reassurance from researchers (Mather, 2008). Because many veterans are dependent on the organization for their medical care and income supplementation (for service connected conditions), the Department of Veterans Affairs closely monitors research

projects. The VAMC also includes statements about the vulnerability of veterans as research participants in their internal review board training and forms.

Patient Adherence to Health Recommendations among Veterans

There are very few long term studies related to cardiovascular risk reduction and patient-provider adherence to recommendations among veterans. As found in other populations, the greatest drop in patient adherence occurs in the first six months of treatment and is influenced by whether patients have symptoms, the complexity of their medication regimen, and the number of medications prescribed (DiMatteo, 2004; Johnson et al., 2006). The lowest persistence rates were found among the elderly which is not surprising given the cost and number of medications they are often prescribed (Johnson, et al, 2006; Mantel-Teeuwisse, Goettsch, Klungel, de Boer, & Herings, 2004).

Less than half of participants met therapeutic goals for hypertension and hyperlipidemia in a retrospective three year study at six VAMCs (Johnson et al., 2006). Researchers found that many veterans do not receive recommended medications, receive insufficient doses of medications to reach their goals, and demonstrate poor adherence to their drug regimen. One year after treatment, only 20% met their blood pressure goals and 25% continued to take their cholesterol lowering medications at five years (Johnson et al, 2006).

Adherence is defined as persistence in the practice and maintenance of desired health behaviors and is the result of active participation and agreement. It is dependent on a collaborative decision-making process and relationship between patient and health care provider (Benner et al., 2002; Carpenter, 2005; Chatterjee, 2006; Treharne, Lyons, Hale, Douglas, & Kitas 2006). The concept of adherence is explored in more depth in Chapter

2 along with a review of the literature related to adherence, goal-setting and decision support, and cardiovascular disease risk reduction. The study methodology is reviewed in Chapter 3. Chapter 4 and 5 contain the data analysis and discussion of the results and implications for practice.

Purpose of the Study

As in the private sector, cardiovascular disease is one of the leading causes of death in the veteran population. It is the primary diagnosis in approximately one out of every 17 veteran hospital admissions (Yu et al., 2003). Cardiovascular disease risk reduction was the focus of this longitudinal study. The purpose of this study was to examine the influence of patient adherence and patient-provider goal-setting and decision support on factors related to cardiovascular disease risk among veterans. The study was a longitudinal study utilizing secondary data encompassing a five-year time frame (2003-2007) reviewing veteran outpatient care data through electronic data extraction and chart reviews at a VAMC. A secondary analysis of five years of intermediate biological outcomes related to patient adherence to recommended cardiovascular disease guidelines was performed. In addition, patient-provider goal setting and decision support as well as demographic information were analyzed.

The study was unique as all of the patients are veterans with few published research studies on adherence and patient-provider goal-setting among this vulnerable population. Few longitudinal studies of this nature were found in the literature as well. The population studied benefitted from the results of this study as part of the Department of Veterans Affairs focus on program improvement and evaluation of standards of care.

The research study questions are presented below followed by a review of the conceptual framework for the study.

The Study Research Questions and Hypotheses were:

1. How prevalent are risk factors for heart disease (age, obesity/ elevated BMI, diabetes, elevated LDL cholesterol, tobacco use) among the veteran population receiving outpatient care?

2. Is patient-provider goal-setting and decision support a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL cholesterol, and HbA1c over the 5-year span of 2003-2007 given that demographic and patient adherence factors are also considered in the model?

Null Hypothesis for Research Question 2: Patient-provider goal-setting and decision support will not significantly predict values of the dependent variables of BMI, LDL, and HbA1c given that demographic and patient adherence factors are also considered in the model.

Alternative Hypothesis for Research Question 2: Patient-provider goal-setting and decision support will significantly predict values of the dependent variables of BMI, LDL, and HbA1c given that demographic and patient adherence factors are also considered in the model.

The next section will provide a general overview of health belief theories related to adherence.

Conceptual Framework

Theories about health behavior provide the framework for understanding patient adherence to recommendations regarding health. The health behavior theories take into

account many factors that influence patient decision-making; however it is the patient's behavioral intentions which ultimately determine if he will make a change. When the patient decides a behavior is important, he will adhere to the plan of care and is more likely to sustain a change over time.

As there are many overlapping theories pertaining to health behavior, the following section will briefly review the major theories that focus on the individual, cognitive perspective. These theories state that a person must believe he is able to perform a behavior and trust there will be a desirable outcome before changing his behavior. The belief in one's ability to change is the main influence on action (Johnston et al., 2004). Increasing motivation for change is essential in influencing the undecided and sustaining a new behavior (Johnston et al., 2004). In addition, belief in personal risk and susceptibility must be present as well as the perception that the benefits of change will outweigh the cost and barriers to adherence (Linde et al., 2006).

Review of Health Belief Theories in Relation to Adherence, Goal-Setting and Decision Support, and Cardiovascular Risk Reduction

Key concepts of the health belief model include perceived susceptibility, severity, benefits, barriers, cues to action and self efficacy. In this model a person weighs the risk of contracting a disease, how severe it will be if untreated, and the cost- benefit ratio. If a patient experiences chest pain (cue to action) for example, he may weigh the cost and time expenditure of traveling to the emergency room in addition to considering if the chest pain evaluation will be painful, inconvenient, or interfere with his afternoon plans. Self efficacy was added to the model later to incorporate changes needed for long term

lifestyle behavior change such as maintenance of a low fat diet and exercise (Glanz, Rimer, & Lewis, 2002).

The theory of reasoned action (TRA) and theory of planned behavior (TPB) overlap. They spotlight behavioral intention with a focus on beliefs, attitudes, intentions, and behavior. TRA "postulates that intentions represent a person's motivation to perform a behavior" and are influenced by attitudes and social expectations (Wang, Charron-Prochownik, Sereika, Siminerio, & Kim, 2006, p.109). The TPB is an extension of TRA with control beliefs, perceived power, and behavioral control added to the model. The TPB states that behavior is influenced by beliefs and attitudes and there is a strong motivation to act on credible information learned and comply with the desires of family and peers (Ajzen, 1991). For example, the patient believes that if he takes his blood pressure medication he will feel better, that feeling better is desirable, his family wants him to take the medication and he wants to please them, and knows that remembering to take the medication will require a change in routine.

Social cognitive theory (SCT) was developed by Bandura and Walters who noted that children learned by observing others (modeling) and did not need direct rewards (vicarious reinforcement) (Glanz et al., 2002). SCT also includes perception of the environment, knowledge and skills, anticipatory outcomes, and self efficacy. This theory adds family and peer support and interaction, reinforcement and the addition of coping strategies, and explains and predicts health related behavior (Glanz et al., 2002). For example in this theory, a partner or spouse models the desired behaviors of eating a low fat diet and exercising, makes changes in the household menu, encourages the family to walk after dinner together, and encourages and reinforces positive behavior change.

The Transtheoretical model (TTM) focuses on progressive stages of readiness for change and decisional balance (consideration of pros and cons of change). With TTM the patient moves toward considering making a change (precontemplation), to deciding he probably should take his blood pressure pill (contemplation), to preparation for change such as making a reminder calendar, to taking the medication and crossing it off on the calendar (action) and finally maintenance of a habitual behavior. Periodic relapse is an expected part of the change process. TTM was developed to address behavior change which is a very complex ongoing process that unfolds over time (Glanz et al., 2002).

None of these models include all aspects of health behavior. Most patients are not ready to embrace change right away and must work their way through the stages of change. Perceived susceptibility to illness and the emotions this arouses are not included in the theory of reasoned action (TRA). However the TRA and TPB are the only cognitive theories that include behavioral intentions which are strong predictors of change (Glanz et al., 2002), and incorporate patient-provider goal-setting which is an excellent method of promoting adherence.

The Andersen behavioral model has been recently adapted and used in research studies that address patient needs related to health care access and adherence to health recommendations. In the model, health behaviors and adherence are influenced by patient predisposing factors (i.e., age, gender, ethnicity, education) and health beliefs, enabling factors such as access to health care and continuity of care, and need as perceived by the patient and health care provider. The framework stresses that providing health care access, education, and decision support enhances patient adherence to healthy lifestyle

recommendations with subsequent improvement in health status. See Table 2 for a comparison of health behavior theories.

Andersen Behavioral Model

The Andersen behavioral model (ABM) provided a conceptual framework for addressing patient needs related to adherence, goal-setting and decision support, and cardiovascular disease risk reduction in this study. The model demonstrates that health behaviors and patient adherence are influenced by patient socio-demographics and health beliefs, enabling factors such as access to health care and continuity of care, and need as perceived by the patient and health care provider. The framework stresses that providing patient-provider goal-setting and decision support enhance patient adherence to healthy lifestyle recommendations. Patient adherence improves health status and biological outcome measures. The model includes health care provider guideline adherence and assessment of patient risk factors for disease. The model focuses on whether current care is effective in improving health and if intention leads to measurable behavioral change.

The ABM has been adapted and used in research studies that address health care access and patient adherence to health recommendations. The model was developed in 1968 and has undergone modifications approximately every 10 years (Andersen, 1995). The major use of the model has been related to health care utilization but it has also been adapted for patient adherence research. De Smet, Erickson, and Kirking (2006) utilized the ABM to evaluate medication adherence to asthma controller medications. They evaluated patient predisposing factors (i.e., age, gender, ethnicity, number of years with asthma) and health beliefs, enabling factors such as income, perceived access to health

care and continuity of care, and need as perceived by the patient and health care provider (patient beliefs regarding symptom severity and quality of life). They found that patient adherence was increased when participants believed treatment was beneficial, and with higher perception of asthma severity and longer duration of diagnosis.

Murray et al. (2004) adapted the model in a narrative review of the literature pertaining to medication adherence in adults over age 50. They examined predisposing characteristics of health beliefs, health literacy and health information, and presence of vision and hearing impairment. Enabling resources included income, distance to health services and transportation, insurance, relationship with provider, and social support. Need included perception of illness and its severity and treatment with prescriptions. Outcomes included improved health related quality of life, improved blood pressure, and increased satisfaction with health care and health care cost and use. This model stresses that providing health care access, education, and decision support enhances patient adherence to healthy lifestyle recommendations with subsequent improvement in health status.

Likewise Campione (2005) used the model to examine patient and physician adherence to cholesterol medication recommendations and associated health outcomes. She found that physician adherence to ordering annual lipid evaluation, follow up and monitoring including provision of feedback regarding goal attainment was a significant influence on patient adherence to recommendations. Figure 2 is a conceptual framework on patient adherence in the context of cardiovascular disease (CVD) which is based on the Andersen behavioral model.

Summary

Cardiovascular disease risk can be reduced through changes in health behavior and patient adherence to health recommendations. Patient-provider goal-setting is an integral part of promoting patient adherence to recommendations and cardiovascular risk reduction. This study examined the effects of patient-provider goal-setting and decision support and patient education on patient adherence and CVD risk reduction among veterans. This study evaluated veteran intermediate biologic outcomes in an effort to improve patient care and provide a platform for the development and support of future programs.

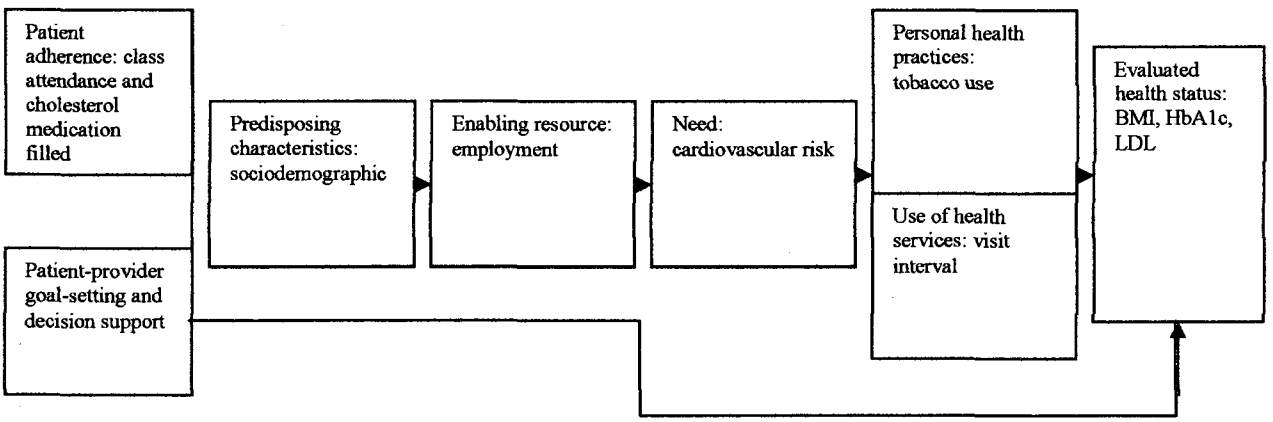


Figure 2. Conceptual framework based on Andersen behavioral model (Andersen, 1995)

Table 2

Comparison of Health Behavior Theories (adapted from Noar & Zimmerman, 2005)

Concept	HBM	TRA	TPB	SCT	TTM	ABM
Attitudinal beliefs: Engaging in the behavior likely if positive outweighs the negative	Benefits, barriers, health motive	Evaluation of beliefs/ attitudes re: behavior	Evaluation of beliefs/ attitudes re: behavior	Outcome expectations expectancies	Pros/ cons/ decisional balance	Health beliefs as predisposing factors
Self efficacy: confidence in one's ability to perform the behavior	Self efficacy	-	Perceived behavioral control	Self efficacy	Self efficacy/ temptation	Predisposing factors
Normative beliefs: social and peer support a change in health behavior	Cues to action: education, symptoms, media	Subjective norms	Subjective norms	Social support, environment reinforcement, norms, modeling	Helping relationship process of change, social liberation, reinforcement/ management stimulus control	Family and social support as enabling resources
Risk related belief: person feels there will be a negative outcome if he engages in unhealthy behavior	Perceived threat, susceptibility severity	–	–	Emotional coping responses/ expectancies, environmental cues	Dramatic relief (process of change)	Perceived need for service and perceived health status
Intention/ commitment/ planning: person has set goals and made a decision regarding behavior	-	Behavioral intentions	Behavioral intentions	Self control/ self regulation	Contemplation preparation, stages of change, liberation	Health behavior, outcomes, care utilization, evaluated health status

Note: HBM= Health belief model, TRA= Theory of reasoned action, TPB= Theory of planned behavior, SCT= Social cognitive theory, TTM= Transtheoretical model, ABM= Andersen behavioral model

CHAPTER 2

REVIEW OF THE LITERATURE ON PATIENT ADHERENCE, PATIENT-PROVIDER GOAL-SETTING, AND CARDIOVASCULAR RISK REDUCTION

> Something [is] wrong with an expensive system of service delivery in which one of its primary products, advice, so often remains unused (DiMatteo, 2004, p.207)

Patient Adherence as a Concept

Adherence has long been a desired patient outcome and differs from compliance as the patient and health care provider agree on the plan of care. The word adherence is viewed more positively than compliance which has its roots in medical paternalism. The term adherence empowers patients to become actively involved in their care, encourages the development of self- management skills, and is intended to be nonjudgmental (McDonald, Garg, & Haynes, 2002). Adherence is defined as persistence in the practice and maintenance of desired health behaviors and is the result of active participation and agreement (Benner et al., 2002; Carpenter, 2005; Chatterjee, 2006; Treharne et al., 2006).

Compliance, in contrast, implies obedience and a passive relationship and views patients as powerless recipients of care (Chatterjee, 2006; Mullen, 1997). Compliance includes the issue of enforcement and bending the will of another (Treharne et al., 2006). The term compliance is falling out of favor due to its negative connotations.

Concordance takes the concept of adherence a step further and is defined as a process of enlightened communication that optimizes health gains and is a harmonious partnership between health care provider and patient (Treharne et al, 2006). Therapeutic alliance and concordance suggest equality, sharing of power, and ongoing negotiation

respecting the beliefs of the patient (Cameron, 1996; Carpenter, 2005; Chatterjee, 2006; Weiss & Britton, 2001). Concordance depends on the ability of the patient to make an informed decision. It is unlikely that the power inequality between health care providers and patients will be completely resolved thus limiting the use of this concept.

Adherence is the heart of this study's focus on therapeutic outcomes of patient-provider relationships. Adherence is useful when looking at the patient's ability to follow recommended health behavior guidelines. Expanding the concept of adherence to include patient-provider concordance or therapeutic alliance reflects the change in health care provision to consensual prescribing, patient-provider, and decision-making. For the purposes of this secondary data analysis, adherence will be measured by patient educational class attendance and cholesterol medication on active medication list.

Adherence is dependent on a collaborative decision-making process and relationship between patient and health care provider (Benner et al., 2002; Carpenter, 2005; Chatterjee, 2006; Treharne et al., 2006). Adherence is not associated with medical paternalism and does not mean loss of personal decision-making or control. Adherence does not take away all responsibility from the health care provider but does make education of the patient a priority so that he can make informed decisions.

Nonadherence is a patient choice that health care providers may disagree with and view as a waste of resources that leads to preventable disease and death (WHO, 2003). Nonadherence, whether intentional or unintentional, occurs when patients who previously agreed with a plan of care do not take their medications correctly due to unclear instructions, forgetfulness, depression, financial constraints, transportation issues, denial, and other factors (Tabor & Lopez, 2004). The negative consequences of poor adherence

to medication and recommended lifestyle changes include: (a) increased office visits, (b) no response or poor response to medications, (c) exacerbation of chronic illness, (d) increased risk of future health problems, (e) hospitalization and invasive procedures, (f) increased risk for future inappropriate medical recommendations, (g) impaired provider-patient relationship, and (h) increased morbidity and mortality (Christophersen & VanScoyoc, 2004). See Table 3 for an overview summarizing the definitions of compliance, adherence, and concordance.

Table 3

Summary of the Definitions of Compliance, Adherence, and Concordance in the Literature

Compliance	Implies obedience and the expectation that patients will passively follow orders (Mullen, 1997). Bending the will of another; yields to health instructions (Murphy & Canales, 2001;Treharne et al., 2006) Paternalistic view that the informed but still passive patient will stick to the treatment plan (Treharne et al., 2006) Extent to which a person's behavior coincides with medical or health advice (Cameron, 1996)

Table 3 (Continued)

Summary of the Definitions of Compliance, Adherence, and Concordance

Adherence	Patients are considered adherent when they do what the health care provider recommends (DiMatteo, 2004) Adherence is defined as persistence in the practice and maintenance of desired health behaviors and is the result of active participation and agreement. It is dependent on a collaborative decision-making process and relationship between patient and health care provider (Benner et al., 2002; Carpenter, 2005; Chatterjee, 2006; Treharne et al., 2006).
Concordance	The process of enlightened communication which leads to an agreed treatment and ongoing assessment of this as the optimal course (Treharne et al., 2006). A consultative process that emphasizes self- management (Weiss & Britten, 2003). The harmonious partnership between health care provider and patient leads to a therapeutic alliance that optimizes health gains compatible with what the patient desires and is capable of achieving (Treharne et al., 2006) Suggests equality, sharing of power and ongoing negotiation and interaction respecting the beliefs of the patient. Concordance depends on the ability of the patient to make their own informed decision; the patient is the decision maker. (Cameron, 1996; Carpenter, 2005; Chatterjee, 2006; Weiss & Britton, 2001). The most important decisions are made by the patient through a reciprocal alliance (Royal Pharmaceutical Society, 1997)

Provider Adherence to Guidelines

Provider adherence is also an integral part of cardiovascular risk reduction. At the Department of Veterans Affairs Medical Centers (VAMC), it is an expectation that health care providers refer interested patients to educational programs on cardiovascular risk reduction. In addition to referral, a clinical reminder system instituted in 2002 alerts the health care provider to patient needs for preventive care. The Computerized Patient Record System (CPRS) is a comprehensive electronic medical record system which allows the health care provider to review and order laboratory and diagnostic tests, order and review medications, and enter referrals (Calabrisi, Czarnecki & Blank, 2002). The health care provider is asked to address electronic clinical reminders at the time of each visit; the clinical reminders in CPRS must be clicked on as they do not "pop up" automatically. Clinical reminders are appropriate to the age and gender of the patient and include the need for annual lipid evaluation, elevated blood pressure recheck, ace inhibitor for diabetics, beta blocker therapy for patients with CVD, body mass index (BMI) above 30, diabetic hbA1c and renal tests, smoking cessation, pneumonia and influenza vaccination, colorectal screening and mammography, depression, PTSD, and other important health factors.

Health care providers at the VAMC are also provided regular updates on clinical guidelines for cardiovascular disease risk reduction. They are given written information on evidence based guidelines and receive regular educational programs about improving patient care and outcomes. Feedback on overall clinic performance related to clinical reminders, emergency room visits and hospital admissions is reviewed at monthly meetings, and the goals for adherence to guidelines for the institution are reviewed. All

members of each clinic team participate in quality improvement initiatives with the goal of health promotion and disease prevention.

Health care providers influence adherence through patient-provider goal-setting and shared decision-making (Vale et al., 2003; Weiss & Britten, 2001). When patients feel supported in their decision-making and there is open communication, adherence to healthy behaviors increases (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Schaffer & Yoon, 2001). Decision support is referred to as shared decision-making in the literature and for the purposes of this study involves the provision of verbal and written feedback on attainment of goals set by the patient and health care provider.

Sustaining change is difficult even for the most motivated person with relapse common (Winnett, Tate, Anderson, Wojcik & Winnett, 2005). Adherence is decreased when patients do not perceive any benefit from changing their behavior (Fodor et al., 1998; Resnick, 2002; Schaffer & Yoon, 2001). Perceived self efficacy is an activator for healthy behaviors but change occurs when the reasons, motives, and goals come from the client (Danhauer, Oliveira, Myll, Berra, & Haskell, 2004; Miller, 2000; Northwehr, 2004; Winnett et al., 2005).

Patient-Provider Adherence Research

Researchers have found that patients who have a trusting secure attachment style rate communication with their health care provider more favorably than those with a dismissing attachment style (Ciechanowski, Katon, Russo, & Walker, 2001). Provider frustration with low treatment adherence may also adversely affect communication with patients (Ciechanowski et al., 2001).

In addition to communication issues, patient outcomes are affected by provider guideline adherence. Health care providers may not follow recommended guidelines affecting optimal medical management (Coon & Zulkowski, 2002). To remedy this, decision support aids and guideline reminders for patients and providers have been found to strongly affect predicted patient outcomes (Datto et al., 2003; Weingarten, 2002). Reasons for clinical inertia include the perception that patient adherence is improving, acute patient illness and refusal, and disagreement with the guidelines (El-Kebbi, Ziemer, Gallina, Dunbar & Phillips, 1999; Powell-Cope, Luther, Neugaard, Vara & Nelson, 2004).

Spitler et al. (2004) evaluated provider adherence to guidelines and use of interdisciplinary teams and education in a U.S. Air Force ambulatory care clinic. She found lower HbA1c, blood pressure readings, and higher rates of aspirin use among patients with diabetes participating in group education and interdisciplinary teams compared to patients followed by their outside primary care provider. They used a model very similar to the one adopted by the VAMC and also utilized a clinical reminder system in the form of a diabetes care record. See Table 4 for a review of studies related to provider adherence and relationships and Table 5 on page 37 for a review of patient-provider barriers to adherence.

Table 4

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

Ciechanowski et al. (2001)	Purpose of study	Evaluate patient and provider factors involved in lack of adherence to treatment in diabetic patients
	Theory	Attachment theory
	Sample	367 patients with type 1 or 2 diabetes in a primary care setting
	Design/ methods and instruments	Quantitative study evaluated glucose control, and adherence to medications and clinic appointments using 7 questionnaires.
	Salient findings	Patients who have a trusting, secure attachment style were more likely to rate provider communication higher and have a lower HbA1c. Provider frustration with poor treatment adherence may adversely influence communication with patients. Patients who have a dismissing, distrustful attachment style had higher HbA1c.

Table 4 (Continued).

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

Coon, & Zulkowski (2002)	Purpose of study	To determine whether rural health care providers were adherent with American Diabetes Association clinical practice guidelines for glycemic, blood pressure, lipid management and preventative services.
	Theory	None noted
	Sample	399 patients over age 45 with diagnosis of diabetes at 4 rural health clinics in Montana
	Design/ methods and instruments	Retrospective chart review
	Salient findings	Health care providers were not adequately following guidelines and patient's diabetes, hypertension, and hyperlipidemia were not being optimally managed. A decision support system for providers with prompted reminders was recommended.

Table 4 (Continued).

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

Datto et al., (2003)	Purpose of study	Evaluated patient- provider adherence to a depression management program
	Theory	None noted
	Sample	154 patients
	Design/ methods and instruments	Retrospective review of a depression management program which assessed patient and provider adherence, timing of clinician assessment and treatment decision-making, and self report of patient adherence to recommendations regarding medication and counseling, CES-D score of 11 was defined as symptom remission
	Salient findings	Provider guideline at 6 weeks predicted 12 week adherence. Patients who adhered to recommendations had decreased depressive symptoms.

CES-D = Center for Epidemiologic Studies Depression Scale

Table 4 (Continued).

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

El-Kebbi et al. (1999).	Purpose of study	To determine whether health care providers appropriately identify patients with poor glycemic control and investigate failure to intensify therapy in these patients.
	Theory	None noted
	Sample	1,144 patient visits at an urban diabetes clinic
	Design/ methods and instruments	Questionnaire given to health care providers after patient visits asking whether a patient's diabetes was well controlled and whether therapy was advanced per management protocol.
	Salient findings	Reasons for failure to intensify therapy included perception that diabetes control was improving, patient was not adherent to diet/ medications, acute patient illness, patient refusal, recurrent hypoglycemia.

Table 4 (Continued).

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

Powell-Cope et al. (2004)	Purpose of study	To test the effect of an intervention on provider adherence to cardiovascular disease guidelines
	Theory	None noted.
	Sample	32 primary care providers, cardiologists, and internists at 3 Veterans Affairs Medical centers
	Design/ methods and instruments	Five focus groups to identify key barriers and facilitators of adherence to guidelines
	Salient findings	Perceived advantages included improvements in quality of care and cost savings. Perceived barriers were the lack of ability to individualize care, guideline access, and high workloads with complex patients. Providers could not reach a consensus about contraindications, difficulty in providing follow up, dosage titration, and patient adherence.

Table 4 (Continued).

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

Spitler et al. (2004).	Purpose of study	To assess the impact of provider education and systems improvement on attainment of clinical goals for patients with diabetes and compare the outcomes of patients who received care from an interdisciplinary team and those who received care from an outside primary care provider.
	Theory	None noted.
	Sample	111 charts were reviewed at a U.S. Air Force ambulatory care clinic
	Design/ methods and instruments	Primary measures were HbA1c, LDL cholesterol and blood pressure. Charts were reviewed for annual recommended screening: foot and eye exams, renal status, and utilization of medications recommended in diabetes and heart disease management guidelines.
	Salient findings	Lower HbA1c, blood pressure readings, and aspirin use among patients with diabetes participating in group education and interdisciplinary teams

Table 4 (Continued).

Review of Studies Related to Provider Adherence and Patient-Provider Relationships.

Weingarten (2002).	Purpose of study	To evaluate published evidence regarding the characteristics and effectiveness of disease management programs
	Theory	None noted
	Sample	102 articles evaluating 118 disease management programs
	Design/ methods and instruments	Meta-analysis of articles published between 1987-2001
	Salient findings	Provider education, feedback, and reminders were associated with significant improvements in provider adherence to guidelines and with significant improvement in patient disease control.

Examination of the antecedents, attributes and outcomes related to adherence and cardiovascular risk reduction help one gain a better understanding of patient decision-making and maintenance of desired behavior.

Review of Antecedents, Attributes, and Outcomes of Adherence and CVD Risk Reduction

Patient adherence is influenced by many factors including trust and the length of the relationship with the health care provider. Before adherence can occur, the health care provider discerns the patient's meaning of health and heart disease, and sense of personal risk. Other factors examined include socioeconomic status, presence of support,

motivation and desire for change, self efficacy and prior knowledge (WHO, 2003). Belief about risk and disease susceptibility is a key component in adherence to recommended guidelines (Conrad, 1985).

Societal messages about health maintenance and available resources for exercise such as presence of neighborhood parks, stores, and restaurants within walking distance and the ability to provide healthy food choices for the family all play a role in cardiovascular health (Ockene, Hayman, Pasternak, Schron, & Dunbar-Jacob, 2002). Family and peer support help the patient adhere to newly adopted behaviors such as following a low fat diet. Patient readiness and motivation for change are also imperative for adherence.

Antecedents related to adherence and cardiovascular risk reduction include perceived health risk status and the meaning of heart disease, patient-provider goal-setting and decision support, presence of health education, health care provider influence and presence of a collaborative relationship, self efficacy, and the influence of socio-demographics. Health risk status may include tobacco use, weight, physical activity, cholesterol measurements, diabetic control, and the presence of pre-existing medical conditions such congestive heart failure and hypertension. Researchers have measured health risk status by counting the number of individual health risks for an individual with zero to one defined as low risk, two as medium risk, and three or more factors as high risk (Musich, Hook, Barnett & Edington, 2003).

Research has shown that belief in personal risk and susceptibility must be present to influence patient adherence. Change only occurs when the importance of risk reduction is appreciated on a personal level and one is motivated to follow recommendations

(Guadagnoli & Ward, 1998). The perceived benefits must also outweigh the cost and barriers to patient adherence for change in health behaviors to occur (Linde, Rothman, Baldwin & Jeffery, 2006). A common belief about cardiovascular disease is that it is a quick desirable death and is not feared as much as other illnesses such as cancer (Emslie, Hunt & Watt, 2001). Cardiovascular disease risk is often underestimated and thought to be a natural part of aging (Emslie et al., 2001). It is not believed to be a chronic disorder yet 66% of people who have a heart attack do not make a complete recovery (CDC, 2004).

Patient-provider goal-setting and decision support and patient education are antecedents to patient adherence. Education must be clear and accurate as mixed messages and health misinformation affect involvement in treatment plan (Woodard, Hernandez, Lees, & Petersen, 2005). Lack of knowledge impacts decision-making and is a factor in poor medication, diet and exercise adherence (Chyun, Amend, Newlin, Langerman & Melkus, 2003; Chockalingam et al, 1998). Tailored print communication increases recall and is perceived as a credible source of health information (Skinner, Campbell, Rimer, Curry & Prochaska, 1999). Decision-making is also influenced by prior experiences. For example, patients often wait until the first heart attack to follow advice. Unfortunately, after the effect of the experience fades, patient adherence decreases (Angus et al., 2005).

Societal support for healthy lifestyles and food choices also impact cardiovascular disease (Ockene et al., 2002). Family and peer support help patients adhere to recommendations regarding low fat diet (Ockene et al., 2002). In addition, simplified

medication regimens help increase adherence (Cameron, 1996; Chockalingam et al., 1998; Johnston, Johnston, Pollard, Kinmonth, & Mant, 2004; Tabor & Lopez, 2004).

Attributes of successful adherence include alignment of patient behavior and provider advice, patient sense of mastery of a new behavior and health knowledge, ongoing collaborative relationships between the patient and health care provider and their perceived ability to meet the outcome targets (Bosworth, Oddone & Weinberger, 2006; Hearnshaw & Lindenmeyer, 2005). The attributes of a successful transition to a healthier lifestyle include health knowledge, presence of social support and sources of credible information. Change that is internally motivated is more likely to be successful rather than the patient seeking to please the provider (Vik, Maxwell & Hogan, 2004).

Adherence implies an interaction and a partnership between patients and health care providers as well as family and friends. This partnership focuses on behavior change, achievement, and mutual goal attainment. If the patient finds positive meaning in his plan of care and views the provider as a caring advocate, patient adherence is improved (Kyngas, 1999; Tabor & Lopez, 2004). Consequences of patient adherence in the setting of a collaborative relationship and patient-provider goal-setting include a sense of mastery, improved confidence, and ability to cope.

The long term outcome of adherence and cardiovascular risk reduction for patients at risk or already diagnosed with heart disease include maintenance of a healthier lifestyle with a subsequent decrease in cardiovascular disease rates and decreased societal financial burden (Tabor & Lopez, 2004). Patients who are adherent to the agreed upon plan of care through shared decision-making have increased patient satisfaction,

improved knowledge of their condition and treatment, improved health outcomes, fewer medication related problems and less wasted medication (Weiss & Britten, 2001).

Patient adherence is a difficult concept to measure but many studies have attempted to quantify it through pill counts, electronic monitoring, self report, laboratory data monitoring and measurement of body mass index, etc (Osterberg & Blaschke, 2005). Researchers have found that patients take less than half of medications prescribed and the more complicated the medication regimen, the less likely the patient will adhere (DiMatteo, 2004; Haynes, Degani, Kripalani, Garg & McDonald, 2005; Tabor & Lopez, 2004). New studies are needed that measure clinical outcomes and patient adherence to healthy behaviors. Such studies would add to the existing literature which focuses on medication usage. Research on medication adherence is an important first step but the precise benefit and amount of adherence required with cholesterol lowering medications is unknown (Applegate, 2002; Kravitz & Melnikow, 2004).

Literature Review

Adherence, Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

This section reviews the literature on adherence, patient-provider goal-setting and decision support, and cardiovascular disease risk reduction. Promotion of adherence to current health guidelines is essential in reduction of cardiovascular disease risk. Health care provider identification of patient risk factors, attention to recommendations for cardiovascular disease prevention, and encouragement of patient involvement in health planning are vital parts of shared decision-making. Patient-provider goal-setting is an

important component of shared decision-making. It is through this alliance that adherence to health recommendations is promoted and cardiovascular disease risk is reduced.

Decision support involves the provision of verbal and written feedback on attainment of goals set by the patient and health care provider. Health care providers offer support and patient education about health care issues and choices while considering patient priorities, values, goals, and abilities. The patient and provider develop a mutually acceptable plan of care and achievable goals through negotiation (Cho, Voils, Yancy, Oddone & Bosworth, 2007). Patient-provider goal-setting is defined as a task that one wants to accomplish which has been set by the patient in concert with the health care provider's guidance and support (Langford et al., 2007). Goals can have varying degrees of difficulty and are a valuable tool in helping patients manage cardiovascular disease and reduce risk factors.

Patient adherence rates were highest in studies that incorporated patient-provider goal-setting and decision support, patient education, self- management techniques, and personalized printed communication (Barlow et al., 2002; Danhauer et al., 2004; Northwehr, 2004; Winett et al, 2005). In order to assist patients in achieving their long term health goals and maintenance of recommended behaviors, health care providers cultivate a collaborative relationship with patients, and develop an awareness of patient beliefs about cardiovascular disease, risk perception, and motivation for change (Lau-Walker, 2006). Gaining patient perspectives about chronic disease and the development of appropriate, achievable goals promotes patient adherence to cardiovascular health recommendations.

Consensual prescribing, patient-provider goal-setting and decision support empower patients and encourage adherence to health recommendations. Health care providers and researchers are challenged to find ways to influence patient perception of cardiovascular risk, increase adherence to recommended prevention guidelines, and meet individual needs for support and education at their level of understanding.

Barriers to Patient and Provider Adherence to Recommendations

Patient and provider adherence to cardiovascular health recommendations reduces morbidity and mortality (ATP III, 2004). However there are multiple barriers to patient-provider adherence. Poor adherence to health recommendations is an issue for patients with and without disease symptoms and is an ongoing challenge for providers. Health care providers often have little training in behavior change, lack support and resources needed, and do not feel equipped to assist patients in maintenance of healthy behaviors (El-Kebbi et al.,1999; Fonarow, 2007; Powell-Cope et al.,2004). See Table 5 for a summary of the literature on patient and provider barriers to adherence.

Table 5

Patient and Provider Barriers to Adherence

Patient barriers to adherence	Inadequate understanding of disease
	Complex treatment regimens, Unclear instructions
	Not involved in plan
	Does not agree with advice
	Poor relationship with provider
	Does not perceive need
	Forgetfulness, cost, time, lack of insurance/ access to care

Table 5 (Continued).

Patient and Provider Barriers to Adherence

Patient barriers to adherence	Worry about medication side effects
	Prescription ran out, difficulty swallowing, problem opening medication container
	Stopping drug to see if still needed
	Not feeling well when taking medication
	Societal beliefs, lack of support
	Cannot exercise outside as concerned about safety/ weather
	More pressing priorities
	Psychiatric co-morbidity, substance abuse
Provider barriers to adherence	Inability to individualize care
	High workloads with many complex patients
	Lack of consensus about guidelines
	Inadequate training, guidelines too complex
	Difficulty in providing follow up and dosage titration
	Patient refusal and nonadherence
	Patient reporting side effects or acute illness thus therapy not maximized.
	Lack of incentive/ lack of reimbursement for extra time
	Insufficient resources and facilities

(El-Kebbi et al.,1999; Fonarow, 2007; Hill et al.,1999; Powell-Cope et al., 2004; Vik, Maxwell & Hogan, 2004; WHO, 2003; Williams, Manias & Walker, 2008).

A descriptive summary of the literature related to patient adherence, patient-provider goal-setting and decision support in the context of cardiovascular disease risk reduction is summarized in Tables 6-8 with a discussion of research methods and salient findings. Table 6 contains a summary of three literature review studies related to patient adherence, decision support, and cardiovascular disease risk reduction. Table 7 contains a review of four qualitative studies and Table 8 contains a summary of 12 quantitative studies related to the same categories including patient-provider goal-setting. There was no mention of the terms patient-provider goal-setting in the meta-analyses.

There was one narrative literature review and two meta-analysis studies included in this section addressing patient-provider adherence and patient decision support, and cardiovascular disease risk reduction. The terminology patient-provider goal-setting was not mentioned in these three review studies. The purpose of the reviews was to assess and compare adherence rates, tools, and methods designed to enhance adherence. The largest meta-analysis was done by DiMatteo (2004) who reviewed 733 studies published in a 50 year time span from 1948-1998. The other two review studies analyzed 33 and 61 studies, respectively, over a 34 year time span between 1966-2001. The review studies were not based on any theoretical models but DiMatteo (2004) mentioned the health belief model, theory of planned behavior, and transtheoretical model in the discussion.

DiMatteo (2004) focused on patient adherence to medically prescribed treatments and preventive measures covering numerous chronic diseases. Cardiovascular disease intervention studies had a mean adherence rate of 76.6% which ranked in the middle of the 17 disease conditions studied. Studies involving patients with mental illness or substance abuse issues or studies involving military personnel were not included due to

concerns about institutional influence on adherence. DiMatteo (2004) confirmed that higher levels of adherence were found with medication regimens as opposed to health behavior change such as diet.

Medication adherence was the focus of the meta-analysis by Peterson et al., (2003). Randomized controlled trials utilizing behavioral interventions, educational interventions, and combined interventions were analyzed. The data sets were not homogenous thus inferences could not be derived from all of the information. Both meta-analyses by DiMatteo (2004) and Peterson (2003) categorized studies by behavioral or education intervention. There was an overall increase in adherence of 4-11% after interventions reviewed in the Peterson (2003) study. As found in the DiMatteo (2004) study, complex medication regimens and studies related to health behaviors, appointment keeping, and dietary change had the lowest rates of adherence.

Greater resources such as income and education resulted in higher rates of adherence in the studies. Age and gender were not related to adherence rates in the Peterson (2003) study but DiMatteo (2004) found that younger adults and children were more adherent. DiMatteo (2004) found that gender was not correlated with adherence except for young female pediatric patients. Illness severity or duration was not measured in these review studies. There was little information on population demographics and no information on race/ ethnicity addressed in these review studies.

Similar to Peterson's work (2003), McDonald et al. (2002) also focused on randomized controlled studies related to medication adherence during the same time frame (1967-2001). Modest but statistically significant increases in medication adherence were found in 49% of the interventions reviewed and 17 out of 33 studies

reported improvements in biological outcome measures. There were several studies reviewed that included behavioral, cognitive, and social aspects. All of the effective interventions were complex including counseling via various means such as telephone and computer, family involvement, provision of care at the workplace, provision of blood pressure monitors to participants, reminder pill packages, and appointment reminders. McDonald et al. (2003) reviewed 10 common diseases including cardiovascular disease, hypertension, and hyperlipidemia.

The definition and measurement of patient adherence varied widely making it difficult for researchers to compare studies. Many studies relied on self report with questionable reliability although the consensus was that self report is an acceptable method of data collection (DiMatteo, 2004; Garber, Nau, Erickson, Aikens, & Lawrence, 2004; McDonald et al. 2002; Petersen, 2003). None of the studies followed participants for longer than 2 years. Teasing out successful interventions from complex adherence regimens was difficult; most of the studies with multiple interventions did not assess each component separately. Researchers agreed that showing an increase in patient adherence behaviors without improvement in biological outcomes (lowered cholesterol for example) or clinical end points such as reduction in myocardial infarctions were not clinically relevant. Lastly researchers agreed that improving patient attendance at appointments was an important first step followed by a collaborative approach to the decision-making process.

Table 6

Literature Review Findings

DiMatteo (2004)	Purpose of study	To assess, compile and average adherence rates between 1948-1998 and determine the effect of patient demographics
	Theory	Health belief model, theory of planned behavior, and transtheoretical model were mentioned
	Sample	733 studies on adherence to medical treatment and 164 studies providing correlations between adherence and demographics between 1948-1998.
	Design/ methods and instruments	Meta-analysis of studies that defined or measured patient adherence to a medically prescribed treatment or preventive measure.
	Salient Findings	Overall nonadherence rate was 24.8%. Adherence was highest in HIV, arthritis, gastrointestinal disorders, and cancer and lowest in pulmonary disease, diabetes and sleep disorders. Adherence was highest in those with higher education and income. Studies focusing on health behaviors, appointment keeping and diet had lower rates of patient adherence compared to other regimens.

Note: HIV= human immunodeficiency virus

Table 6 (Continued).

Literature Review Findings

McDonald, Garg, & Haynes (2003)	Purpose of study	To review published randomized controlled studies on patient adherence to medications
	Theory	No theory noted
	Sample	33 studies between 1967 to August 2001
	Design/ methods and instruments	33 studies reviewed (findings too disparate for meta-analysis). Studies were included if they reported a randomized controlled trial of an intervention to improve patient adherence with prescribed medications; both adherence and treatment outcome were measured
	Salient Findings	Patient adherence was defined as taking all of medication doses as prescribed. Almost all the interventions that were effective for long term care were complex and did not lead to large improvements in adherence and treatment outcomes. Less than half of the interventions reviewed were associated with increases in medication adherence but 17% reported improvement in treatment outcomes. The most effective interventions combined counseling, reminders, self monitoring, decision support, and reinforcement.

Table 6 (Continued).

Literature Review Findings

Peterson, Takiya, & Finley (2003).	Purpose of study	To review tools and methods designed to enhance patient medication adherence
	Theory	No theory noted
	Sample	18,922 subjects in 61 studies from 1966-2000
	Design/ methods and instruments	Meta analysis of 61 randomized controlled trials evaluating behavioral and educational interventions including dosage schedule change, packaging change, skill building, reward, pill counts and pillboxes, calendars, reminders and education, oral and written education, audiovisual education
	Salient Findings	The definition of patient adherence varied depending on the study and was measured by patient report, pill counts or medication profile. Results: no single patient adherence strategy seemed to work best. Patient adherence increased 4-11% with behavioral interventions which emphasized patient involvement in decision- making. Mailed reminders had the largest impact.

Qualitative Studies

Participants in the following qualitative studies described their beliefs about heart disease and its etiology and their thoughts about recommended lifestyle changes. These studies confirmed the need to develop and evaluate educational programs which focus on patient-provider goal-setting and offer education when patients are motivated to change. Researchers primarily used a phenomenographic approach and utilized individual interviews and focus groups. Table 7 outlines four qualitative studies specifically related to patient-provider adherence, patient-provider goal-setting and decision support, and cardiovascular disease risk reduction.

Three of the studies highlighted in Table 7 had small sample sizes of less than 25 participants which is typical of qualitative studies. Participants in two studies reported a positive cardiac stress test or cardiac procedure such as bypass grafting or angioplasty within 2 years of the study and were under age 60 at the time of their cardiac event. Researchers in the Bell and Kravitz study (2008) reported that 80% of their sample was Caucasian with the majority over age 50. Woodard et al. (2005) stratified their focus groups by race and age to facilitate discussion about racial issues; there were 24 male participants between age 48-83 which was 69% Caucasian and 31% African American. The Bach-Nielsen (2005) study had 5 females and 9 males in the sample between ages 33-50 and Karner et al. (2002) had a sample of 9 females and 14 males with a mean age of 51. There was no information available on the race/ ethnicity of the participants in the Bach-Nielsen (2005) and Karner et al. (2002) studies. Theoretical frames of references for the studies included the Theory of Self Efficacy, Health Belief Model, and Change Theory.

Participants in the Bach-Nielsen et al. (2005) study were randomly invited to participate in a screening for cardiovascular disease and participate in interviews if deemed high risk. Participants deemed at risk for cardiovascular disease were between ages 33-50 years old. The purpose of the Bach-Nielsen (2005) study was to explore how an elevated cardiovascular risk score related to participants' desired lifestyle. Researchers utilized qualitative semi-structured interviews to explore concerns about cardiovascular disease risk screening, views about overall health and health promotion, and beliefs about involvement in decision-making and collaboration with health care providers. Themes in the study included awakening, action, limitations, and priorities.

Bach-Nielsen et al. (2005) found that participants were initially alarmed that they had an elevated cardiovascular disease risk but made changes in their behavior only if it did not adversely affect their perceived quality of life. If more pressing individual and family needs were present, cardiovascular disease risk reduction was considered a low priority. Participants preferred to follow simple health recommendations and avoided advice they disliked such as exercising or eating more fish. Tobacco users felt the benefits of smoking ('relaxation') outweighed the potential risk to their health and did not like discussing their habit. Prevention paradox was discussed by the authors; participants often compared themselves to others who had followed healthier lifestyles yet died young anyway and to others who lived an unhealthy lifestyle yet lived a long life. Because of these comparisons, participants were less willing to follow health recommendations.

Bell and Kravitz (2008) audio-recorded 860 patient appointments, transcribed the tapes and coded results to examine physician counseling. A post visit questionnaire was given to patients and physicians to assess their satisfaction with the appointment. The

study objective was to describe physician counseling on hypertension and lifestyle. They found that most physicians assessed patient adherence to medications but there was limited education offered on hypertension and adherence to healthy lifestyle recommendations. Feedback on blood pressure readings was given less than half the time and physician provided blood pressure goals were suggested in less than 25% of the visits.

When counseling included advice about lifestyle, physicians and patients reported greater satisfaction but this resulted in a longer appointment time by approximately two minutes. Researchers recommended a collaborative goal-setting approach to promote patient adherence. Surprisingly patients with the most risk factors for a cardiac event were not given any more counseling than those with lower risk. It was speculated that providers felt it was too late for the sickest patients to benefit from lifestyle changes and hypertension counseling.

Karner et al. (2002) used a phenomenographic approach utilizing taped semi-structured interviews in participants' homes one year after a cardiac event. Researchers identified the following categories: conceptions regarding drug treatment adherence, risk factors, fat intake, physical activity, and smoking. Participants did not follow health recommendations when they did not feel their condition was serious. There were many misconceptions about heart disease, its treatment and prevention. Participants had difficulty describing the reasons for taking their medications or how they worked and had a fatalistic view about their condition. Many felt that nonadherence to medications was not harmful because they had no symptoms if they skipped doses. Others worried they would become *addicted* to their medications.

Woodard et al. (2005) explored coronary heart disease health care experiences and discussed racial disparities with veterans receiving outpatient care two years after a cardiac procedure. Four focus groups were led by a Caucasian moderator and an African American internist to discuss participants' thoughts about their cardiac health care experience. Researchers identified four themes: risk factor knowledge, patient-physician relationship, medical system access, and treatment beliefs. The participants had a similar general understanding of cardiovascular disease risk factors related to diet and tobacco. African Americans had a less specific understanding of cholesterol and the etiology of heart disease.

The focus groups in the Woodard et al. (2005) study believed they were predestined to develop heart disease and expressed a degree of pessimism that following recommendations would lower their risk. Participants expressed a desire for a stronger role in their health care and reported greater patient adherence when they shared in the decision-making process.

Challenges in using qualitative methods include the desire for participants to please the interviewer particularly in face to face interviews. The time lapse between cardiovascular disease risk screening and interviews was a limitation in the Bach-Nielsen study (2005). Likewise the delay in interviewing in the Karner et al. (2002) and Woodard et al. (2005) study may have affected results. It is also possible that a qualitative approach reflects the researcher's own ideas instead of the participants' thoughts. However most of the studies used a negotiating consensus which involved analysis by several reviewers to reduce this risk.

The qualitative researchers in this review agreed that patient perception of risk and openness to health behavior change varies and is strongly influenced by competing priorities. If patients are advised to make numerous lifestyle changes they may feel overwhelmed by the number of tasks. Change occurs when patients believe the benefits outweigh perceived sacrifices in changing their lifestyle. Researchers agreed that participants had not received the tools needed for a complete understanding of their medical condition, were not encouraged to fully participate in decision-making about their own health, and seldom understood that adherence to health recommendations could improve their prognosis. Table 7 provides a summary of the qualitative review findings.

Table 7

Qualitative Studies Related to Patient Adherence, Patient-Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Bach-Nielsen, et al (2005)	Purpose of study	To explore how persons with an elevated cardiovascular risk score balanced health related advice against the life they wanted to live
	Theory	Theory of self efficacy and the health belief model
	Sample	14 study participants with an elevated CV risk score
	Design/ methods and instruments	Qualitative semi- structured interviews assessing experiences and findings from the screening, assessment of his/her own health, views of health promotion, and opinions of consultation with their health care provider.
	Salient Findings	Themes included awakening, action, limitations, and priorities. Elevated cardiovascular risk was viewed as alarming. Lifestyle changes were initiated if quality of life was affected adversely. Cardiovascular risk was given less attention when stressful circumstances occurred in life, or if other results were normal.

Table 7 (Continued).

Qualitative Studies Related to Patient Adherence, Patient-Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Bell & Kravitz (2008)	Purpose of study	To describe patient counseling by physicians on hypertension and lifestyle
	Theory	Health belief model
	Sample	860 audio-recorded outpatient visits with 30 primary care physicians, 11 cardiologists and 120 patients with hypertension
	Design/ methods and instruments	Qualitative study reviewing transcripts of audio recorded visits. Transcripts were coded into categories descriptive of physician behaviors including health risks of hypertension, benefits of controlling hypertension, and assessment of patient adherence to medications.
	Salient Findings	Physician feedback and mutual goal-setting with patients related to blood pressure was provided in less than 25% of visits. There were no differences in counseling between patients with and without cardiovascular risk factors or complications with speculation by the researchers that providers felt the sickest patients were "too far gone" for counseling about hypertension and recommended lifestyle changes.

Table 7 (Continued).

Qualitative Studies Related to Patient Adherence, Patient-Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Karner, Goransson & Bergdahl (2002)	Purpose of study	To analyze beliefs about drug treatment and lifestyle changes
	Theory	Health belief model
	Sample	23 patients studied one year after a coronary event and had undergone bypass grafting or angioplasty in Sweden
	Design/ methods and instruments	Phenomenographic approach using individual interviews one year after an acute cardiovascular event. The results were transcribed, analyzed, and placed in categories. During hospitalization patients attended a group information session about heart disease rehabilitation, diet, activity, and smoking cessation.
	Salient Findings	The following categories were obtained from the transcripts: conceptions regarding drug treatment adherence, risk factors, fat intake, physical activity, and smoking. Patients who did not feel their condition was serious were less adherent. Misconceptions about heart disease were reported. Knowledge and understanding of cardiovascular disease favored patient adherence.

Table 7 (Continued).

Qualitative Studies Related to Patient Adherence, Patient-Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Woodard, Hernandez, Lees, & Petersen (2005)	Purpose of study	To explore coronary heart disease beliefs to determine potential causes of racial disparity on cardiovascular outcomes
	Theory	Change theory
	Sample	24 Veterans between age 48-83, 69% Caucasian, 31% African American with positive cardiac stress test in the past 2 yrs
	Design/ methods and instruments	Focus group interviews were utilized and verbatim transcripts of the groups were analyzed by independent investigators to identify key themes
	Salient Findings	Four themes were identified: risk factor knowledge, physician–patient relationship, medical system access, and treatment beliefs. Racial differences were apparent in the experience of racism as a stress, knowledge of specifics of CHD risk factors, and assertiveness and decision support in the physician–patient relationship. The researchers recommend increasing patient involvement in decision-making and patient assertiveness in the health care relationship.

Quantitative Studies

This section will address findings of the quantitative studies highlighted in Table 8 related to patient adherence, patient-provider goal-setting and decision support, and cardiovascular disease risk reduction. Twelve quantitative studies were chosen for review with sample sizes ranging from 50 to 3,175 participants with cardiovascular disease and/or a related diagnosis. The mean age of participants in these studies was 58 years. Females were represented slightly more often than males with an average of 55%. Information on ethnicity was only included in one third of the studies. The participants' ethnicity was defined as African American (42%), Caucasian (55%) and *Other* (3%).

Pre and post-testing questionnaires, retrospective cohort studies, and secondary analysis were among the methods used. Instruments used in the quantitative studies included health behavior and adherence questionnaires, risk and benefit scales, participation scales, and biological outcome measures such as LDL cholesterol and body mass index. There were four randomized controlled trials. The overall purpose of the studies was to determine whether educational programs including patient-provider goal-setting and decision support were effective. The Andersen behavioral model, chronic illness care model, stages of change model, and social cognitive theory served as theoretical frameworks for these studies.

Combined interventions targeting both patients and health care providers were successful in the Afonso, Nassif, Aranha, DeLor and Cardozo (2006) and Campione (2005) studies. The purpose of the Afonso et al. (2006) study was to determine if patient education and provider awareness could improve National Cholesterol Education Program goal attainment among participants at high risk for a cardiac event. They taught

107 patients with cardiovascular disease about cholesterol, target goals, risk factors, and importance of medication adherence.

Participants completed the Morisky questionnaire pertaining to adherence; a score of three or higher was considered high adherence and below two as low adherence. Physicians were provided cholesterol medication dosing cards and were asked to evaluate participants' lipid management. Not surprisingly the high adherers showed improvement with a 10 point reduction in their LDL cholesterol from baseline 12 weeks after the intervention; the low adherers' LDL increased despite the intervention. Clinical inertia is part of the reason study participants and health care providers did not meet their goals and occurs when providers do not maximize therapy when it is appropriate. Patient-provider goal-setting and provider feedback and reminder systems were predictive of improved outcomes in this study.

Campione (2005) examined cholesterol lowering medication (statin) adherence in a retrospective cohort study of 3,175 veteran patients over a 3 year period along with a review of primary care provider adherence to guidelines. Poor statin adherence kept participants from reaching their LDL cholesterol goals. Length of time on cholesterol medication did not affect patient adherence but higher doses were associated with nonadherence. Campione (2005) found that providers continue to raise doses when they have not assessed whether the patient is tolerating and taking the medication; patients often disagree and do not take the up-titrated dose. As in the Afonso (2006) study, researchers agreed that dosage adjustment is a part of negotiation and shared decision-making. Simple strategies to improve provider adherence included reminders to order

annual lipid panels, and increased emphasis on appropriate medication initiation and dosage titration which reduced participant LDL levels (Campione, 2005).

Utilizing laypersons in educational programs did not have an appreciable effect on patient adherence. Dobs et al. (1994) sought to determine the effect of a hospital based cholesterol lowering educational program on 36 adults with total cholesterol values greater than 200. Regardless of whether participants were taught by experts or peers there was little effect on their health behaviors 3 months later, less than half remembered their total cholesterol value, and only 9% could remember one goal set by the nutritionist two weeks after the intervention.

Individualized patient-provider goal-setting and decision support were utilized in four studies by Edelman et al. (2006), Levetan et al. (2005), Martin, Wu, Taveira, Eaton and Sharma (2007) and Vale et al. (2003). In a randomized controlled study by Edelman et al. (2006), researchers found modest improvement after participants attended educational sessions supplemented by individualized coaching and telephone follow up. Researchers measured body mass index, waist circumference, blood pressure, and lipid panels in addition to reviewing self reports regarding exercise, smoking status, and readiness for change. They found a 16% improvement in the intervention arm as well as a 12% improvement in the control group who received usual care (Edelman et al., 2006). The control group improvement may have been prompted by being invited to participate in the study.

Levetan et al. (2005) provided participants with a wallet card and poster for their refrigerator with their LDL status and goal reminders. Participants sustained a significant decrease in LDL levels six months after the decision support and patient-provider goal-

setting intervention and had fewer cardiac interventions than the control group. Likewise Martin et al. (2007) provided participants with an electronic report card pertaining to their cardiovascular risk, negotiated goals, and progress. Participants showed significant improvements in blood pressure, LDL cholesterol, HbA1c, and body mass index.

In the Vale et al. (2003) study, participants received feedback on their laboratory data and other outcome measures and were randomized to telephone and mailed support or the usual care after discharge following a cardiac related procedure. Participants received a written report of their progress which served as a reference for the each coaching session. Researchers found a significant reduction in triglyceride levels six months after the intervention compared to baseline as well as reductions in weight and body mass index, blood pressure, cholesterol levels, and reported decreased symptoms of chest pain and breathlessness. They also found increased rates of exercise, improved well being, and elevated mood six months after hospital discharge (Vale et al., 2003).

Stages of activation or readiness for change and self-management behaviors were the focus of the study by Hibbard and Tusler (2007), Jacobs (2002), and Johnston et al. (2004). The participants in these studies had hypertension and/or cardiovascular disease. Participants who were motivated to change and actively participated in their health care decisions were more likely to demonstrate healthy behaviors and adhere to a mutually agreed upon plan of care. Researchers confirmed that intention is a powerful predictor in changing behavior and is helpful in developing interventions. Increasing motivation through decision support makes one more likely to follow health recommendations but that may not relate to actual outcomes if participants do not follow through.

In addition to consideration of readiness to change, educational efforts are enhanced by personalized written information. Tailored print communication has been associated with improved recall of information, is read more often, and is perceived as credible health information (Weymiller et al., 2007). Weymiller et al. (2007) found that the tailored decision aid *Statin Choice* supported participant decision-making to take cholesterol lowering medication and adherence related to continuing that medication.

Thomas (2001) found that individualized education and provision of personalized written information did not require more time than standard care and produced a reduction in cardiovascular risk score on the *RISKO* tool from the American Heart Association. Participants in the Jacobs (2002) study showed improvements in total cholesterol and HDL cholesterol after receiving tailored health mailings and individualized counseling but there was little change in blood pressure or weight in the intervention group. This supports earlier assertions that patients are willing to take medications but less eager to exercise and make changes in their diet.

For any behavioral strategy to demonstrate improved cardiovascular outcomes there must be health care provider adherence to recommended guidelines in addition to patient adherence. The most successful programs incorporated behavioral strategies, collaborative decision-making, and self-management approaches.

Challenges of Quantitative Studies

Challenges cited by the researchers included difficulty in quantifying the effects of individual components of complex regimens, inability to generalize to a larger population or female population, short study length, and lack of comparison groups in some of the studies.

Researchers in these quantitative studies agreed that sustained change was difficult to achieve. Personalized intervention studies that encouraged patient involvement in decision-making showed some success but required a great deal of effort and follow up (Levetan et al., 2005). Group intervention studies related to adherence demonstrated limited change in measurable outcomes although they may improve overall quality of life and knowledge about cardiovascular disease (Dobs et al., 1994; Martin et al., 2007). Studies that measured health behavior change such as weight loss and low fat diet had the lowest rates of patient adherence overall as they are very reluctant to change their lifestyle (Jacobs, 2002). Table 8 summarizes the quantitative findings related to adherence and decision support, patient-provider adherence, patient-provider goal-setting, and cardiovascular disease risk reduction.

Table 8

Quantitative Studies Related to Patient Adherence, Patient-Provider Goal- Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Afonso et al. (2006)	Purpose of study	To determine whether a combined program of patient education and provider awareness could improve National Cholesterol Education Program goal attainment among high risk patients
	Theory	No theory noted
	Sample	107 high risk cardiovascular patients in Michigan
	Design/ methods and instruments	Prospective pre-post evaluation using Morisky medication adherence questionnaire, physicians were provided with cholesterol lowering medication dosing cards to help with provider adherence to lipid management guidelines
	Salient Findings	8-12 weeks after the patient and provider education and awareness intervention, 59.8% of patients met the recommended LDL goal <100 mg/dl. Patient adherence was defined as LDL >100 mg/dl prior to the intervention and <100 mg/dl after the intervention. Failure to initiate/ titrate dosing to maximal effect was found to be a common provider adherence issue thus preventing patients from meeting guideline recommendations.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Campione (2005)	Purpose of study	To examine the effects of patient cholesterol lowering medication (statin) adherence and primary care provider guideline adherence on associated health outcomes in veterans
	Theory	Andersen behavioral model
	Sample	3,175 veterans at a North Carolina center who were prescribed cholesterol lowering medication (statins) between 1999-2002
	Design/ methods and instruments	Retrospective cohort study which included review of statin prescribing including dose titration, LDL levels, diagnosis codes related to heart disease, hypertension and diabetes, and demographic information
	Salient Findings	Patient adherence and effectiveness of therapy was improved with annual lipid evaluations and provider guideline adherence. There was no statistical relationship between duration of therapy and adherence.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Dobs et al. (1994)	Purpose of study	To determine effect of a educational program on cholesterol values and health behaviors
	Theory	No theory noted
	Sample	36 people over age 21 with total cholesterol over 200 recruited with advertisements in hospital and community
	Design/ methods and instruments	Pre and post design using preventative health behavior questionnaire, perceived risk scale, perceived benefit index, and perceived level of difficulty [of change] questionnaire. Pre and post cholesterol values and dietary intake were measured.
	Salient Findings	Participants were randomly assigned to 3 groups. The expert designed group used a traditional lecture type format to teach about diet, exercise, smoking cessation, medications and blood tests. The patient designed group used an informal format with testimonials and skill specific approaches. There was no difference in cholesterol values or health risk behaviors at 3 month follow up.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Edelman et al. (2006)	Purpose of study	To determine whether personalized health planning and goal- setting focusing on diet and exercise reduces 10 year risk of heart disease
	Theory	No theory noted
	Sample	154 outpatients, age 45+ with 1+ CVD risk factors, BMI >25
	Design/ methods and instruments	Randomized controlled trial, usual care vs. care with a health coach. Used "know your number tool," Framingham risk scale
	Salient Findings	Participants in the intervention arm worked with a health coach and used the "know your number" tool to learn about reducing cardiovascular risk and construct a personalized health plan and goals. They received decision support through biweekly telephone counseling and met with a nutritionist twice. Body mass index, LDL cholesterol, blood pressure, smoking, and frequency of exercise were measured. The risk of heart disease dropped from 11.1% to 7.8% for intervention subjects (compared to 9.8% in usual care).

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Hibbard et al. (2007)	Purpose of study	To determine occurrence of behaviors at different stages of activation. In stage one the patient is a passive recipient of care. In stages 2 & 3 patients are beginning to learn the information needed to take action. In stage 4, patients adopt new self-management behaviors but need support to sustain these behaviors.
	Theory	Chronic illness care model
	Sample	479 participants from a previous health plan study
	Design/ methods and instruments	Secondary analysis. Patient activation measure (PAM) used to assess self- management skills for heart disease, hyperlipidemia, diabetes, and COPD through telephone and self administered surveys.
	Salient Findings	Patients were offered health coaching and encouraged to participate in their health decision-making. Stages of activation were assessed with strategies based on the "next step" and target goals. Those at a higher stage of activation were more likely to make recommended lifestyle changes and demonstrate ability to manage their health needs.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Jacobs (2002)	Purpose of study	To develop and evaluate effectiveness of decision support and a computer tailored maintenance intervention to reduce cardiovascular risk
	Theory	Stages of change model
	Sample	421 women in the North Carolina Wise Woman program
	Design/ methods and instruments	During a one year program the intervention group received 6 computer tailored health mailings and two phone counseling sessions, pre and post cholesterol, blood pressure and body weight screenings, pre and post surveys assessed diet and physical activity, and beliefs and attitudes related to cardiovascular disease risk reduction
	Salient Findings	Intervention participants were more likely to make dietary and physical activity changes. Both usual care and the decision support group showed improvements in total and HDL cholesterol at follow up however there was little change in blood pressure or weight.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Johnston et al. (2004)	Purpose of study	To explore perceived behavioral control and intention and cardiovascular risk behaviors one year after diagnosis of coronary artery disease.
	Theory	Social cognitive theory and self efficacy
	Sample	597 patients in angina clinic followed one year after diagnosis of coronary artery disease
	Design/ methods and instruments	Randomized controlled trial. Pre and post hospitalization self report measured intention to stop smoking and begin exercise, measured distance walked in 6 minutes, lab tests for presence of nicotine. Intervention group received follow up with a nurse.
	Salient Findings	Increasing motivation in the undecided and decision support made it more likely for those intending to act to follow through. There was no significant difference between the counseling intervention and control groups in smoking, total cholesterol, blood pressure, or distance walked however body mass index was slightly lower in the intervention group.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Levetan et al. (2005)	Purpose of study	To evaluate impact of education on LDL values and patient adherence
	Theory	No theory noted
	Sample	80 patients with coronary artery disease hospitalized on cardiology unit in 1998
	Design/ methods and instruments	Randomized controlled trial, utilized questionnaire about cholesterol, standard care versus care plus wallet card and poster outlining LDL goal and steps to meeting goals
	Salient Findings	Patients received cholesterol lowering education while in the hospital. The intervention group received a decision support, goal-setting tool (wallet card and poster) with a significant decrease in LDL six months after the intervention and 73% still had a poster with LDL status and goal reminders on their refrigerator at end of study. The intervention group was more likely to discuss exercise, cholesterol, and hypertension with their physician. They had fewer cardiac procedures than the control group (7.6% vs. 21.6%) but not at statistically significant levels.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Martin et al. (2007)	Purpose of study	To evaluate effectiveness of a multidisciplinary team (MEDIC) providing group education and medication management for cardiac risk reduction in diabetic patients
	Theory	Chronic care model
	Sample	41 veterans with diabetes at a VA Medical Center
	Design/ methods and instruments	Retrospective correlational study. Electronic records reviewed and blood pressure, HbA1c, lipid profile, body mass index, as well as diagnosis codes were recorded pre and 3 months post intervention
	Salient Findings	After weekly education for 2.5 hours including self- management and goal-setting techniques, participants were given an electronic report card pertaining to cardiovascular risk so they could track their progress on biological outcome measures. There were significant improvements found in all measures: 54.5% improvement in systolic blood pressure (BP), 75% improvement in diastolic BP, 42.9% reached LDL goal <100 mg/dl, 41.9% HbA1c <7%, 8.7% achieved body mass index <30.

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Thomas (2001)	Purpose of study	To assess effectiveness of individualized educational counseling and decision support in reducing cardiovascular risk and compare time required for general versus individual education
	Theory	No theory noted
	Sample	50 participants from a veterans health care center in Tennessee
	Design/ methods and instruments	Descriptive correlational study using 2 group pre and post test design using RISKO tool from the American Heart Association which is based on blood pressure, weight, total cholesterol, diabetes and tobacco use.
	Salient Findings	Individualized education and provision of written material required no more time than standard care and produced a statistically significant reduction in cardiovascular risk

RISKO= health risk appraisal

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Vale et al. (2003)	Purpose of study	To determine efficacy of COACH program and goal- setting with patients with heart disease to meet cholesterol goals
	Theory	No theory noted
	Sample	792 cardiac patients assigned to usual care or usual care plus decision support (coaching) in Australia
	Design/ methods and instruments	Multi-center randomized controlled trial stratified by cardiac diagnosis and assigned to usual care or usual care plus coaching
	Salient Findings	Participants received education about coronary risk and recommendations, plan negotiation, goal-setting. Significant improvements in cholesterol, risk factors, recommended lifestyle changes. Intervention arm had better adherence to dietary advice and lipid lowering medication with a 14 mg/dl greater reduction in triglyceride levels.

COACH= coaching patients on achieving cardiovascular health

Table 8 (Continued).

Quantitative Studies Related to Patient Adherence, Patient- Provider Goal-Setting and Decision Support, and Cardiovascular Disease Risk Reduction

Weymiller et al. (2007)	Purpose of study	To determine effect of a statin choice decision aid on treatment decision-making for patients
	Theory	No theory noted
	Sample	98 patients with diabetes seen at the metabolic clinic at the Mayo clinic
	Design/ methods and instruments	Randomized trial of statin choice decision aid versus pamphlet on cholesterol management. Acceptability, knowledge about treatment options and cardiovascular risk, and decisional conflict were measured immediately after the visit, and patient adherence to pill taking was measured 3 months later.
	Salient Findings	Patients favored using the decision aid. Those in the intervention arm showed improvement in their estimated cardiovascular risk and potential absolute risk reduction with statin drugs. They also missed fewer doses of their cholesterol lowering medication three months after the intervention

Chapter 2 contained a review of the literature on the concepts of adherence, patient-provider goal-setting, and cardiovascular disease risk reduction. There was a

narrative analysis of 19 studies related to these concepts including three literature review studies, 4 qualitative studies, and 12 quantitative studies. Participants in the qualitative studies expressed a desire for a stronger role in their health care and reported greater adherence when they shared in the decision-making process. The focus group participants believed they were predestined to develop cardiovascular disease, felt it was a quicker more desirable death than other diseases like cancer, and did not recognize heart disease as a chronic disorder. The qualitative researchers agreed that patient perception of risk and openness to health behavior change was strongly influenced by competing priorities.

The researchers of the quantitative and review studies found the lowest rates of patient adherence with complex medication regimens and studies related to health behaviors, appointment keeping, and dietary change. Patient adherence was highest in those with greater financial resources and education. Health care providers and participants were jointly targeted in several intervention studies to ensure adherence to clinical guidelines. The highest rates of patient adherence were found in studies that combined counseling, reminders, self monitoring, patient-provider goal-setting and decision support, and reinforcement. The common thread throughout these studies is the link to behavioral psychology and self- management theories. This review gives the reader a broad overview of the current research on this topic and suggests a need for refinement in the way health care providers approach patient care and decision-making. This review of the literature has shown that there is a need for additional research pertaining to patient adherence, patient-provider goal-setting, and decision support in the context of cardiovascular disease risk reduction.

Implications for Nursing Research

Patient adherence and patient-provider goal-setting is an area of nursing research which has room for further development. The studies reviewed have shown there is a gap in the literature related to collaboration in decision-making. Reducing cardiovascular risk includes screening for risk factors, diagnosing disease, initiating appropriate interventions and monitoring, and providing care in a collaborative environment. Some patient risk factors related to lifestyle choice can be reduced with patient education and decision support. Additional implications are outlined in Chapter 5.

Nursing Education and Practice

Nurses have always been leaders in patient education and the development of creative ways to meet patient needs. Nurses need a thorough understanding of patient adherence, and patient-provider goal-setting and decision support techniques to facilitate self- management skill development to reduce cardiovascular disease risk. Nursing curriculum should incorporate patient-provider goal-setting and decision support to improve patient adherence rates to health recommendations. Consideration of patient priorities and goals is a part of holistic nursing practice and additional research is needed to improve our collaborative efforts.

Summary

Advances in the prevention and treatment of cardiovascular disease have prolonged the lives of many. However the potential for substantial reduction in quality of life remains as the public continues to view heart disease as a quick death and not a chronic life altering disease. The inexact nature and outcome of heart disease makes promoting healthy lifestyles more challenging. Assessing motivation for change and

perception of personal risk for heart disease is part of the collaborative relationship between patient and health care provider. Education incorporating patient-provider goal-setting and decision support improve patient adherence and the chances that patients will make sustained lifestyle changes to decrease their cardiovascular risk.

In Chapter 2, adherence was reviewed as a concept and its antecedents, attributes, outcomes and measurements were outlined. The literature related to patient-provider adherence, patient-provider goal-setting, and cardiovascular disease risk reduction was reviewed and barriers to adherence were discussed. Chapter 3 discusses the study methodology.

CHAPTER 3

RESEARCH METHODOLOGY

The purpose of this study was to examine the influence of patient adherence and patient-provider goal-setting and decision support on factors related to cardiovascular disease risk among veterans. This chapter describes the design and methods, sample, definition of study variables, procedure and data collection methods, data analysis, and human rights subjects' protection.

Research Design and Methods

The study was a longitudinal study utilizing secondary data encompassing a five-year time frame (2003-2007) reviewing veteran outpatient care data through electronic data extraction and chart reviews at a VAMC. The study was a panel study, as all veteran visits to primary care from the sample were included for Research Questions 1 and 2. The study was non-experimental and reviewed existing data with no direct contact with the sample. The data was de-identified and secured per Department of Veterans Affairs Medical Center policies so that no personal health information could be linked to any veteran.

Sample

Veteran Demographics

According to the Department of Veterans Affairs (2007), there are 23.8 million living veterans in the United States with a median age of 60; 7.5% of whom are female veterans. Nearly 75% of these veterans served during a time of war or conflict. The budget for the medical care of veterans is over $40 billion annually (Department of Veterans Affairs, 2008). There are approximately five million veterans who receive care

at a VA facility with 806,987 veterans served in the study area (Department of Veterans Affairs, 2007). See Table 9 for a review of the age and ethnicity of veterans in the study setting receiving care.

Table 9. Summary of Veterans, by Age and Ethnicity, in the Outpatient Care Study Setting

Age	n	%
20-29	47,259	6.0
30-39	94,816	11.7
40-49	161,130	20.0
50-59	165,636	20.5
60-69	164,677	20.4
70-79	107,557	13.3
80-89*	59,934	7.4
90+	5,978	0.7
Total	806,987	100.0
Ethnicity	n	%
Caucasian	604,143	74.8
African American	161,202	20.0
Hispanic	18,233	2.3
Asian/ Pacific islander	10,936	1.4
Native American	3,585	0.4
Other or multiple race	9,226	1.1
Total	806,987	100.0

(Department of Veterans Affairs, 2007). *Not permitted to sample over age 89**

Data for the study was extracted and de-identified from the electronic records of veteran patients assigned to an outpatient VAMC for the time-frame of years 2003 through 2007, inclusive. A sample of 1,865 patients assigned to outpatient primary care was utilized in this study. At the Department of Veterans Affairs Medical Center chosen for the study, approximately 150,000 male and 8,000 female veterans receive outpatient medical care which is similar to other VA facilities in the sample state (see Table 14).

Definition of Study Variables

The next section defines the terms and variables used in the study. Independent variables in this study included patient-provider goal-setting and patient adherence (educational class attendance and cholesterol medication on the active medication list). Demographic information obtained included age and year of birth, gender, ethnicity, tobacco use, and employment status, visit interval, and type of health care provider. Existing diagnoses of cardiovascular disease, congestive heart failure, and/or diabetes were noted in this study. Intermediate biological outcome measures served as the dependent variables and included HbA1c for patients with diabetes, LDL cholesterol levels, and BMI (body mass index). The terms cardiovascular risk reduction and patient adherence are also briefly reviewed.

Cardiovascular Disease Risk Reduction

Cardiovascular disease risk reduction is an ongoing process to lower cardiac risk and includes increasing physical activity, management of hypertension and diabetes, reduction in smoking, and reduction in obesity and hyperlipidemia (ATP III, 2004). In this study, the Andersen behavioral model (ABM) provided a conceptual framework for addressing patient needs related to patient adherence, patient-provider goal-setting and

decision support, and cardiovascular risk reduction. These factors are related to evaluated health status. Predisposing characteristics such as sociodemographic factors and enabling resources (employment) impact perception of need for care as it pertains to cardiovascular risk. These factors impact personal health practices, use of health services, and visit interval which in turn has an effect on evaluated health status: BMI, HbA1c, and LDL. These cardiovascular risk reduction interventions lead to improved health status (ATP III, 2004). The model focused on whether patient-provider goal-setting and decision support had an impact on evaluated health status: BMI, LDL, and HbA1c as measured in Research Question 2.

Patient Adherence

Promotion of patient adherence to current health guidelines is essential in reduction of cardiovascular disease risk and is a component of the Andersen behavioral model. In this model, the patient and health care provider follow a mutually agreed upon plan of care which reflects current evidence based clinical guidelines. It is through this alliance that patient adherence to health recommendations is promoted and cardiovascular disease risk is reduced (ATP III, 2004). Patient adherence was measured by examining cholesterol medication on active medication list and attendance at educational programs. See Table 13 for operational definitions of the study variables in Research Question 2.

Patient-Provider Goal-Setting and Decision Support

Patient-provider goal-setting is defined as a task that one wants to accomplish which has been set by the patient in concert with the health care provider's guidance and support (Langford et al., 2007). Patient-provider goal-setting is a component of the study model and is the result of a collaborative decision-making process providing a valuable

tool for improving motivation, self-management skills, and adherence to recommendations among patients with chronic disease (Locke, Latham, & Erez, 1985; Pierce & Hicks, 2001; Strecher et al., 1995). Frameworks related to patient-provider goal-setting and mutual decision-making include social learning theory and cognitive behavior modification theory (Bandura, 2004). Individualized goal-setting is part of the development of autonomy and self efficacy (Bandura, 2004). It helps patients feel they are competent decision makers and valued partners in the health care team and leads to increased patient adherence to medical recommendations (Fraenkel & McGraw, 2007). Decision support includes the verbal and written feedback on patient progress as a part of patient-provider goal-setting. The patient-provider goal-setting protocol below includes multiple tasks and is adapted from the work of Funnell, Tang and Anderson in 2004 and 2007. It was recorded in the electronic medical record of patients who participated. The patient-provider goal-setting and decision support protocol used in this study is outlined below:

Pre visit work:

1. Prior to each patient visit, the provider reviews previous progress notes and laboratory results to determine if standards of care are being provided for the patient. Review computer clinical reminders i.e.: need for diabetic foot exam, repeat HbA1c.
2. If fasting labs are needed, nursing personnel or ancillary staff contacts the patient.

At initial and subsequent visits:

1. Explore health issues (i.e.: obesity, hyperlipidemia, diabetes)
    a. Clarify health care provider role as coach and decision support

b. Identify patient concerns, motivation, and barriers to change

c. Discuss the effect of these issues on their health and lifestyle

d. Educate patient about recommendations for a healthier lifestyle

2. Clarify feelings and health beliefs

a. Ascertain patient opinion about their home blood glucose monitoring results and other laboratory and outcome measures

b. Repeat back patient concerns, barriers to change, and roll with resistance

c. Determine the influence of feelings and health care beliefs on self-management and patient adherence to recommendations

3. Develop a plan and commit to action

a. Referral to nutritionist, exercise program, group educational programs

b. Determine what patient wants to achieve

c. Engage in problem solving

d. Develop small obtainable goals together and record in medical record

e. Include the family in the plan of care if patient desires their involvement

f. Provide positive feedback, written instructions and verify understanding

4. Evaluate the plan (ongoing)

a. Provide verbal and written feedback on patient's goal attainment

b. Reevaluate met and unmet goals and the steps needed for attainment and maintenance of new behaviors

c. After the visit, mail personalized lab letters with results comparing previous results and patient goals and follow up on referrals and care coordination

Participation in patient-provider goal-setting and decision support was noted in the electronic medical record and extracted through retrospective chart reviews. In Research Question 2, patient-provider goal-setting and decision support was a dichotomous variable (yes/no). The number of years each patient participated was noted in the descriptive data obtained in Research Question 1.

Educational Class Attendance

Healthy lifestyle behaviors and patient adherence to health recommendations are promoted through health education for veterans nationwide. Veterans have the opportunity to participate in formal educational programs on *diabetes, cholesterol lowering, and weight management*. After attending class, many patients feel a sense of mastery of new behaviors, increased health knowledge, and ability to meet their health goals. They are more receptive to provider advice and have the opportunity to continue ongoing supportive relationships with staff and classmates (P. Moreland, personal communication, August 4, 2008).

Per the records of a nutritionist at the study setting (P. Moreland, 2008), 2,324 veterans participated in diabetic education between 2004-2007 with 25.2% having diet controlled diabetes type 2, 54% with diabetes type 2 on oral medications, 19.4% with type 2 diabetes on insulin, and 1.4% had type 1 diabetes receiving insulin. The majority of participants were between ages 45-64 with a third over age 65. After attending diabetic education, there was an average decrease in HgbA1c of 1.6% in participants with a baseline HbA1c over 7.0% (P. Moreland, 2008). The weight management classes reported that 111 participants completed the 12 week program during 2003-2008 with an average weight decrease of 9.6 pounds (P. Moreland, 2008).

The desired outcomes of participating in health education programs include improved coping, meeting personal health goals, and maintenance of a healthier lifestyle. See Tables 10-12 for an overview of each class structure.

Table 10

Structure of 6 Week Diabetes Education Classes

Profession	Topic	Time
Nurse	Overview of diabetes, complications, foot care	1 hr
Dietician	Meal planning, portion control, carbohydrates, cholesterol	2 hrs
Pharmacist	Medications and monitoring	1 hr
Psychology department staff	Dealing with diabetes, stress, depression	1 hr
Physical Therapist	Starting and maintaining regular exercise	1 hr

Table 11

Structure of 12 Week Weight Management Classes

Profession	Topic	Time
Health care provider	Preparing for change; medical implications and treatment of obesity, fallacies of fad diets and supplements	2 hrs
Dietician	Reading food labels, protein, serving sizes; increasing fiber, cutting fat and alcohol and using spices; lowering cholesterol; dining out and packing lunches; low calorie low fat recipes, healthy snacks and grocery shopping	4 hrs
Physical Therapist	Physical activity and energy expenditure	1 hr
Behavioral Psychologist	Behavior modification, understanding binging and craving, coping with emotion based eating; stress control/ time management; family support; motivational enhancement and relapse prevention	4 hr
Social worker	Overcoming prior attitudes about food, eating, and exercise	1 hr

Table 12

Structure of Cholesterol Lowering Class*

Profession	Topic	Time
Dietician	Low fat heart healthy diet guidelines	1 hr
Pharmacist	Cholesterol lowering medications and monitoring; individual laboratory test result review and feedback/ medication adjustment with provider input done separately	
Social worker	Impact of mood, substance dependence	

*Note: * This class was offered during the study time period but was replaced by another program.*

Routine Care

For the purposes of this study, routine care was defined as patient care management done regularly in a habitual manner which did not include patient-provider goal-setting.

Procedure and Data Collection Methods

The research proposal was submitted to and approved by the Institutional Review Boards of the University of Hawai'i at Mānoa and the Department of Veterans Affairs Medical Center. After approval, data was extracted from the VAMC electronic medical record (CPRS) from a sample of 1,865 veterans who received outpatient care in a primary care clinic. The variables listed below and described in Table 13 were extracted using existing software utilized by the VAMC and through electronic chart reviews. Chart reviews were needed to gather information on educational class attendance, and participation in patient-provider goal-setting. All of the veterans who were enrolled in

one outpatient primary care clinic between the years 2003-2007 were eligible for this study. The data compiled did not include any identifiable information and the list of participant names was only accessible by the VAMC information security officer after the data collection was completed.

The data collected was de-identified and secured, per Department of Veterans Affairs' policies. Independent variables in this study included (a) patient-provider goal-setting and decision support, and (b) patient adherence measured by educational class attendance, and cholesterol medication on the active medication list (filled). Demographic information obtained included age and year of birth, gender, ethnicity, tobacco use, and employment status, visit interval and type of health care provider, and current diagnosis of cardiovascular disease, congestive heart failure, and diabetes. Intermediate biological outcome measures served as the dependent variables and included HbA1c for patients with diabetes, LDL cholesterol levels, and BMI (body mass index). Please refer to Table 13 for operational definitions of the study variables used in Research Question 2. Dates of care and complete birth dates were not specified per VA policy.

Data Analysis

Two research questions guided this study. SPSS v. 15.0 was used for the descriptive analyses and STATA v. 10 was used for the inferential statistics. The research questions and their related statistical hypotheses are given as follows:

Research Question 1: *How prevalent are the risk factors for heart disease (age, obesity/ elevated BMI, diabetes, LDL cholesterol values, tobacco use) among the veteran population?*

Descriptive analysis was performed to find the frequency, means, standard deviation, and percentages of the cardiovascular risk factors of age, obesity (elevated BMI), tobacco use, diagnosis of diabetes mellitus, and elevated LDL cholesterol in addition to examining the demographic characteristics of the entire sample population. The descriptive analysis included data for all five years combined, and for each of the five individual years (2003-2007).

The variables of diabetes and tobacco use are categorical and the variables of age, BMI, HbA1c and LDL cholesterol are continuous. Tobacco use was reported as (1) former smoker, (2) current smoker, and (3) never smoked for the descriptives.

Research Question 2: Is patient-provider goal-setting and decision support a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL cholesterol, and HbA1c over the 5-year span of 2003-2007 given that demographic and patient adherence are also considered in the model?

Null Hypothesis for Research Question 2: Patient-provider goal-setting and decision support will not significantly predict values of the dependent variables of BMI, LDL, and HbA1c given that demographic and adherence factors are also considered in the model.

Alternative Hypothesis for Research Question 2: Patient-provider goal-setting and decision support will significantly predict values of the dependent variables of BMI, LDL, and HbA1c given that demographic and adherence factors are also considered in the model.

Research Question 2 included patient-provider goal-setting, aspects of patient adherence (attended education classes, lipid lowering medication on active medication list), and demographic variables in the model. The time variable baseline was coded 1

and subsequent measurement times were 2, 3, 4, 5. Data format for repeated measures was one row per person per measurement time with a mean recorded for each year from 2003 to 2007. Participants were measured at the times of their appointments; only the year of care was revealed per VAMC policy. Each data row contained an identification variable for the person, a time variable (1, 2, 3, 4, 5), and the outcome effects being modeled. The interaction of group and time was modeled as a fixed effect and the slope indicated the linear time trend of each patient and change in the outcome measure (BMI, LDL, HbA1c measured in separate regressions). Predictor variables included patient-provider goal-setting, and patient adherence as measured by educational class attendance and cholesterol medication filled. Confounding demographic variables included age, ethnicity, employment status, and number of visits annually.

There were three equations in this analysis, each containing nine independent variables and one dependent variable. The intercept B0 was not counted in the nine variables. The variables were repeated for each equation. Regressions by nature can only have one dependent variable. The first variable, the intercept, did not vary for each equation (fixed intercept); it is the y-intercept if all of the variables that are chosen (age, ethnicity, etc.) equal zero.

GEE is a "generalization of the standard linear model that enables the analysis of data generated from several sources of variation instead of just one and associates one continuous dependent variable with several explanatory variables which are either continuous or categorical" (Peretz, Goren, Smid, & Kromhout, 2002, p.71). This model includes fixed factors and provides estimates of the average responses (the same as a multiple regression model) (Peretz, et al, 2002).

Repeated measures on the same individuals are correlated, so this correlation must be taken into account by the model. The dependence among the repeated responses can be of different types, leading to specific covariance/correlation structures (Peretz, et al, 2002). GEE "allows the assumption of several covariance structures and enables estimation of effects in addition to variance parameters" (Peretz, et al, 2002, p.71). The number of observations per subject does not have to be the same and time intervals can vary (Peretz, et al, 2002). Histograms were utilized in the analyses to examine the distribution of the variables and are described in more detail later in the chapter.

Let $i = 1,\ldots,k$ = individuals

Let $j = 1,\ldots,n_i$ = repetitions of the ith individual

Y_{ij} = response for the ith individual and the jth repetition

B_0 = the overall intercept that corresponds the mean value of the response for the group when all factors equal zero.

$B_1,\ldots,B_p$ = fixed effects

$X_{ij1},\ldots,x_{ijp}$ = the values of the variables for the ith individual on the jth repetition.

$z_1,\ldots,z_k$ = dummy variables that correspond to individuals' indicators.

$Y_i = (B_0 + B\ \text{Age}) + B_2(\text{Ethnicity} = \text{Caucasian}) + B_3(\text{Ethnicity} = \text{African American}) + B_4(\text{Provider}) + B_5(\text{goal-setting}) + B_6(\text{class attendance}) + B_7(\text{cholesterol medication prescribed}) + B_8(\text{employment status}) + B_9(\text{number of visits})$

GEE Model with Exponential Regression

Exponential regression was needed to reduce the outliers that produced a slight positive skew for the HbA1c and BMI. For the exponential regressions, the predicted outcome is Y_i. The predicted value of the outcome (Y_i) is the exponential regression of the predictors and the equation will be:

$Y_i = \exp (B_0 + B\ Age) + B_2(Ethnicity = Caucasian) + B_3(Ethnicity = African\ American) + B_4(Provider) + B_5(goal\text{-}setting) + B_6(class\ attendance) + B_7(cholesterol\ medication\ prescribed) + B_8(employment\ status) + B_9(number\ of\ visits)$.

Y_i is the outcome variable, the little $_i$ is an indicator and a particular outcome so Y_i is $Y_{(HbA1c)}$ or $Y_{(LDL)}$ etc. depending on the regression.

All of the variables except ethnicity were measured annually (which was measured once). Patient-provider goal-setting and educational class attendance were categorized as yes/no per year of study. Cholesterol medication on the active medication list (filled) and employment status were gathered annually as well and categorized as yes/no. The categorical variable of "number of visits for the year" had 3 categories, (1) 1-2 years, (2) 3-5 years, (3) 6+ years. The last category of 6+ years was represented in the equation when both b_5 and b_6 equal zero. Similarly for ethnicity, there were 3 categories, (1) Caucasian, (2) African American, (3) no data or response. The last category of "no data or declined to answer" was represented in the equation when both b_6 and b_7 were set equal to zero. The model for LDL and HbA1c were the same as the BMI except the response variable was changed. Figure 3 is the statistical model for this study which was adapted from the Andersen behavioral model.

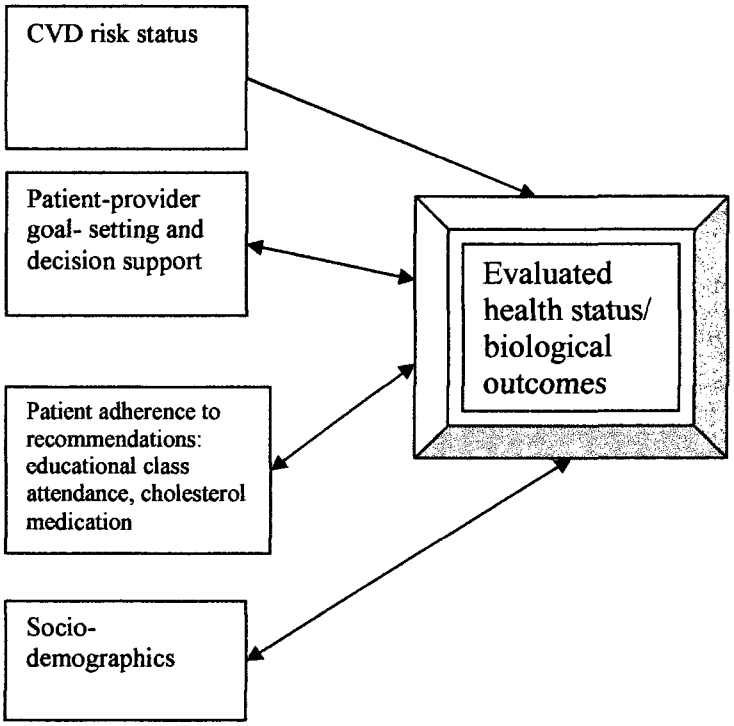


Figure 3. Statistical Model for Cardiovascular Risk Reduction (Andersen, 2008; Andersen, Rice, & Kominski, 2007; Andersen, 1968).

Power Analysis and Recommended Sample Size

A power analysis was completed in the planning stages of the study to find out the actual number of participants needed for the sample size (Cohen, 1992). G*power statistical software was used to define the minimum required sample size. Parameters used in the power analysis were alpha of .05, power of .80, and a medium effect size of .25 (Cohen, 1992). The total sample size required using this software was a minimum of 114 subjects for the regression analyses in Research Question 2. However using the guidelines of 15-20 participants per variable which researchers often use, the sample size required would be 135-180 for each regression (Israel, 1992). With an initial estimated

sample size of 2,000 participants (final sample 1,865), it was determined that the data set contained an adequate number for all statistical analyses. As Research Question 1 was descriptive in nature nearly any sample size is sufficient but a sample over 500 is generally preferred (Israel, 1992).

Limitations of the Study

Limitations of this secondary data analysis included lack of survey information regarding previous education regarding cardiovascular risk reduction, physical activity levels, readiness to change, and behavioral intention. Depth of exploration was limited by VA restrictions related to protected health information. For example, revealing zip codes was not allowed thus limiting the study of geographical variation. The lack of availability of data (i.e.: attended high school or college, marital status) and lack of accurate documentation (i.e.: missing ethnicity) was also a limitation. Measurement and electronic recording of body mass index, LDL, HbA1c was also subject to varying potential errors unknown to the researcher.

Missing data and attrition due to the length of this study as well as mortality due to the age of the participants could also have affected results. A recommended sample size was *at least* 114 participants which was calculated with G* power statistical analysis with a power of .80, with medium effect size and alpha level of .05 to reduce errors in external validity (Cohen, 1992). This study serves as a pilot study related to patient-provider goal-setting and decision support and its generalizability is limited by the number of health care providers and patients involved. Additional limitations are outlined in Chapter 5.

Data Monitoring Plan and Human Subject Protection

All research material obtained from participants was used specifically and exclusively for research purposes and de-identified per Department of Veterans Affairs Medical Center policy. After the data collection, codes that link the participant names and study ID's will remain on the secure, encrypted computer system at the Department of Veterans Affairs Medical Center accessible only to the information security officers. The data extraction was done with the assistance of a physician in primary care who developed the soft ware. With VAMC information security officer approval, the student received a copy of the de-identified data on excel spreadsheet to perform data analysis using SPSS and STATA. The doctoral student, supervisor, and the information security officer ensured ongoing monitoring of data security.

Approval of this study was obtained from the University of Hawai'i at Mānoa Committee on Human Subjects and the Internal Review Board of the Department of Veterans Affairs Medical Center. This study carried low risk to participants. This study involved review of existing records and collection of de-identified demographic and health information. This study did not include direct interaction with veterans and did not involve review or disclosure of sensitive information such as HIV status, drug use, pathology reports, etc. Potential benefits to the target population were: 1) to improve educational efforts related to cardiovascular disease risk reduction 2) to improve patient and health care provider adherence to cardiovascular risk reduction guidelines.

Maintaining privacy and confidentiality of information shared with the researcher was of utmost importance. Each participant and health care provider's identity was coded and kept on the secure, encrypted computer system at the Department of Veterans Affairs

Medical Center accessible to the information security officers. Participant information will remain de-identified after publication.

The following Health Insurance Portability and Accountability Act (1996) identifiers were not used in the study:

1. Names
2. Zip codes
3. All elements of dates except year and all ages over 89
4. Telephone numbers
5. Fax numbers
6. E-mail addresses
7. Social security numbers (SSN)
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate or license numbers
12. Vehicle identifiers and license plate numbers
13. Device identifiers and serial numbers
14. URLs
15. IP addresses
16. Biometric identifiers
17. Full-face photographs and any comparable images

18. Any other unique identifying number, characteristic or code, unless otherwise permitted by the Privacy Rule for re-identification including: scrambled social security numbers, initials, last four digits of social security numbers, employee numbers, etc.
19. The entity does not have actual knowledge that the [remaining] information could be used alone or in combination with other information to identify an individual who was the subject of the information

Inclusion of Women, Children, and Minorities

Male and female adult veterans up to age 89 who received outpatient primary care assigned to one clinic between the years 2003-2007 were included in this research study. This study included all ethnicities, men and women over age 18. Of particular interest for cardiovascular risk were participants over age 50 per ATP III guidelines (2004).

Exclusion Criteria

Veterans must have been seen in the primary care clinics at least twice over a two year time period to be included in this five year study. Therefore patients seen only once and/or seen for less than one year were not included. Non-veterans were not included; non-veterans do not receive care at the sample study location. Veterans who were admitted with psychiatric diagnoses were not included due to the possibility of perceived coercion to take medications and participate in educational programs.

Anticipant Results

It was anticipated that this longitudinal study would provide data to evaluate the prevalence of cardiovascular risk factors among veterans receiving outpatient care and evaluate the effect of patient-provider goal-setting and decision support. Results of this

study may be used in the development of programs which emphasize mutual decision making and promote patient adherence to clinical guidelines.

Summary

The purpose of this study was to examine the influence of patient adherence and patient-provider goal-setting and decision support on factors related to cardiovascular disease risk among veterans. The study was a longitudinal study encompassing a five-year time frame (2003-2007) reviewing veteran outpatient care data through electronic data extraction and chart reviews at a VAMC. This study design and methodology allowed the researcher to investigate the dynamics of this high risk population compared to those without cardiovascular disease risk factors, compare certain demographic characteristics of at risk veterans, and explore patient adherence and the effects of patient-provider goal-setting and decision support. Table 13 provides the operational definitions of the variables analyzed in Research Question 2.

The following research study questions were addressed:

1. *How prevalent are the risk factors for heart disease (age, obesity/elevated BMI, diabetes, LDL cholesterol values, tobacco use) among the veteran population receiving outpatient care?*
2. *Is patient-provider goal-setting and decision support a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL cholesterol, and HbA1c over the 5-year span of 2003-2007 given that demographic and patient adherence factors are also considered in the model?*

Table 13

Operational Definitions Research Question 2.

		Variable	Definition	Type	Value label	Time period
Independent variables	Patient-provider goal-setting and decision support	Patient-provider goal-setting	Goal set by the patient with health care provider support and guidance, participation documented in electronic medical record, protocol	Categorical (yes/no)	0= no goal-setting 1= goal-setting	1,2,3,4, 5 years
	Patient adherence	Educational class attendance	Education program on diabetes, cholesterol lowering, and/or weight management. Defined as attendance at one class or more.	Categorical (yes/no). The actual number of classes attended was not available to the researcher.	Education 0= no educational class attendance 1= educational class attendance	1,2,3,4, 5 years
	Patient adherence	Cholesterol medication on active medication list (filled)	HMG-Co-A reductase inhibitor (statin) filled?	Categorical	Cholesterol medication 0= no 1= yes	1,2,3,4,5 years

Table 13 (Continued).

Operational Definitions Research Question 2.

	Variable	Definition	Type	Value label	Time period
Confounding variables	Age	Patient age and year of birth recorded in electronic medical record at each appointment, age reported annually	Continuous	Age	1,2,3,4,5 years
	Ethnicity	Patient ethnic group	Categorical	Ethnic group (1) Caucasian (2) Non-Caucasian (3) No data/declined to answer **More information on ethnicity given in descriptives in RQ1**	Measured baseline (year 1)
	Employment status	Patient employment status at appointment as noted in electronic record	Categorical	Employment 0= Retired/ unemployed 1= Employed	1,2,3,4,5 years

Table 13 (Continued).

Operational Definitions Research Question 2.

	Variable	Definition	Type	Value label	Time period
Confounding variables continued	Number of visits	How many times did the patient visit primary care annually?	Categorical	1= 1-2 visits 2= 3-5 visits 3= 6+ visits	1,2,3,4,5 years
	Provider type	Health care provider type	Categorical	0= physician or resident 1= nurse practitioner or physician assistant	1,2,3,4,5 years
Dependent variables	Body mass index	BMI= weight in kilograms/ height in m^2 ATP III (2004): normal BMI <25, overweight BMI 25-30, obese BMI >30	Continuous	BMI	1,2,3,4,5 years

Table 13 (Continued).

Operational Definitions Research Question 2.

	Variable	Definition	Type	Value label	Time period
Dependent variables continued	LDL cholesterol	LDL cholesterol values for patient. LDL is a "lipoprotein that transports cholesterol from the liver to the rest of the body and can cause buildup of plaques in the arteries" (Harvard, n.d.). ATP III (2004) (1) Higher than recommended: LDL>130 mg/dl (2) Above optimal: LDL 100-130 mg/dl (3) Optimal: LDL <100 mg/dl	Continuous	LDL	1,2,3,4,5 years
	HbA1c	Test for glycated hemoglobin, used to determine blood sugar control for patients with diabetes, expressed as a percentage. Normal HbA1c is 4-6%, target HbA1c in diabetes is lowest HbA1c tolerated, action recommended HbA1c >7.0%	Continuous	HbA1c	1,2,3,4,5 years

CHAPTER 4: RESULTS OF DATA ANALYSIS

In Chapter 4, the results of the research are presented in a descriptive format as well as with tables. The results of Chapter 4 are divided into three sections based on the results of the study (a) demographic findings, (b) Research Question 1, and (c) Research Question 2. The chapter concludes with a summary of the results.

Demographics as Relates to Study Sample

A total of 1,865 cases were extracted from the original sample of 2,063 electronic records of veteran patients assigned to an outpatient Veteran Affairs Medical Center (VAMC) for the time-frame of years 2003 through 2007, inclusive. Veterans must have been seen in the primary care clinics at least twice over a two year time period to be included in this five year study. Therefore patients seen only once and/or seen for less than one year were not included. Participants who were lost to follow up are discussed later in the chapter (see Tables 15-16).

The 60-69 year-old age group contained the highest frequency for the study sample (534 cases, or 28.7%) with a mean age for the sample of 62.47 with a standard deviation of 13.186. Over sixty percent of participants were between the ages of 40-69 years for the study sample (1140 cases, or 61.1%). The study sample was primarily male (1,798 cases, or 96.4%). Caucasian was the predominant category for the sample (796 cases, or 42.7%) and African American was the second most prevalent ethnic group (175 cases, or 9.4%). Table 14 outlines the sample demographics.

There was a steady trend for the variable of employment (26% employed) over the 5 year study with the majority of the sample retired or unemployed. Over the 5 year study period, 33.9% of veterans were seen 1-2 times a year, 40.4% were seen 3-5 times a

year, and 7.3% were seen more than 6 times per year. There were 11,166 patient visits during the study years 2003-2007 and this includes patient appointments with the medical assistant or licensed practical nurse for blood pressure recheck, etc. The care of 1,069 participants (57.4%) was managed by a physician or resident, and 796 participants (42.5%) were managed by either a nurse practitioner or physician assistant. Over 75% of the sample were current or former smokers (1447 cases); 21.9% of veterans never smoked (408 cases).

Table 14

Sample Demographics (*n= 1,865*)

Variable	n	%
Age		
20-29	35	1.9
30-39	79	4.2
40-49	169	9
50-59	437	23.4
60-69	534	28.7
70-79	431	23.1
80-89	177	9.5
Missing data (no year of birth)	3	0.1
Total	1865	100.0

Table 14 (Continued).

Sample Demographics (*n= 1,865*)		
Variable	n	%
Gender		
Male	1798	96.4
Female	67	3.6
Total	1865	100.0
Ethnicity		
Caucasian	796	42.7
African American	175	9.4
Hispanic	6	0.3
Asian/Hawaiian/ Pacific Islander/	4	0.2
Native American	1	0.1
Other or multiple race	0	0
No data recorded or declined to answer	883	47.3
Total	1865	100.0
Overall employment status 2003-2007		
Employed	490	26.2
Retired or unemployed	960	51.4
Data not available to researcher	415	22.4
Total	1865	100.0

Table 14 (Continued).

Sample Demographics (*n= 1,865*)

Variable	n	%
Average number of visits per patient 2003-2007		
1-2 visits	632	33.9
3-5 visits	753	40.4
6+ visits	136	7.3
Missing (# visits not recorded)	3	0.2
Health care provider		
MD or resident	1069	57.5
NP or PA	796	42.5
Total	1865	100.0
Tobacco use reported		
Current smoker	543	29.1
Former smoker	904	48.5
Never smoked	408	21.9
Data not recorded	10	0.5
Total	1865	100.0

Note: MD= medical doctor, NP= nurse practitioner, PA= physician assistant

Comparison of Study Sample with State Population Demographics

In Table 15 demographic information on the study sample, state veteran population, and missing veterans are displayed. The study sample data was similar to the state population data in regards to age and ethnicity. The 60-69 year-old age group contained the highest frequency for both the study sample (534 cases, or 28.7%) and the population (164,677 cases, or 20.4%). Over sixty percent of cases were between the ages of 40-69 years for both the study sample (1140 cases, or 61.1%) and the population (491,443 cases, or 60.8%). The study sample was predominantly male (1,798 cases, or 96.4%) which was consistent with the state population gender demographic for veterans (92.5%). Ethnicity was commonly divided for both the sample and population data. Caucasian was the predominant category for both the sample data (796 cases, or 42.7%) and the population data (604,143 cases, or 74.8%). African American was the second most prevalent ethnic group. One hundred and seventy five cases (9.4%) and 161,202 cases (20.0%) were reported as African American for the sample and population data respectively. Ethnicity was not well documented at the study site.

Type of health care provider was not available from the state population data, however, for the study sample, 1,069 cases (57.4%) were evaluated by a physician or resident, and 796 cases (42.6%) were seen by either a nurse practitioner or physician assistant. Seven health care providers were included in this study: 4 attending physicians or residents under the supervision of the attending physician, and 3 nurse practitioners or physician assistants. The identities of the providers will remain protected.

Table 15.

Demographic Characteristics of Study Sample (n = 1,865), Missing Veterans (lost to follow up under age 89, n= 146) and State Population Data (Department of Veterans Affairs, 2007, N = 807,325).

Variable	Sample n	Sample %	Missing Veteran n	Missing Veteran %	State Population N	State Population %
Age						
20-29	35	1.9	8	5.5	47,259	5.8
30-39	79	4.2	14	9.6	94,816	11.8
40-49	169	9	18	12.4	161,130	19.9
50-59	437	23.4	41	28.1	165,636	20.5
60-69	534	28.7	28	19.1	164,677	20.4
70-79	431	23.1	26	17.8	107,487	13.3
80-89	177	9.5	11	5.5	59,934	7.4
90+	0*	0*	0*	0*	5,978	0.7

Table 15 (Continued).

Demographic Characteristics of Study Sample (n = 1,865), Missing Veterans (lost to follow up under age 89, n= 146), and State Population Data (Department of Veterans Affairs, 2007, N = 807,325).

Variable	Sample n	Sample %	Missing Veteran n	Missing Veteran %	State Population N	State Population %
Ethnicity						
Caucasian	796	42.7	73	50	604,143	74.8
African American	175	9.4	15	10.3	161,202	20.0
Hispanic	6	0.3	0	0	18,233	2.3
Asian/Hawaiian/ Pacific Islander/	4	0.2	2	1.4	10,936	1.4
Native American	1	0.1	0	0	3,585	0.4
Other or multiple race	0	0	0	0	9,226	1.1
No data or declined to answer	883	47.3	56	38.4	**	**
Total	1,865	100.0	146	100.0	807,325	100.0

*Note:*not permitted to sample veterans over age 89, ** not available to researcher*

Table 15 (Continued).

Demographic Characteristics of Study Sample (n = 1,865), Missing Veterans (lost to follow up under age 89, n= 146), and State Population Data (Department of Veterans Affairs, 2007, N = 807,325).

Variable	Sample n	Sample %	Missing Veteran n	Missing Veteran %	State Population N	State Population %
Gender						
Male	1798	96.4	138	94.5	746776	92.5
Female	67	3.6	8	5.5	60549	7.5
Employment status						
Employed	490	26.2	**	**	**	**
Not employed or retired	960	51.4	**	**	**	**
Missing information	415	22.4	**	**	**	**
Visit interval						
1-2 visits	632	33.9	**	**	**	**
3-5 visits	753	40.4	**	**	**	**
6+ visits	136	7.3	**	**	**	**
Health care provider type						
MD or Resident	1069	57.4	106	72.6	**	**
NP or PA	796	42.6	40	27.4	**	**

*Note:***= not available to researcher, NP= nurse practitioner, MD= medical doctor, PA= physician assistant*

Table 15 (Continued).

Demographic Characteristics of Study Sample (n = 1,865), Missing Veterans (lost to follow up under age 89, n= 146), and State Population Data (Department of Veterans Affairs, 2007, N = 807,325).

Variable	Sample n	Sample %	Missing Veteran n	Missing Veteran %	State Population N	State Population %
Tobacco use						
Current smoker	543	29.1	36	24.7	168731	20.9
Former smoker	904	48.5	**	**	**	**
Never smoked	408	21.9	**	**	**	**

*Note:***= not available to researcher*

Missing Veterans Lost to Follow up

Department of Veterans Affairs Medical Center policy prohibits inclusion of veterans over age 89 in any study. Of the original sample, 41 veterans (1.9%) were eliminated due to age and 146 veterans (7.1%) moved, were reassigned to another clinic or facility, or otherwise lost to follow up. Over half of the sample (1015 cases or 54.4%) joined the study in 2003 with 76% of the sample (1412 cases) joining before the end of 2004. About a quarter of the sample (453 cases) joined the study in 2005 and 2006. Over half of the sample (974 cases or 52.2%) came to appointments in primary care every year during the five year study period.

The majority of the missing veterans were male (138 cases or 94.5%) and 50% (73 cases) were Caucasian, 10.3% (15 cases) were African American, and 1.4% (2 cases) were listed as Hawaiian or Pacific Islander. Almost 40% of the veterans (56 cases) did

not have their ethnicity recorded by the clinic staff which was an issue for veterans included in the study as well. There was a wide spread of ages with a slightly higher number of younger veterans lost to follow up than the included cases; 6.2% (9 cases) lost to follow up were under age 30. The highest frequency (41 cases) was between the ages of 50-59 with a mean age of 57.49. Forty two percent (65 cases) were between the ages of 60-89.

Among the missing veterans, 35% (35 cases) had a BMI of 30 or above, 10.3% (15 cases) had the diagnosis of cardiovascular disease, 11.6% (17 cases) had diabetes, 2.1% (3 cases) had diabetes and cardiovascular disease, and 16.4% (25 cases) were prescribed a HMG-Co-A reductase inhibitor (statin). A fourth of the missing veterans (36 cases, or 24.7%) had tobacco use on their list of diagnoses. Almost three quarters of the missing veterans (106 cases or 72.6%) were followed by a physician or resident in training. Veterans lost to follow up comprised 7.1% of the original sample of 2,063. In the study setting, participants who received regular care traveled from a wide radius including six nearby states. Zip code and geographic information was not collected per VAMC policy. Of veterans lost to follow up, however, over 25% traveled over 150 miles to receive care. Table 16 outlines the demographic and other information available on the 146 veterans missing from the original sample.

Table 16

Missing Veteran Demographics and Other Variables (n= 146)

Variable	n	%
Age		
20-29	8	5.5
30-39	14	9.6
40-49	18	12.4
50-59	41	28.1
60-69	28	19.1
70-79	26	19.8
80-89	11	5.5
Total	146	100.0
Gender		
Male	138	94.5
Female	8	5.5
Total	146	100.0

Table 16 (Continued).

Missing Veteran Demographics and Other Variables (n= 146)		
Variable	n	%
Ethnicity		
Caucasian	73	50.0
African American	15	10.3
Hispanic	0	0
Asian/Hawaiian/ Pacific Islander/	2	1.4
Native American	0	0
Other or multiple race	0	0
No data recorded by staff	56	38.3
or declined to answer		
Total	146	100.0
Body mass index		
*16-20	8	5.5
21-30	97	66.4
31-40	33	22.6
41-50	2	1.4
50+	0	0
Missing data	6	4.1
**height or weight not recorded		
Total	146	100.0

* *No patients had a BMI under 16*

Table 16 (Continued).

Missing Veteran Demographics and Other Variables (n= 146)

Variable	n	%
Presence of CVD or CHF diagnosis	15	10.3
Presence of diabetes diagnosis	17	11.6
Presence of CVD and/or CHF and diabetes	3	2.1
Presence of obesity, BMI ≥ 30	49	33.7
Health care provider		
MD or resident	106	72.6
NP or PA	40	27.4
Total	146	100.0
Tobacco use		
Smoking on diagnosis list	36	24.7
Nonsmoker or tobacco use not recorded	110	75.3
Total	146	100.0

Note: CVD= cardiovascular disease, CHF= congestive heart failure, NP= nurse practitioner, MD= medical doctor, PA= physician assistant

Research Question 1

Research Question 1 asked: "How prevalent are the risk factors for heart disease (age, obesity/ elevated BMI, diabetes, LDL cholesterol values, tobacco use) among the veteran population?" Descriptive analysis was performed to find the frequency and

percentages of the cardiovascular risk factors of: age ≥ 50, obesity (elevated BMI ≥ 30), tobacco use (current or former user), diagnosis of diabetes mellitus, diagnosis of cardiovascular disease (CVD) or congestive heart failure (CHF), and elevated LDL cholesterol ≥ 130 mg/dl, in addition to examining the demographic characteristics of the entire sample. The descriptive analysis included data for all five years combined, and for each of the five individual years (2003-2007). Table 17 reviews the prevalence of risk factors for heart disease among the sample, and Table 18 includes count and percentage data for BMI and LDL as it relates to high or low risk status for the study sample.

Veteran Risk Factor Prevalence for Cardiovascular Disease

Veteran risk factor prevalence among the sample will be discussed in this section and shown in Table 17. The prevalence of a disease is "the proportion of a population that are cases at a point in time" (Coggin, Rose, & Barker, 1997, n.p.). As stated previously, modifiable risk factors for cardiovascular disease include obesity, hypertension, hyperlipidemia, diabetes, and tobacco use (Kirk, et al, 2002). Previous history of cardiovascular disease or congestive heart failure places veterans at high risk for decreased quality of life and increased mortality. Major risk factors for cardiovascular disease include age above 50 years, family history of cardiovascular disease, cigarette smoking, hypertension, elevated LDL cholesterol ≥130 mg/dl, diabetes, obesity, and physical inactivity (ATP, 2004).

The cases were predominantly high risk for age, with 1,579 cases (84.7%) at age 50 or older in the year 2007.The mean age of the sample was 62.7 with a standard deviation of 13.186. Nearly a quarter of the sample (428, 22.9%) had an existing diagnosis of cardiovascular disease and/or congestive heart failure, 26.2% (489) of the

cases had the diagnosis of diabetes, and 6.6% (124) had both cardiovascular disease and diabetes. BMI ratios were similarly trended for all five study years with nearly 40% of the cases at high risk with a BMI ≥30. Twenty eight percent (526) had an LDL higher than recommended. LDL levels showed a decrease in risk over the 5 years of the study, from 42.9% high risk cases in 2003 to 24.2% high risk cases in 2007.

Over three-quarters of the cases (1,446 or 77.5%) were current or former tobacco users. Tobacco use accelerates atherosclerosis, adversely affects lipid values (elevates LDL and reduces HDL), damages the lining of blood vessels, and causes the formation of blood clots (Eliasson, Hjalmarson, Kruse, Landfeldt, & Westin, 2001). The amount of tobacco use, duration of smoking, and use of smokeless tobacco was not available to the researcher. The cardiovascular effects of tobacco use may persist for several months or years after cessation thus current or former tobacco use was chosen as a high risk variable (Eliasson et al, 2001).

Table 17

Risk factor prevalence among veterans in study sample (n= 1,865)

	n	%
Age ≥ 50 years	1579	84.7
Presence of obesity BMI ≥ 30	724	38.8
Presence of diabetes diagnosis	489	26.2
Preexisting diagnosis of CVD or CHF	428	22.9
Presence of both diabetes and CVD or CHF	124	6.6
Hyperlipidemia with LDL ≥ 130 mg/dl	526	28.2
Current or former tobacco use	1446	77.5

Note: BMI= body mass index, CVD= cardiovascular disease, CHF= congestive heart failure, LDL= low-density lipoprotein.

Outcome variables of BMI, LDL, and HbA1c

Rates of obesity, hyperlipidemia, and diabetes were high among this sample as previously noted. The outcome (dependent) variables of BMI, LDL, and HbA1c were measured in this study. As noted in Table 13, body mass index was used to help objectively quantify weight and was defined as normal <25, overweight BMI 25-29, and obese as BMI ≥ 30. No patients in the study had a BMI under 16 (which is considered underweight). BMI equals weight in kilograms divided by height in meters squared. LDL cholesterol was used to measure lipid control and is defined as higher than recommended LDL ≥ 130, above optimal 100-129, and optimal as <100. HbA1c was used to determine

blood sugar control in diabetics with normal defined as 4-6%, and action recommended if HbA1c is $\geq$ 7%.

Patients were not included in this study if they were not seen in primary care at least twice during the study period and were not included if they did not have any laboratory results. Patients who were not diabetic did not have a HbA1c drawn unless their blood sugar was noted to be higher than normal. HbA1c is occasionally used by health care providers to screen for diabetes when patients are unable to obtain a two hour glucose tolerance test or more than one fasting blood sugar test. BMI was recorded on the majority of the sample, however it was missing on about 17% of participants who did not have a height and/or weight recorded. Over half of the sample had their cholesterol checked annually. Table 18 includes frequency and percentage data for BMI for the study sample over the five year period.

As noted in Table 18, BMI and HbA1c remained steady over the 5 year study period but LDL values declined significantly. The mean BMI in 2003 and 2007 were 29.2 and 29.1 respectively. The mean HbA1c in 2003 and 2007 were 7.3 and 7.2 respectively. The LDL cholesterol mean declined from 125.6 in 2003 to 106.3 in 2007. BMI values did not decline over the course of the study from the baseline.

Table 18
Descriptives for the Outcome Variables BMI, LDL, HbA1c (n= 1,865)

	n	%	Mean	Median	95% CI	SD	Lowest value	Highest value
BMI 2003	1332	71.4	29.2	28.5	(28.933, 29.500)	5.2740	15.5	57.3
BMI 2004	1509	80.9	29.1	28.5	(28.904, 29.438)	5.2922	16.6	59.3
BMI 2005	1664	89.2	29.2	28.4	(28.886, 29.407)	5.4174	15.9	61.8
BMI 2006	1699	91.1	29.2	28.5	(28.938, 29.465)	5.5418	15.9	63.7
BMI 2007	1516	81.3	29.1	28.5	(28.906, 29.475)	5.6457	15.2	67.6
HbA1c 2003	245	13.1	7.3	6.9	(7.063, 7.469)	1.6141	5.0	14.8
HbA1c 2004	348	18.7	6.9	6.7	(6.854, 7.115)	1.2369	4.9	12.9
HbA1c 2005	429	23.0	7.1	6.8	(7.010, 7.277)	1.4061	5.0	15.4

Table 18 (Continued).

Descriptives for the Outcome Variables BMI, LDL, HbA1c (n= 1,865)

	n	%	Mean	Median	95% CI	SD	Lowest value	Highest value
HbA1c 2006	459	24.6	7.1	6.8	(6.98, 7.22)	1.338	5.0	16.0
HbA1c 2007	429	23.0	7.2	6.9	(7.015, 7.277	1.3793	5.0	18.8
LDL 2003	941	50.5	125.6	124.0	(123.35, 127.87)	35.287	34	245
LDL 2004	1043	55.9	120.1	117.0	(118.12, 122.14)	33.146	31	362
LDL 2005	1039	55.7	112.5	111.0	(110.51, 114.57)	33.321	14	263
LDL 2006	1320	70.8	111.6	109.0	(109.86, 113.33)	32.067	23	266
LDL 2007	979	52.5	106.3	103.0	(104.11, 108.43)	34.438	19	254

CI = confidence interval, SD= standard deviation

BMI and LDL levels were categorized by high and low risk for each year of the study and overall in Tables 19 and 20.

Table 19

BMI Levels Categorized by Risk Category for Each Year of Study (2003-2007) and Over Entire Study (n = 1865)

Variable/Year	n	%	Mean	*SD*
BMI - 2003				
Overall Average	1332	-	29.22	5.27
Low Risk	831	62.4	26.06	2.69
High Risk	501	37.6	34.45	4.25
BMI – 2004				
Overall Average	1509	-	29.17	5.29
Low Risk	952	63.1	26.06	2.74
High Risk	557	36.9	34.48	4.28
BMI – 2005				
Overall Average	1664	-	29.15	5.42
Low Risk	1004	62.7	25.93	2.76
High Risk	620	37.3	34.57	4.36
BMI – 2006				
Overall Average	1699	-	29.20	5.54
Low Risk	1060	62.4	25.90	2.81
High Risk	639	37.6	34.68	4.53
BMI – 2007				
Overall Average	1516	-	29.19	5.65
Low Risk	941	62.1	25.83	2.86
High Risk	575	37.9	34.68	4.70

Table 19 (Continued).

BMI Levels Categorized by Risk Category for Each Year of Study (2003-2007) and Over Entire Study (n = 1865)

Study Average	n	%	Mean	*SD*
Total Average over 5 years	1863	-	29.11	5.29
Low Risk	1164	62.5	25.95	2.71
High Risk	699	37.5	34.37	4.23

Note: BMI = Body Mass Index; SD = Standard Deviation. Risk Categories for BMI are as follows: Low Risk = BMI < 30, High Risk = BMI ≥ 30. Study average for BMI Level was compiled by averaging each case according to values of the measurements divided by the number of measurements taken over the five year time interval.

Table 20

LDL Levels Categorized by Risk Category for Each Year of Study (2003-2007) and Over Entire Study (n = 1774)

Variable/Year	n	%	Mean	SD
LDL 2003				
Overall Average	941	-	125.61	35.29
Low Risk	537	57.1	101.37	20.02
High Risk	404	42.9	157.83	23.40
LDL 2004				
Overall Average	1043	-	120.13	33.15
Low Risk	664	63.7	100.36	19.44
High Risk	379	36.3	154.76	21.84
LDL 2005				
Overall Average	1039	-	112.54	33.32
Low Risk	736	70.8	96.00	21.50
High Risk	303	29.2	152.73	20.10

Table 20 (Continued).

LDL Levels Categorized by Risk Category for Each Year of Study (2003-2007) and Over Entire Study (n = 1774)

Variable/Year	n	%	Mean	SD
LDL 2006				
Overall Average	1320	-	111.59	32.07
Low Risk	975	73.9	97.11	20.77
High Risk	345	26.1	152.52	21.16
LDL 2007				
Overall Average	979	-	106.27	34.44
Low Risk	742	75.8	91.49	22.88
High Risk	237	24.2	152.54	20.86
Study average				
Total Average over 5 years	1774	-	115.35	29.66
Low Risk	1248	70.3	100.69	19.29
High Risk	526	29.7	150.12	19.10

Note: LDL = Low-Density Lipoprotein; SD = Standard Deviation. Risk Categories for LDL are as follows: Low Risk, LDL < 130; High Risk, LDL ≥ 130. Study average for LDL level was compiled by averaging each case according to values of the measurements divided by the number of measurements taken over the five year time interval.

Inferential Analysis

This section begins with a discussion of the variables utilized in Research Question 2 then moves into a discussion of the inferential analysis. The research question

asks: *Is patient-provider goal-setting a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL cholesterol, and HbA1c over the 5-year span of 2003-2007 given that demographic and patient adherence factors are also considered in the model?* Patient-provider goal-setting was an independent variable in the study. Patient adherence was evaluated by the independent variables of educational class attendance and presence of cholesterol medication on each veteran's active medication list due to the limitations of this secondary data analysis. Confounding demographic variables included age, ethnicity, employment status, number of visits annually, and type of health care provider. The biological outcome measures of BMI, HbA1c, and LDL were dependent variables measuring the evaluated health status in this study. Table 13 on page 95 outlines the variables used in this study.

The continuous variables of age, BMI, HbA1c, and LDL were described previously in Tables 17-20. Question 2 included: (1) patient-provider goal-setting classified as dichotomous (yes/no); (2) patient adherence as measured by: educational class attendance classified as dichotomous (yes/no) and cholesterol medication prescribed (yes/no); (3) ethnicity recorded as Caucasian, African American, or no data/ declined to answer (4) annual employment status categorized as (a) employed, and (b) unemployed or retired; (5) number of annual patient visits categorized as (a) 1-2 visits (b) 3-5 visits, (c) 6 or more visits; and (6) type of health care provider (a) physician or resident (b) nurse practitioner or physician assistant. Participants who did not have their LDL value checked were not included in the inferential analysis.

All participants in the study sample were invited to participate in patient-provider goal setting and were told about the availability of patient educational classes on weight

management, diabetes, and cholesterol lowering. High and low risk categories for this study were based on the number of risk factors which ranged from 0-6 and included age ≥ 50, BMI ≥ 30, diagnosis of diabetes, diagnosis of cardiovascular disease, LDL ≥ 130, and current or former tobacco user. The low risk category had 0-1 risk factors and the high risk category consisted of two or more risk factors. Table 21 outlines the independent variables of patient-provider goal-setting and decision support and class attendance according to high and low risk patient group. Cholesterol medication was not included in this table as the majority of the veterans prescribed this medication are in a high risk group.

Goal-setting for high risk cases presented an even trend over time, with an overall average percentage of 39.4% of high risk cases participating in goal-setting for the study time-frame. Class attendance for the entire sample averaged 4.9% over the 5 years of study which 6.0% of the high risk sample participating. The average percentages for employment indicated that 66.3% of low risk cases were employed, and 31.9% of high risk cases were employed (see appendix). More cases in the high risk group were retired or unemployed (68.5%) than were in the low risk group (33.1%). The numbers of annual visits for the low risk group were predominantly two or less, with an overall average percentage of 82.2% of cases for the study timeframe. The high risk group cases visited the clinic more often year after year, with an overall average percentage of 65.1% visiting 3 or more times annually.

Table 21a.

2003-2007 Patient-Provider Goal-Setting According to Patient Risk Group.

Variable	Low Risk		High Risk	
	Freq.	Valid %	Freq.	Valid %
Goal-setting 2003				
Yes	0	0.0	348	36.5
No	33	100.0	606	63.5
Missing/not reported	---	---	---	---
Goal-setting 2004				
Yes	2	10.5	443	41.8
No	17	89.5	617	58.2
Missing/not reported	---	---	---	---
Goal-setting 2005				
Yes	2	5.9	487	44.4
No	32	94.1	609	55.6
Missing/not reported	---	---	2	---
Goal-setting 2006				
Yes	3	5.7	473	36.4
No	50	94.3	826	63.6
Missing/not reported	---	---	2	---
Goal-setting 2007				
Yes	1	3.1	401	38.0
No	31	96.9	654	62.0
Missing/not reported	---	---	1	---

Note. Freq. = Frequency; Valid % = percentage of reported counts (excludes missing data). Patients considered low risk would not be prescribed a cholesterol lowering medication therefore that independent variable is not included on this table.

Table 21b (Continued).

2003-2007 Educational Class Attendance According to Patient Risk Group.

Variable	Low Risk		High Risk	
	Freq.	Valid %	Freq.	Valid %
Class attendance 2003				
Yes	0	0.0	146	15.3
No	33	100.0	808	84.7
Missing/not reported	---	---	3	---
Class attendance 2004				
Yes	0	0.0	126	11.9
No	19	100.0	933	88.1
Missing/not reported	---	---	4	---
Class attendance 2005				
Yes	0	0.0	87	7.9
No	34	100.0	1010	92.1
Missing/not reported	---	---	1	---
Class attendance 2006				
Yes	0	0.0	41	3.2
No	53	100.0	1258	96.8
Missing/not reported	---	---	2	---
Class attendance 2007				
Yes	0	0.0	45	4.3
No	32	100.0	1009	95.7
Missing/not reported	---	---	2	---

Note. Freq. = Frequency; Valid % = percentage of reported counts (excludes missing data). Patients considered low risk would not be prescribed a cholesterol lowering medication therefore that independent variable is not included on this table.

Table 22 contains the annual frequency and percentage of the independent variables of patient-provider goal setting and decision support, educational class

attendance, and cholesterol medication on veteran active medication list. Patient-provider goal-setting participation rose from 19.2% (368) to as high as 24% at the end of the 5 year period. Class attendance declined over the 5 year period with an overall average of 4.9% of the sample participating. Cholesterol medication found on veteran active medication list rose from 22.4% in 2003 to 42.4% in 2007 with an average 34.7% of the sample prescribed a HMG-Co-A reductase inhibitor.

The number of employed veterans and the number of retired veterans reported both increased over the 5 year study and the amount of missing information declined. The overall rate of employment was 26.2%, retired or unemployed was 51.4%, and missing data was 22.4% over the study time period. The researcher did not have access to veteran financial information and relied solely on the EMR. Over the 5 year study period, 33.9% of veterans were seen 1-2 times a year, 40.4% were seen 3-5 times a year, and 7.3% were seen more than 6 times per year.

Table 22

Research Question 2: Independent variables (*n= 1,865*)

	2003		2004		2005		2006		2007	
	n	%	n	%	n	%	n	%	n	%
Goal-setting yes	368	19.2	467	25.1	500	26.9	483	26.0	446	24.0
Goal-setting no	1486	80.2	1394	74.7	1361	73	1376	73.7	1409	75.5
Missing	11	0.6	4	0.2	4	0.1	6	0.3	10	0.5
Total	1865	100.0	1865	100.0	1865	100.0	1865	100.0	1865	100.0
Adherence										
Class attendance	155	8.3	131	7.0	90	4.8	42	2.3	46	2.5
No Class attendance	1699	91.1	1729	92.7	1773	95.1	1818	97.5	1809	97.0
Missing	11	0.6	5	0.3	2	0.1	5	0.2	10	0.5
Total	1865	100.0	1865	100.0	1865	100.0	1865	100.0	1865	100.0
Cholesterol medication yes	415	22.4	567	30.5	697	37.4	760	41.0	783	42.4
Cholesterol medication no	1436	76.8	1290	69.1	1166	62.5	1094	58.4	1065	56.7
Missing	14	0.8	8	0.4	2	0.1	11	0.6	17	0.9
Total	1865	100.0	1865	100.0	1865	100.0	1865	100.0	1865	100.0

Table 22 (Continued)

Research Question 2: Sample Variables per Year (*n= 1,865*)

	2003		2004		2005		2006		2007	
	n	%	n	%	n	%	n	%	n	%
Employed	369	19.8	459	24.6	538	28.8	558	29.9	524	28.1
Not employed or retired	711	38.1	904	48.5	1028	55.2	1090	58.4	1065	57.1
Missing	785	42.1	502	26.9	299	16.0	217	11.6	276	14.8
Total	1865	100.0	1865	100.0	1865	100.0	1865	100.0	1865	100.0
Number of visits per veteran annually										
0 visits	752	40.3	439	23.5	218	11.7	121	6.5	181	9.7
1-2 visits	457	24.5	599	32.1	704	37.7	719	38.6	683	36.6
3-5 visits	541	29.0	701	37.6	799	42.8	864	46.3	855	45.8
6+ visits	112	6.0	123	6.6	144	7.7	160	8.6	140	7.5
Missing	3	0.2	3	0.2	0	0.0	1	0.1	6	0.3
Total	1865	100.0	1865	100.0	1865	100.0	1865	100.0	1865	100.0

See Table 14 for a review of the confounding variables of age and ethnicity in the sample demographics and Table 18 for the dependent variables of BMI, LDL, and HbA1c

Provider Type and Goal-Setting

As seen in Table 23, patients were more likely to participate in patient-provider goal setting when their health care was managed by a nurse practitioner or physician assistant. Almost a quarter of the sample of NP/PA patients participated in patient-provider goal-setting during the five year study. Only 1.4% of the patients managed by physicians participated in goal-setting during the five year period.

Table 23

Patient participation in patient-provider goal-setting by provider type and study year (*n=1,865*)

Patient-provider Goal-setting	MD or resident	NP or PA
2003	1.3% (25)	18.3% (343)
2004	1.2% (21)	24.0% (446)
2005	1.2% (23)	25.5% (477)
2006	1.4% (26)	24.5% (457)
2007	2.1% (40)	21.7% (406)

Note: MD= medical doctor, NP= nurse practitioner, PA= physician assistant

Research Question 2

Research Question 2 asked: *Is patient-provider goal-setting and decision support a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL cholesterol, and HbA1c over the 5-year span of 2003-2007 given that demographic factors and patient adherence are also considered in the model?* GEE for panel data was utilized to investigate Research Question 2. The statistical hypotheses are as follows: *Null Hypothesis for Research Question 2:* Patient-provider goal-setting and decision support will not significantly predict values of the dependent variables of BMI, LDL, and HbA1c given that demographic and adherence factors are also considered in the model. *Alternative Hypothesis for Research Question 2:* Patient-provider goal-setting and decision support will significantly predict values of the dependent variables of BMI,

LDL, and HbA1c given that demographic and adherence factors are also considered in the model.

Generalized Estimating Equations

Hypothesis testing for Research Question 2 involved mixed effect model regressions via generalized estimating equations (GEE). The GEE is similar to standard regression but relaxes several assumptions and represents an extension of the general linear model to accommodate correlated data (Ghisletta & Spini, 2004). GEE is used to fit the parameters of a generalized linear model when unknown correlations are present (Hardin & Hilbe, 2003). In this study the random effects of the individuals are not the primary interest as the focus is on estimating the average response over the population.

Assumptions for Generalized Estimating Equation Analyses

Unlike standard regression GEE allows for dependence within clusters, such as in the longitudinal data of this study. GEE requires three specifications: (1) a mean function, (2) a working variance function, and (3) a working correlation matrix for the clusters, which models the dependence of each observation with other observations in the same cluster. The appeal of a GEE model is that it gives consistent estimates of the parameters, and consistent estimates of the standard errors can be obtained using a robust sandwich estimator even if the working correlation matrix is incorrectly specified. This estimator is consistent as the number of case clusters becomes large and is considered robust to any type of correlation within panels or groups of people surveyed over a given time span (Hardin & Hilbe, 2003; Yafee, 2003). Within a GEE model framework, marginal means are taken from the data and used for parameter estimation; participants with missing data are not excluded from the analysis (Hardin & Hilbe, 2003; Twisk & deVente, 2002).

GEE models a known function of the marginal expectation of the dependent variable as a linear function of the explanatory variables. The parameters estimated are derived as population-averaged and include within panel dependence by averaging effects; measuring change among the sample as a whole was the focus of this study (Hardin & Hilbe, 2003). GEE in STATA requires a fitting distribution, the default being a Gaussian or normal distribution. The GEE regression makes use of the marginal means (consideration of each mean in proportion to its sample size) and it was therefore determined that the normality assumption was not violated and the Gaussian distribution (default) was used with the "xtgee" command in STATA to perform the regression analyses for Hypothesis 2.

Histograms

Histograms were used to show the distribution of the continuous variables and were valuable in examination of the distribution of the data. Histograms were used to look for measurement or calculation errors that would lead to a non-normal distribution and determine whether there was adequate data cleaning (Tulane University, 2009). The dependent variables of BMI, LDL, and HbA1c were plotted with histograms for each year. All variables indicated a roughly bell shaped distribution with slight positive skew. As there were some outliers for the BMI and HbA1c, the final models were repeated using an exponential regression to reduce skewness and confirm it was robust. The LDL histogram did not require transformation as the model was normally distributed. The exponential regression improved the bell shaped distribution for the BMI and HbA1c. The histograms for LDL cholesterol and exponential regression of BMI and HbA1c for each year are included in the appendix.

Results of the GEE

Generalized estimating equations (GEE) for panel data was utilized to investigate Research Question 2. STATA v10, via the "xtgee" command for longitudinal/panel data was used for GEE analysis. Three separate regression analyses were performed on the data, one for each of the outcome, dependent variables of (1) BMI, (2) LDL, and (3) HbA1c. All regressions included the same nine predictors as follows: (a) goal-setting, coded as yes = 1, no = 0; (b) patient adherence as measured by class attendance, coded as yes = 1, no = 0 and (c) cholesterol medications prescribed, coded as yes = 1, no = 0; (d) age in years (e &f) ethnicity, dummy coded as Caucasian = 1, non-Caucasian = 0; a dummy variable for African American ethnicity coded as African American= 0, not African American= 1, and a reference category, not included in the actual regression but included in the model, when both the Caucasian and African American ethnicity dummy variables were coded as 0 (g) employment, coded as 1 = yes, 0 = no or retired; and (h) number of visits annually, coded into four dummy variable groups of (1) 0 visits, (2) 1-2 visits, (3) 3-5 visits, and (4) 6+ visits; and (i) health care provider type, dummy coded as medical doctor (MD) = 0 and nurse practitioner or physician's assistant (NP/PA) coded as = 1. The variables of age, ethnicity, employment status, and number of visits annually were included as possible confounding variables. A 95% level of significance was set for all regression analyses. A total of 11 records of patients with ethnicity that were not one of the three dummy coded ethnicity categories of (a) Caucasian, (b) African American, or (c) Missing/Unknown were removed before analysis in Research Question 2. In the tables, patient-provider goal-setting was shortened to goal-setting, health care provider is listed as provider, patient educational class attendance was shortened to class attendance,

and cholesterol medication on active medication list is listed as cholesterol medication Rx. Adherence is measured by patient educational class attendance and cholesterol medication on the veteran active medication list due to the limitations of this secondary data analysis. Demographic information for the GEE included age, ethnicity, employment status, number of annual visits, and type of health care provider.

Regression of BMI on Nine Predictor Variables – Hypothesis 2a

BMI was regressed on the nine predictors of goal-setting, class attendance, cholesterol medication prescribed, age, ethnicity (2 dummy groups), employment, number of annual visits, and provider type. Table 24 displays the results of the regression, including regression coefficients, standard errors, confidence intervals, and the *p*-value for predictor significance in the model.

Table 24

Generalized Estimating Equation Regression of BMI Levels on Nine Predictors (n = 1,733 groups; 6,832 observations).

Variable	*b*	*SE b*	95% CI for *b*	*p*
Goal-setting	0.05	0.08	(-0.104, 0.202)	0.533
Class attendance	0.04	0.07	(-0.097, 0.171)	0.587
Cholesterol medication RX	0.28	0.11	(0.068, 0.490)	0.010
Age	- 0.03	0.01	(-0.048, -0.016)	<0.0005
Ethnicity Caucasian	0.08	0.27	(-0.445, 0.607)	0.764
Ethnicity African American	0.22	0.44	(-0.648, 1.089)	0.618
Employed	0.21	0.19	(-1.710, 0.588)	0.280
Number of visits	0.32	0.08	(0.162, 0.470)	<0.0005
Provider	0.07	0.26	(-0.448, 0.579)	0.803

Note. b = Regression coefficient; SE b = Standard error of regression coefficient; CI = Confidence Interval; p = p-value for significance; Rx = prescription.

The regression model for BMI was significant (Wald χ^2 (df 9) = 44.94, p < 0.0005), indicating that the predictor model using the data set was improved over a model in which all predictors were set to zero. Significant predictors included age ($p < .0005$), cholesterol medication filled ($p = 0.010$), and number of visits ($p < 0.0005$). The regression coefficient for the predictor of age ($b = -0.03$) indicates that the value of BMI decreases by 0.03 for each 1 unit increase in age if all other predictors remain constant. This predictor is statistically significant. With time the decline in BMI with age could be clinically significant as well but the value was very close to zero. The regression

coefficient for cholesterol medication prescribed ($b = 0.28$) indicates that the value of BMI increases by 0.28 when medications are prescribed. The regression coefficient for number of visits annually ($b = 0.32$) indicates that the value of BMI increases as the number of annual visits for a case increase. A higher value of BMI was a predictor for cholesterol lowering medication prescribed and increased number of visits annually. Accept Null Hypothesis 2a (BMI). Goal setting was not a significant predictor of BMI. However significance was found for the predictor of age, cholesterol medication filled, and number of visits.

Regression of LDL on Nine Predictor Variables – Hypothesis 2b

LDL was regressed on the nine predictors of goal-setting, class attendance, cholesterol medication prescribed, age, ethnicity (2 dummy groups), employment, number of annual visits, and type of provider. Table 25 displays the results of the regression, including regression coefficients, standard errors, confidence intervals, and the *p*-value for predictor significance in the model.

Table 25

Generalized Estimating Equation Regression of LDL Levels on Nine Predictors (n = 1,633 groups; 4,818 observations)

Variable	*b*	*SE b*	95% CI for *b*	*p*
Goal-setting	2.93	1.42	(0.154, 5.704)	0.039
Class attendance	8.15	1.32	(5.564, 10.737)	<0.0005
Cholesterol medication RX	-18.96	1.34	(-21.594, -16.324)	<0.0005
Age	-0.33	0.06	(-0.451, -0.219)	<0.0005
Ethnicity Caucasian	-2.91	1.44	(-5.734, -0.083)	0.044
Ethnicity African American	-1.08	2.38	(-5.746, 3.587)	0.650
Employed	4.71	1.53	(1.710, 7.704)	0.002
Number of visits	-0.05	1.04	(-2.081, 1.971)	0.958
Provider	-2.51	1.62	(-5.689, 0.665)	0.121

Note. b = Regression coefficient; SE b = Standard error of regression coefficient; CI = Confidence Interval; p = p-value for significance; Rx = prescription.

The regression model for LDL was significant (Wald χ^2 (df 9) = 398.67, $p <$ 0.0005), indicating that the predictor model using the data set was improved over a model in which all predictors were set to zero. Significant predictors included goal-setting (p= 0.039), age ($p < 0.0005$), ethnicity Caucasian ($p = 0.044$), class attendance ($p <$ 0.0005), cholesterol medications filled ($p < 0.0005$), and employment ($p = 0.002$). The regression coefficient for the predictor of age (b = -0.33) indicates that the value of LDL decreases by 0.33 for each 1 unit increase in age if all other predictors remain constant. The regression coefficient for ethnicity Caucasian (b = -2.91) indicates that cases that are

Caucasian in race are associated with lower LDL values. Similarly, those who participate in goal-setting (b= 2.93), attend classes (b= 8.15) and are employed (b= 4.71) are associated with higher LDL values. Those who have their cholesterol medication filled are associated with a decrease in LDL values (b = -18.96).

Reject Null Hypothesis 2b (LDL). Significance was found for the predictors of patient-provider goal-setting and decision support. Age, employment, class attendance, and cholesterol medication filled were also significant predictors of LDL. The regression coefficient for provider (b = -0.061) indicates that LDL decreases by 0.06 if the provider is an NP/PA.

Regression of HbA1c on Nine Predictor Variables – Hypothesis 2c

HbA1c was regressed on the nine predictors of goal-setting, class attendance, cholesterol medication prescribed, age, ethnicity (2 dummy groups), employment, number of annual visits, and provider type. Table 26 displays the results of the regression, including regression coefficients, standard errors, confidence intervals, and the p-value for predictor significance in the model.

Table 26

Generalized Estimating Equation Regression of HbA1c on Nine Predictors
(n = 535 groups; 1,736 observations)

Variable	*b*	*SE b*	95% CI for *b*	*p*
Goal-setting	0.26	0.10	(0.073, 0.456)	0.007
Class attendance	0.09	0.05	(-0.013, 0.192)	0.090
Cholesterol medication RX	0.003	0.09	(-0.171, 0.177)	0.974
Age	-0.02	0.004	(-0.027, -0.009)	<0.0005
Ethnicity Caucasian	0.006	0.10	(-0.196, 0.208)	0.953
Ethnicity African American	0.03	0.16	(-0.281, 0.346)	0.839
Employed	-0.05	0.11	(-0.270, 0.173)	0.667
Number of visits	0.24	0.06	(0.125, 0.354)	<0.0005
Provider	-0.75	0.12	(-0.986, -0.506)	<0.0005

Note. b = Regression coefficient; SE b = Standard error of regression coefficient; CI = Confidence Interval; p = p-value for significance; Rx = prescription.

The regression model for HbA1c was significant (Wald χ^2 (df 9) = 87.72, p < 0.0005), indicating that the predictor model using the data set was improved over a model in which all predictors were set to zero. Significant predictors included age ($p < .0005$), provider ($p < .0005$), goal-setting ($p = .007$) and number of visits ($p < .0005$). The regression coefficient for the predictor of age ($b = -0.02$) indicates that the value of HbA1c decreases by 0.02 for each 1 unit increase in age if all other predictors remain constant. This predictor is statistically significant, but not clinically significant as the value is very close to zero. The regression coefficient for provider ($b = -0.75$) indicates

that HbA1c decreases by -0.75 if the provider is an NP/PA. The regression coefficient for goal-setting ($b = 0.26$) indicates that HbA1c value increases by .026 if goal-setting is implemented. The regression coefficient for number of visits annually ($b = 0.24$) indicates that the value of HbA1c increases as the number of annual visits for a case increase.

Reject Null Hypothesis 2c (HbA1c). The predictor for patient goal-setting was statistically significant. The other variables of age, number of visits, and health care provider were also significant.

Research Question 2: Analysis and Results Using Gaussian Distribution with Exponential Regression

As the histograms of the dependent variables BMI and HbA1c indicated a slight positive skew, GEE analyses were specified to use a Gaussian distribution with exponential regression. Exponential regression was used to facilitate interpretation of all the dependent variables, as the coefficients can be exponentiated (raising a quantity to a power) to define values of the dependent variables. The GEE with exponential regression was used as a confirmatory measure for predictor significance of the Gaussian GEE which was presented in Tables 24 through 26. Tables 27 through 29 present the findings from the models using the GEE with exponential regression. All models were significant ($p < .0005$)

Table 27

Generalized Estimating Equation Regression with Exponential Regression of BMI Levels on Nine Predictors (n = 1,633 groups; 4,818 observations)

Variable	*b*	*SE b*	95% CI for *b*	*p*
Goal-setting	0.003	0.003	(-0.002, 0.008)	0.252
Class attendance	0.001	0.002	(-0.004, 0.005)	0.767
Cholesterol medication RX	0.016	0.004	(0.008, 0.024)	<0.0005
Age	-0.002	0.0003	(-0.003, -0.001)	<0.0005
Ethnicity Caucasian	-0.005	0.010	(-0.023, 0.014)	0.627
Ethnicity African American	0.005	0.02	(-0.027, 0.036)	0.772
Employed	0.005	0.007	(-0.008, 0.018)	0.451
Number of visits	0.011	0.003	(0.006, 0.016)	<0.0005
Provider	0.002	0.01	(-0.016, 0.020)	0.819

Note. *b* = Regression coefficient; *SE b* = Standard error of regression coefficient; CI = Confidence Interval; *p* = p-value for significance; Rx = prescription.

Wald χ^2 (9) = 71.85, $p < .0005$

The effect of ethnicity was not significant after using exponential regression as seen in Table 28. Type of health care provider was a significant predictor of LDL with the exponential regression (p= 0.001).

Table 28

Generalized Estimating Equation Regression with Exponential Regression of LDL Levels on Nine Predictors (n = 1,633 groups; 4,818 observations)

Variable	*b*	*SE b*	95% CI for *b*	*p*
Goal-setting	0.039	0.01	(0.012, 0.067)	0.005
Class attendance	0.062	0.01	(0.042, 0.082)	<0.0005
Cholesterol medication RX	-0.179	0.01	(-0.208, -0.150)	<0.0005
Age	-0.002	0.001	(-0.004, -0.001)	<0.0005
Ethnicity Caucasian	-0.008	0.026	(-0.039, 0.022)	0.588
Ethnicity African American	0.010	0.03	(-0.041, 0.062)	0.694
Employed	0.067	0.02	(0.035, 0.098)	<0.0005
Number of visits	-0.014	0.01	(-0.034, 0.007)	0.202
Provider	-0.061	0.02	(-0.096, 0.026)	0.001

Note. *b* = Regression coefficient; *SE b* = Standard error of regression coefficient; CI = Confidence Interval; *p* = p-value for significance; Rx = prescription.

Wald χ^2 (9) = 303.95, $p < .0005$

Class attendance was found to be significant with the exponential regression as seen in Table 29; participants who attended class had higher HbA1c.

Table 29

Generalized Estimating Equation Regression with Exponential Regression of HbA1c Levels on Nine Predictors (n = 389 groups; 1,469 observations)

Variable	*b*	*SE b*	95% CI for *b*	*p*
Goal-setting	0.04	0.02	(0.005, 0.066)	0.022
Class attendance	0.02	0.02	(0.004, 0.038)	0.018
Cholesterol medication RX	-0.01	0.02	(-0.037, 0.016)	0.441
Age	-0.003	0.001	(-0.004, -0.001)	<0.0005
Ethnicity Caucasian	0.01	0.02	(-0.024, 0.036)	0.695
Ethnicity African American	0.003	0.02	(-0.045, 0.050)	0.913
Employed	-0.004	0.02	(-0.037, 0.029)	0.804
Number of visits	0.03	0.01	(0.009, 0.042)	0.002
Provider	-0.10	0.02	(-0.141, -0.067)	<0.0005

Note. *b* = Regression coefficient; *SE b* = Standard error of regression coefficient; CI = Confidence Interval; *p* = p-value for significance; Rx = prescription.

Wald χ^2 (9) = 78.59, $p < .0005$

Comparison of GEE and GEE with Exponential Regression as Relates to Significant Predictors

Results of the GEE regression were compared to the GEE with exponential regression to investigate predictors which were significant for both models. For the

dependent variable of BMI, both models indicated significance for (a) age,(b) cholesterol medication prescribed, and (c) number of visits. Hypothesis 2a was confirmed in regards to acceptance of the null hypothesis that goal setting was not a predictor of BMI. For the dependent variable of LDL, both models indicated significance for (a) age, (b) goal-setting and decision support, (c) educational class attendance, (d) cholesterol medication prescribed, and (e) employment status. Type of provider was significant for the exponential regression for LDL. Hypothesis 2b was confirmed in regards to rejection of the null hypothesis, as goal-setting and decision support was a significant predictor. Educational class attendance and cholesterol medication prescribed were significant for both models. For the dependent variable of HbA1c, both models indicated significance for (a) age, (b) provider, (c) goal-setting, and (d) number of visits. Class attendance was a significant predictor of HbA1c in the exponential regression. Hypothesis 2c was confirmed in regards to rejection of the null hypothesis, as goal-setting and decision support was a significant predictor for both models. Cholesterol medication prescribed was a significant predictor for BMI and LDL but not HBa1c. Patient-provider goal-setting did not predict BMI. BMI was reduced by advancing participant age.

Summary

Chapter 4 began with a description of the demographics of the participants in the study. Following the report of possible confounding demographics and descriptive analysis for Research Question 1, information pertaining to required assumptions for the inferential analyses of Research Question 2 was discussed, and any remedies or allowances for possible assumption violations were defined. Following the demographic and assumption sections, hypothesis testing was performed.

Research Question 1 asked, "How prevalent are the risk factors for heart disease (age, obesity/ elevated BMI, diabetes, LDL cholesterol values, tobacco use) among the veteran population? Descriptive analysis was performed to investigate attributes of the data, with a focus on frequency and percentage data for the high risk cases. Differences and similarities between the high risk cases vs. low risk cases were described.

Research Question 2 asked, "Is patient-provider goal-setting and decision support a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL cholesterol, and HbA1c over the 5-year span of 2003-2007 given that demographic and patient adherence are also considered in the model? Multiple regression analysis via GEE for panel data was utilized to investigate Research Question 2. STATA v10, via the "xtgee" command for longitudinal/panel data was used for the analysis. Three separate regression analyses were performed on the data, one for each of the outcome variables of (1) BMI, (2) LDL, and (3) HbA1c. All regressions included the same nine predictors as follows: (a) goal-setting, coded as yes = 1, no = 0; (b) adherence as measured by: class attendance, coded as yes = 1, no = 0 and (c) cholesterol medications prescribed, coded as yes = 1, no = 0; (d) age in years (e &f) ethnicity, dummy coded as Caucasian = 1, non-Caucasian = 0; a dummy variable for African American ethnicity coded as African American= 0, not African American= 1, and a reference category, not included in the actual regression but included in the model, when both the Caucasian and African American ethnicity dummy variables were coded as 0 (g) employment, coded as 1 = yes, 0 = no or retired; and (h) number of visits annually, coded into four dummy variable groups of (1) 0 visits, (2) 1-2 visits, (3) 3-5 visits, and (4) 6+ visits; and (i) provider type, dummy coded as medical doctor (MD) = 0 and nurse practitioner or physician's assistant

(NP/PA) coded as = 1. The variables of age, ethnicity, employment status, and number of visits annually were included as possible confounding variables. Patient adherence was measured by class attendance and cholesterol medication on active medication list due to the limitations of this secondary data analysis. A 95% level of significance was set for all regression analyses.

Confirmatory regression analysis via GEE with exponential regression was utilized to further investigate significant predictors from the original GEE model after reviewing the histograms for BMI, LDL, and HbA1c. All models for both types of regression analysis were statistically significant ($p < .0005$ for all models)

Inferential analyses for hypothesis 2a (BMI) indicated that patient-provider goal-setting was not a predictor of BMI. The other variables of cholesterol medication prescribed, age, and number of visits were significant across both models. Therefore the null hypothesis regarding patient-provider goal-setting and BMI was accepted.

Inferential analyses for hypothesis 2b (LDL) indicated that the predictor of patient-provider goal-setting was a significant predictor for LDL across both models. The other variables of age, class attendance, cholesterol medication prescribed, employment, and health care provider were also significant. The null hypothesis for 2b was rejected.

Inferential analyses for hypothesis 2c (HbA1c) indicated that the predictor of patient-provider goal-setting was significant for HbA1c across both models. The other variables of age, class attendance, number of visits, and health care provider were also significant. Therefore the null hypothesis for 2c was rejected.

CHAPTER 5: DISCUSSION

The purpose of this study was to examine the influence of patient adherence and patient-provider goal-setting and decision support on factors related to cardiovascular disease risk among veterans. In this chapter, an analysis and interpretation of the study findings as they relate to current literature and clinical practice are presented. Conclusions derived from the study findings and recommendations for practice are outlined.

The following research questions were examined:

Research Question 1: *How prevalent are the risk factors for heart disease (age, obesity/ elevated BMI, diabetes, LDL cholesterol values, tobacco use) among the veteran population?*

Research Question 2: *Is patient-provider goal-setting and decision support a predictor of the cardiovascular risk reduction outcome measures of BMI, LDL, and HbA1c over the 5-year span of 2003-2007 given that demographic factors and patient adherence are also considered in the model?*

Discussion of Findings

The findings are organized and discussed under headings related to socio-demographic information, prevalence of risk factors for cardiovascular disease, patient adherence and patient-provider goal-setting, and the biologic outcomes of the study. The adapted Andersen behavioral model (ABM) shown in Figure 2 on page 16 provided the conceptual framework for this study and addressed patient needs related to patient adherence, patient-provider goal-setting and decision support, and cardiovascular disease risk reduction.

Sociodemographics

The study sample was comprised of primarily males (1,798, 96.4%) over age 40 (1751, 93.9%) which is similar to the make up of the state veteran population. Over 60% of the sample was between the ages of 40-69 and half of the group was retired or unemployed during this time period. Per VAMC policy, no patients over age 89 were sampled.

Caucasian participants (42.7%, 796) made up the majority of the sample. African American was the next most prevalent ethnic group, comprising 9.4% (175) of the sample. Only 11 participants (0.3%) were listed under another ethnic group.

Employment trends held steady over the 5 year period with the majority of the sample retired or unemployed. Veterans often utilize the VA health system when they are unable to afford or access care with services based upon their income and service connection (Mather, 2008). From the researcher's experience, veterans often take multiple medications and seek care at the VAMC due to the substantial savings on prescription medications. Many veterans live at a considerable distance from the VAMC and have outside health care providers closer to their homes that provide the majority of their health care.

Forty one veterans (1.9%) were excluded from the study due to age >89 and 146 veterans (7.1%) moved or were lost to follow up. Dunbar-Jacob, Dwyer and Dunning (1991) found that dropping out of treatment and nonadherence were common among younger men. Veterans lost to follow up in this study also tended to be younger; 6.2% of veterans were lost to follow up under the age of 30 with lower rates of diabetes and cardiovascular disease. It is possible that the missing veterans were not seen long enough

to be diagnosed or this information was not entered into the computer diagnosis list. Many veterans were seen initially at the study site as they awaited placement in a facility closer to their home.

Despite the considerable distance some veterans had to travel, 33.9% of veterans were seen 1-2 times a year, 40.4% were seen 3-5 times a year, and 7.3% were seen more than 6 times per year. When patients were deemed high risk, they were asked to make more frequent appointments with an average of 65% visiting the clinic three or more times each year. Number of visits increased among patients with high BMI and HbA1c but was not a significant finding for LDL. From the researcher's experience, patients who were high risk tended to be older and retired and attended appointments more often that younger, employed participants. In addition patients who were obese and had diabetes had more health problems necessitating more appointments.

A physician or resident managed the care of 1,069 participants (57.4%) and a nurse practitioner or physician assistant managed the care of 796 participants (42.5%) in the sample. According to the U.S. Department of Health and Human Services (2002), the nationwide tobacco prevalence rate is 30%. In this study, over 29% (543) of participants were current tobacco users and 48% (903) were former smokers which is higher than state civilian tobacco use estimates of 20.9% (CDC, 2005).

Discussion Research Question 1

The next section will review the prevalence of risk factors for cardiovascular disease among the sample of veterans at one VAMC.

Prevalence of risk factors for cardiovascular disease

Veterans are more likely to be diagnosed with multiple chronic diseases, have a lower income, and are less able to afford their medications (Hynes et al, 2007; Mather, 2008). Most of the participants in this study were over age 50 with a high body mass index. Of this sample, 38.8% were considered obese with a BMI ≥30, 22.9% had a pre-existing diagnosis of cardiovascular disease, 26.2% had a diagnosis of diabetes, and 6.6% had both diabetes and cardiovascular disease. The nationwide prevalence of overweight veterans is estimated at 73% with 33% considered obese with a BMI ≥30 (Damschroder, 2008; Kinsinger, 2006). Statewide estimates among the civilian population include: 6.5% cardiovascular disease, 7.1% diabetes, and 24.3% obesity (CDC, 2005; CDC, 2007; CDC, 2008). From the researcher's experience, ICD 9 diagnosis lists were often found to be missing key diagnoses and the rates of these diseases are likely higher than found in the EMR.

Nationwide estimates report that 80% of veterans have more than two risk factors for heart disease, one being elevated LDL cholesterol (Voils, 2008). LDL cholesterol values in the sample were high. However, the LDL values among the high risk group steadily declined from 42.9% to 24.2% at the end of the 5 year study period. Conversely the number of patients in the low risk cholesterol group increased by 18.7% at the end of the study. BMI remained unchanged despite participation in patient-provider goal setting and/or high risk group designation. Weight loss is effort driven, is not easily accomplished or maintained, requires a great deal of commitment on the part of participants, and people are reluctant to change their lifestyle (Dibonaventura & Chapman, 2008, Jacobs, 2002).

People with diabetes are considered high risk for cardiovascular disease (ATP III, 2004). HbA1c is generally monitored 2-4 times a year as a measure of diabetic control (ADA, 2009); HbA1c declined gradually over the course of this study but not by clinically significant amounts. A poll by the CDC (2007) in the state where this study was completed found that 37.1% of participants reported having elevated cholesterol values. Tobacco use was high among this sample as noted in the previous section.

Discussion Research Question 2

Patient-provider goal setting, patient adherence, and biological outcome measures were the focus of this research question. The study examined patient-provider relationship to biologic outcome measures of HbA1c, BMI, and LDL.

Patient-Provider Goal-Setting and Decision Support

In the Andersen behavioral model, health care access, and patient-provider goal-setting and decision support leads to improved health status and biological outcome measures. This study used a patient-provider goal setting protocol, which is outlined on page 78, and included provision of positive verbal and written feedback on patient goal attainment. Each visit patient goals and the steps needed for attainment and maintenance of new health behaviors were reviewed. After the visit, personalized lab letters were mailed to participants that reported their progress toward patient-provider goals. This was received enthusiastically by the majority of patients who often inquired when they did not receive one. The first visit using patient-provider goal setting was a few minutes longer than usual but was believed to save time at future visits. The most time intensive part of utilizing this method was sending the lab letters which became easier with the development of computer software that generated the letters.

The number of studies in the literature utilizing patient-provider goal-setting is increasing. Researchers find adherence to health recommendations improve as patients become more receptive to shared decision making. Peterson, et al (2003) found that patient adherence increased with behavioral interventions that emphasized patient involvement in decision-making and use of written feedback and mailed reminders. Jacobs (2002) utilized personalized health mailings and phone counseling sessions after cholesterol, blood pressure and body weight screenings. Intervention participants were more likely to make recommended dietary and physical activity changes with improvements in cholesterol values at follow up, however, there was little change in blood pressure or body weight. Likewise BMI did not change significantly in the current study.

Levetan et al. (2005) provided participants with a wallet card and poster for their refrigerator with their LDL status and goal reminders with a significant decrease in LDL levels after six months and fewer cardiac interventions than the control group. Likewise Martin et al. (2007) provided participants with an electronic report card pertaining to their cardiovascular risk, negotiated goals, and progress. Participants showed significant improvements in blood pressure, LDL cholesterol, HbA1c, and body mass index. Thomas (2001) found that individualized education and provision of personalized written information did not require a longer appointment time and produced a reduction in cardiovascular risk scores.

Weymiller et al. (2007) offered patients a decision aid about taking a cholesterol lowering medication with subsequent improvement in their patient cardiovascular risk scores, and patients were more adherent to cholesterol lowering medication three months

after the intervention. Lastly, in the Vale et al. (2003) study, participants received written feedback on their laboratory data and other outcome measures with significant reductions in cholesterol values six months after the intervention as well as reductions in body mass index, and blood pressure.

In this study, there was significant improvement in LDL status sustained over a five year period. The study showed that provision of regular verbal and written feedback, collaboration with patients, and having a consistent health care provider was effective in improving diabetes control and cholesterol status. Patients with higher LDL and HbA1c values participated in patient-provider goal-setting and attended educational classes. Many patients began participating in goal-setting mid study or participated intermittently. Patients who received less frequent and consistent follow up and/or received most of their care from civilian providers may have affected the results. There were some patients assigned to providers who participated in patient-provider goal-setting but did not follow the protocol (approximately 1%). As noted in Table 22 and Table 23, 24.4% of the entire sample participated in goal-setting over the 5 year period with involvement of almost 40% of the high risk participants. Body mass index did not improve with patient-provider goal setting or educational classes as weight loss is dependent on the participant's intention and motivation to change, and level of commitment to changing their lifestyle and health behaviors.

Patient Adherence to Recommendations

Collaborative practice including patient-provider goal-setting and decision support has been found to enhance patient adherence to healthy lifestyle recommendations in the literature (Barlow et al., 2002; Danhauer et al., 2004; Northwehr,

2004; Schaffer & Yoon, 2001;Winett et al.,2005). When the patient decides a behavior is important and shares in the decision-making process, adherence to recommendations increases, with sustained health behavior change more likely (De Smet, et al., 2006; Woodard et al., 2005).

Patient adherence is defined as persistence in the practice and maintenance of desired health behaviors and is the result of active participation and agreement (Benner et al., 2002; Carpenter, 2005; Chatterjee, 2006; Treharne et al., 2006). Patient adherence was discussed in depth in Chapter 2. Due to the limitations of this secondary data analysis, patient adherence was evaluated by the independent variables of educational class attendance and presence of cholesterol medication on each veteran's active medication list. Patient-provider goal-setting was also an independent variable. Confounding demographic variables included age, ethnicity, employment status, number of visits annually, and type of health care provider. Body mass index, HbA1c, and LDL cholesterol were dependent variables measuring the evaluated health status in this study.

Despite the finding by DiMatteo (2004) that appointment keeping had the lowest rates of patient adherence, in this study patients returned for care on a regular basis and only 7.1% of the original sample was lost to follow up over the five year period. Over half of the sample (974 cases or 52.2%) came to appointments in primary care every year during the five year study period. Of the veterans lost to follow up, over 25% traveled more than 150 miles to the medical center. It is assumed that many of the veterans sought medical treatment closer to home.

Cardiovascular disease risk is reduced when health care providers encourage patient adherence to behavioral and pharmacological interventions. Health care provider

adherence to recommended clinical guidelines is also an important component of patient adherence. Health programs in the literature that incorporated behavioral strategies, collaborative decision-making, and self-management approaches had the highest rates of patient adherence. In this study, health care providers offered verbal and written feedback and encouraged collaboration in goal-setting and decision-making. Patients with elevated LDL and HbA1c were more likely to participate in goal-setting with their health care provider and attend educational classes. Participants at highest risk sustained improvement in their LDL over the 5 year period therefore use of patient-provider goal-setting and patient-provider adherence to clinical guidelines in future studies is recommended. Body mass index did not improve despite patient-provider goal-setting and educational classes as weight loss requires a great deal more effort than simply taking a medication. Weight loss is driven by intention to change and requires high levels of motivation and perseverance (Dibonaventura & Chapman, 2008; Jacobs, 2002: Johnston et al., 2004). Elevated BMI is a complex issue as previously stated and necessitates lifestyle and behavioral change (i.e.: dieting, walking instead of riding in one's car, cooking rather than going to a restaurant). Patients may lack sufficient motivation to make major changes in their behavior and lose interest when they find it is more difficult than they imagined (Dibonventura & Chapman, 2008).

Patients often underestimate barriers to diet and exercise and do not have the tools they need to deal with obstacles when they occur i.e.: how to exercise when it is raining outdoors (Dibonventura & Chapman, 2008).The gap between behavioral intention and action is a challenge in obesity management and led to the involvement of behavioral

psychologists and development of a new obesity program at the VAMC after the study time period.

HbA1c was not included in a similar table as the diagnosis of diabetes is a cardiovascular disease risk equivalent (thus there would be no "low risk" diabetes category). HbA1c values remained steady but the initial values were close to the ADA (2009) goal of $\leq$7.0 thus there was not a lot of room for improvement. There is concern about hypoglycemia among the elderly population when the HbA1c is less than 6.5. Intensive diabetes control measures results in increased hypoglycemic events among the elderly and has not been found to decrease morbidity or mortality from cardiovascular disease in this cohort (Eldor & Raz, 2009). Thus HbA1c goals may need to be more conservative and individualized among the elderly.

LDL values were utilized in this study as a measure of hyperlipidemia, a risk factor for cardiovascular disease. LDL levels improved with patient-provider goal setting and cholesterol medication. The clinic where the sample was obtained showed dramatic improvements in hypertension, diabetes, and hyperlipidemia management compared to other clinics at the same center when using patient-provider goal-setting. The clinic also met national VAMC goals for those measures.

Educational Class Attendance

Educational class attendance was one measure of patient adherence. Similar to patient-provider goal setting, class attendance was a predictor of LDL and HbA1c but not BMI. Attendance was low for the sample with the highest attendance in 2003 (8.5%) with an overall average of 4.9% across all the years. However the estimated participation in educational classes was <1% for the center based on the records kept by one nutritionist

(P. Moreland, 2008). None of the low risk members of the sample attended an educational class about diabetes, obesity, or cholesterol management. Incentives for educational class attendance for diabetics included learning about their diabetes medications and receiving a diabetic meter at the 3rd class. The weight management course was much longer than the other courses; it was 12 weeks in length which the researcher believes was a disincentive to working patients. Weight loss takes longer than other recommendations and requires more effort on the part of patients. Many veterans received a pedometer as an incentive to join the class. The lipid lowering educational class was shorter in length than the other programs at the time of the study and patients who attended were motivated by the prescribing of HMG-Co-A reductase inhibitors.

Cholesterol Medication

Cholesterol medication prescribed was a significant predictor of LDL. Higher BMI levels were also noted with patients prescribed cholesterol lowering medication. Cholesterol medication was not a predictor of HbA1c. In the literature, the lowest medication persistence rates were found among the elderly due to cost and polypharmacy (Johnson, et al., 2006; Mantel-Teeuwisse, Goettsch, Klungel, de Boer, & Herings, 2004). However at the VAMC pharmacy costs for veterans are much lower than the private sector and prescribing of cholesterol lowering medication rose over the five year period; 35% of the sample took a HMG-Co-A reductase inhibitor during the 5 year period. Of those taking a cholesterol medication it is presumed they were adherent as LDL values declined steadily over the course of the study. Participants at highest risk sustained improvement in their LDL over the 5 year period. It is speculated that taking a medication to lower cholesterol is more appealing to veterans than the more difficult

challenge of weight loss, diet, and exercise thus rates of hyperlipidemia declined and BMI and HbA1c rates did not decline to the same degree.

Sociodemographics and Evaluated Biological Outcomes

The study sample consisted primarily of Caucasian males between the ages of 40-69 years. African American was the second most prevalent ethnic group. The majority of the sample was retired or unemployed.

Age. Age was a significant predictor in the model; the regression coefficient for age indicated that the value of the HbA1c decreased by 0.02, BMI decreased by 0.03, and LDL decreased by 0.33 for each one unit increase in age. If the patients lived long enough, a small steady weight loss and improvement in HbA1c would be relevant but not felt to be clinically significant as the values were close to zero. The improvement in LDL was statistically and clinically significant. Reduction of these three measures could also represent declining nutritional status among the elderly and are worthy of additional study (Chernoff, 1999). Hypoglycemia and worsening dementia from intensive diabetes control and low cholesterol levels are also a risk among the elderly thus therapy should be individualized (Chernoff, 1999).

Ethnicity. Caucasian was the predominant category for the sample (796 cases, or 42.7%) and African American was the second most prevalent ethnic group (175 cases, or 9.4%). There was considerable missing data on ethnicity in this study due to lack of documentation by staff. Ethnicity was not a predictor of BMI, LDL, or HbA1c after the exponential transformation. Caucasians were considered higher risk (92.7%) than African Americans (90.8%) for the first three years of the study. During the fourth and fifth year, African Americans were higher risk (94.0%) than Caucasians at 93.1% (see appendix).

Perhaps African Americans underwent better screening and assessment toward the end of the study or the number of risk factors increased. The researcher feels further exploration is warranted.

Employment status. Employment status was difficult to extract from the electronic medical record. The majority of the employed in this sample were considered lower risk overall for cardiovascular events despite having high LDL values. From the researcher's clinical experience, this is likely due to the lower age of the employed group and intake of fast foods at the workplace. Poor nutritional status among the retired elderly may also have an effect on LDL values (Chernoff, 1999).

It is assumed that employed patients had at least a minimum level of health to maintain employment and were less likely to be in poor health or disabled (Le Moual, Kauffman, Eisen, & Kennedy, 2008). Employed patients presumably have better access to health insurance and transportation. It is speculated that employed patients were less likely to schedule appointments due to their work schedule thus receiving fewer health assessment and screening tests.

Employment was noted to be a restricting factor by Dunbar-Jacob et al. (1991) who stated that men voiced concerns about being diagnosed with a chronic disease and being able to maintain employment. Participants in that study felt that appointments were less important than working and providing for their families. Employment had no effect on HbA1c and BMI but may in fact be due to less frequent visits. A patient's need to maintain employment and provide for his/her family may have influenced the number of visits and educational class attendance.

Visit interval. Access to care and visit intervals were significant predictors in this study. Patients with higher BMI and HbA1c were seen more often as health care providers tried to impact the patient's weight and diabetes control. LDL cholesterol values declined with prescribing of HMG-Co-A reductase inhibitors.

Patient nonadherence to medication and recommended lifestyle changes often leads to more frequent office visits, no response or poor response to medications, exacerbation of chronic illness, increased rates of hospitalization and invasive procedures, and increased morbidity and mortality (ATP III, 2004; Christophersen & VanScoyoc, 2004). In the current study, health care providers asked patients to come in more often when they were deemed high risk and had higher HbA1c and BMI values.

Type of health care provider. The influence of provider type was significant in this study. Patients who were seen by a NP or PA had lower LDL cholesterol and HbA1C values than patients followed by a physician or resident in training. It is postulated that the care of these patients was more consistent with an NP/PA as residents only manage the care of patients for a brief period then transfer to their next clinical training site. Use of patient-provider goal-setting was more prevalent among the NP/PA patients (see table 23) and was used with patients having poorer lipid and diabetes control. Patients benefitted from the consistent care received by nurse practitioners and physician assistants with sustained improvement in LDL and HbA1c.

The majority of veterans lost to follow up were cared for by residents under the supervision of their attending physician for a limited time period. At the end of the resident's clinical rotation, their patients remained with the attending physician or were reassigned to another resident or health care provider, transferred to another VAMC, or

were lost in the change to another provider. It is also possible that a disproportionate number of new patients were assigned to residents and transferred to another facility closer to their home as soon as there was an opening.

In this study, LDL cholesterol values decreased as patients aged, when their care was managed by an NP/PA, and with prescribing of cholesterol lowering medication. LDL values steadily declined over the five year period by a total of 18% in the high risk group. Patients who filled their cholesterol medication had lower LDL values and were more likely to persist with taking their medication year after year. Records of laboratory results obtained outside the VA and non-VA prescribed medications were not well documented in the EMR.

An integral part of cardiovascular disease risk reduction is health care provider and patient collaboration to meet therapeutic goals based on evidence based practice guidelines. The ATP III guidelines emphasize the importance of patient-provider adherence, screening, detection, and treatment with therapeutic lifestyle changes and medications. LDL cholesterol was reduced by consistent NP/PA care and prescribing of HMG-Co-A reductase inhibitors. HbA1c also significantly improved with NP/PA care.

Biological outcome measures. During this study there was a steady decline in LDL values over time. Body mass index remained essentially unchanged throughout the study as weight loss and maintenance are difficult for patients to achieve. Weight loss interventions which are successful require a great deal of patient motivation and intent to change their eating habits and make lifestyle changes.

The study findings of a decline in LDL but BMI that did not change suggests that patients are willing to take a cholesterol lowering medication but less likely to follow

advice pertaining to diet, weight loss, and exercise as previously noted in the literature (Bach-Nielsen et al., 2005; DiMatteo, 2004). HbA1c levels remained steady over the 5 year span and were close to the goals set by the ADA in 2009. Likewise people who have diabetes are asked to learn numerous new skills i.e.: checking blood sugar, administering insulin, etc. and make dietary and lifestyle changes such as carrying snacks to prevent hypoglycemia, counting carbohydrates at meal times and forgoing favorite foods, and weighing the effect of exercise on blood sugar readings. Diabetic management is dependent on patient adherence to medication and lifestyle recommendations.

Study Strengths and Limitations

The next section will discuss the strengths and limitations of this study.

Study Strengths

The study is unique as all of the participants were veterans with few published research studies on patient adherence, patient-provider goal-setting, and cardiovascular risk reduction among this vulnerable population. This study contributes to the science regarding patient-provider goal-setting and decision support. Patient-provider goal-setting is a useful tool in promotion of healthy behavior change and led to sustained change among this group of veterans as it pertains to their cholesterol and diabetic control.

As reported in Chapter 1, veteran health care decision-making and adherence to recommendations is influenced by many factors: military socialization, substance abuse, combat trauma and mental illness, issues of control, and expectation of self reliance (Alcaras & Roper, 2006; Jakupcak, et al., 2006). Also found in the literature and confirmed in this study, veterans are more likely to engage in high risk behaviors such as tobacco use and are more likely to be diagnosed with multiple chronic diseases (Hynes et

al., 2007; Jakupcak et al., 2006; Mather, 2008). Examination of the long term effect of goal-setting and decision support on BMI, LDL cholesterol, and HbA1c sets this study apart from other research. At the time of this analysis, inclusion of the variables of employment, BMI, HbA1c, tobacco use, and type of health care provider were seldom found in other longitudinal studies of this type. This study evaluated veteran intermediate biologic outcomes and found sustained improvement in LDL values over a 5 year period thus providing a platform for the development and support of future programs.

Study Limitations

This section discusses the limitations of this study which are grouped by the headings of external validity, pitfalls of secondary analysis, measurement, historical effect, and rotating care.

External Validity. As the sample consisted of primarily Caucasian males at a single VAMC, the findings cannot be generalized to a larger more diverse population. This study looked at change in biologic outcome measures (BMI, LDL, HbA1c) for the entire panel of patients over a five year period. A larger sample including more clinics or medical centers with a stratified sample would have added to the validity.

Reliability. Health care providers need to be trained in the patient-provider goal-setting protocol to increase reliability for future studies.

Pitfalls of Secondary Analysis. There are many pitfalls to using a secondary data analysis including difficulty finding practical measures of patient adherence and dealing with missing information. Information on ethnicity was missing for a large number of veterans limiting exploration of this factor. Survey information regarding previous education about cardiovascular risk reduction, physical activity levels, family support,

readiness to change, and behavioral intention would have been useful but was not available in this secondary data analysis.

The researcher was hindered by VA restrictions related to protected health information, for example, revealing zip codes was not allowed thus limiting the study of geographical variation. The lack of availability of data on ethnicity, participants over age 89, marital status, and information on high school or college completion were also limitations. The actual type, content, and number of educational sessions attended was not available to the researcher.

Time of diagnosis of cardiovascular disease and diabetes and duration of HMG-Co-A reductase inhibitor use was difficult to confirm in this secondary data analysis. Actual HMG-Co-A reductase inhibitor dose, dosing titration, and starting and stopping therapy was not obtained due to the nature of this study but would be revealing. Health literacy was not measured but it was assumed that providers reviewed literature with patients and those patients who received written feedback in the mail had someone to assist them with reading comprehension if needed.

Measurement. Errors in recording height and weight may have impacted BMI measurement as well as other information entered by staff. Cholesterol measurements can be affected by a nonfasting state particularly if triglyceride values are greater than 400. Measures of patient adherence were limited due to the nature of secondary analysis. Survey information about behavioral intention and patient self-reported adherence would have added to the validity of this study.

Historical effect. During the 5 year study time period, medication co-pays increased, Medicare part D was enacted, and numerous medication formulary changes

may have impacted the results of this study. Polypharmacy and lack of documentation of outside medication received may have impacted results. This study used the active medication lists as a marker for medication use but did not measure actual use of the medication. It was felt to be a generally reliable, objective, and unobtrusive measure of medication adherence.

The ATP III guidelines also changed mid study increasing the pool of patients deemed high risk and in need of cholesterol lowering medication (i.e.: diabetes became a cardiovascular disease risk equivalent). Prescriptions for HMG-Co-A reductase inhibitors rose from 22.4 to 42.4% at the end of the study period with an average of 35% of the sample taking a cholesterol lowering medication. Health care providers may have disagreed with the new clinical guidelines or were confused by them thus there may have been a lack of consensus regarding acceptable LDL levels.

Rotating care. Provision of consistent care in this study improved lipid and diabetic control. Continuity of care for patients was an issue with the medical residents when they left for another clinical rotation and could be remedied by having residents work in teams evaluating patients together to provide overlap, develop a trusting relationship between patients and the team, and alternate visits with the stable NP/PA staff. Preventing the loss of patients during the transition to a new provider is needed as 75% of participants lost to follow up were assigned to residents in training and their attending physician. Due to the nature of this study, the analysis was based on the type of provider the patient was assigned to and presumably cared for at the majority of visits.

Implications for Future Research

Cardiovascular disease risk reduction is a complex issue. Adherence and patient-provider goal-setting is an area of nursing research which has room for further development. The findings showed that close health care provider follow up and monitoring as well as a consistent patient focused, collaborative approach impacts patient outcomes over the long term. Consistent patient care management by nurse practitioners and physician assistants significantly improved LDL and HbA1c values among their patients who were also more likely to participate in patient-provider goal-setting and education. Provision of personalized verbal and written feedback is also an important element in improving health care outcomes. Encouraging patient participation and collaboration in decision-making allows individuals to identify their own health priorities and devise goals that are acceptable to them and their health care provider.

Patients deemed high risk with elevated LDL and HbA1c values were more likely to participate in patient-provider goal-setting and educational class offerings. Improvement in LDL values over time among the high risk group suggests that increased patient involvement in the treatment plan increases adherence to their medications and makes it more likely they will come to appointments. Providing decision support and feedback to patients increases their willingness to follow health recommendations and would be worth exploring on a larger scale in a future study. Additional research suggestions include:

- Further exploration of these findings including the effect of ethnicity, gender, family history, diet and physical activity, and employment status. Records of ethnicity were not well documented at the facility thus limiting study of this

important variable. Ethnicity could be easily added to the electronic medical record by the clerical or nursing staff on patient check in for appointments.

- Qualitative research findings related to veteran perceptions of weight, diet, and exercise would be beneficial in development of programs and interventions that target elevated BMI.
- Intervention studies that utilize patient-provider goal-setting and decision support and lipid ordering reminders is an important second step in developing programs to serve the needs of veterans at high risk for cardiovascular disease.
- Additional study related to increasing patient adherence to pharmacologic and non-pharmacologic interventions related to healthy lifestyle and inclusion of family and patient support are needed.
- A qualitative approach would allow participants to express their learning needs and perception of personal relevance related to cardiovascular disease risk and outline approaches to learning that they prefer.
- Inclusion of participant's prior experiences, perception of cardiovascular disease risk, barriers to patient adherence, and how to increase attendance at educational opportunities within the VAMC would be helpful.
- Exploration of the reasons for medication nonadherence is warranted. It would be helpful to know if perceived side effects were the primary cause of medication discontinuation.
- Provider barriers to adherence to clinical practice guidelines are an important variable deserving of additional study.
- Improve measures of patient adherence including use of self report via surveys.

- A larger sample with a more diverse population would increase validity.
- Closer examination of the issue of patients lost to follow up when residents complete their medical training in primary care to assure that these patients are quickly reassigned to another provider.
- Additional study including involvement in cardiac rehab, hospital stays and emergency room visits, laboratory studies and cardiac testing would provide additional information on cardiovascular disease severity.

Clinical Recommendations

Development of a collaborative relationship and consistent health care partnership with patients promotes adherence, health behavior change, and mutual goal attainment. Health care providers are urged to involve patients in planning educational programs and encourage family support and involvement. Providers enhance learning by encouraging participants to set their own learning objectives and health goals and offer decision support in the form of verbal and written feedback on patient progress. Further assessment of the impact of patient-provider goal-setting and educational class attendance is warranted.

The researcher urges VA health centers to consider exploring the feasibility of a pharmacy only benefit program for patients who receive the majority of their medical care from outside health care providers. This may provide a cost savings for the facility as well as convenience for patients. Improving appointment attendance and increasing rates of annual cholesterol evaluation improve patient adherence to hyperlipidemia guidelines thus impacting cardiovascular disease risk.

Provision of decision support in the form of verbal and written feedback on patient progress toward achievable personal health goals developed with the health care provider is beneficial. Development of a team approach to improve consistency for patients managed by residents may reduce the number of patients lost to follow up and thereby improve patient adherence. By encouraging consistent collaborative care, health care providers improve the quality of services provided, increase patient satisfaction, and impact long term cardiovascular disease risk.

Conclusion

Veterans are an important group with their own distinct military culture and have been shown to be at high risk for cardiovascular disease in this study and in other studies in the literature. An estimated 500,000 veterans have a diagnosis of ischemic heart disease thus it is imperative that interventions targeting risk reduction and prevention be promoted (McDonnell, 2008). High rates of tobacco use, obesity, diabetes, and pre-existing cardiovascular disease were found among veterans.

Health behaviors and patient adherence to health recommendations were influenced by increasing patient age, more frequent visit intervals, type of health care provider, and the prescribing of cholesterol lowering medication. Patients with higher LDL and HbA1c agreed to participate in patient-provider goal-setting and educational class attendance more often than patients at lower risk. Patient-provider goal-setting was not a significant predictor of BMI. However, age, cholesterol medication prescribed, and number of visits were predictors of BMI. BMI was difficult to target as participants were reluctant to make changes that affect their lifestyle, and weight loss requires a great deal of effort. Patients may lack sufficient motivation to make major changes in their behavior

and lose interest when they find it is more difficult than they imagined (Dibonventura & Chapman, 2008).

In this study, health care providers offered consistent care and decision support in the form of verbal and written feedback on patient progress toward health goals and encouraged collaboration in decision-making which led to improved LDL outcomes over a 5 year period; 40% of the high risk group participated in patient-provider goal-setting. LDL levels showed a decline over the 5 years of the study, from 42.9% high risk cases in 2003 to 24.2% in 2007. Participants who had cholesterol lowering medications on their active medication list had a significant decline in LDL values.

Body mass index and HbA1c levels were higher among participants seen more frequently and prescribed cholesterol medication as health care providers tried to impact the patient's health status. Those levels declined over the course of the study but not by clinically relevant amounts. LDL cholesterol values significantly declined with age, prescribing of HMG-Co-A reductase inhibitors, and consistent management by a NP/PA. HbA1C also improved under the care of nurse practitioners and physician assistants. Over a third of patients in this sample were willing to take a cholesterol lowering medication but did not lose a significant amount of weight despite educational efforts. Patients were less likely to follow advice pertaining to diet and exercise as previously noted in the literature.

The highest LDL values were among participants who attended classes and participated in patient-provider goal-setting and patients who were employed. Employed participants however were a younger group with lower risk scores. Educational class attendance was underutilized with 8.5% of the sample attending in 2003 with an overall

average of 4.9% across all the years. None of the low risk patients attended a class on diabetes, weight management, or cholesterol. BMI, LDL, and HbA1c declined with participant age. Number of health care visits, type of health care provider, and patient-provider goal-setting and decision support should be considered in planning interventions that target patient adherence.

The health care provided at the Department of Veterans Affairs Medical Center was found to be effective in improving LDL cholesterol and diabetic control. In particular, patient care managed by nurse practitioners and physician assistants was more consistent (than the rotating care provided by residents) with significant improvements in LDL and HbA1C. Study participants sustained significant improvement in hyperlipidemia over a 5 year period.

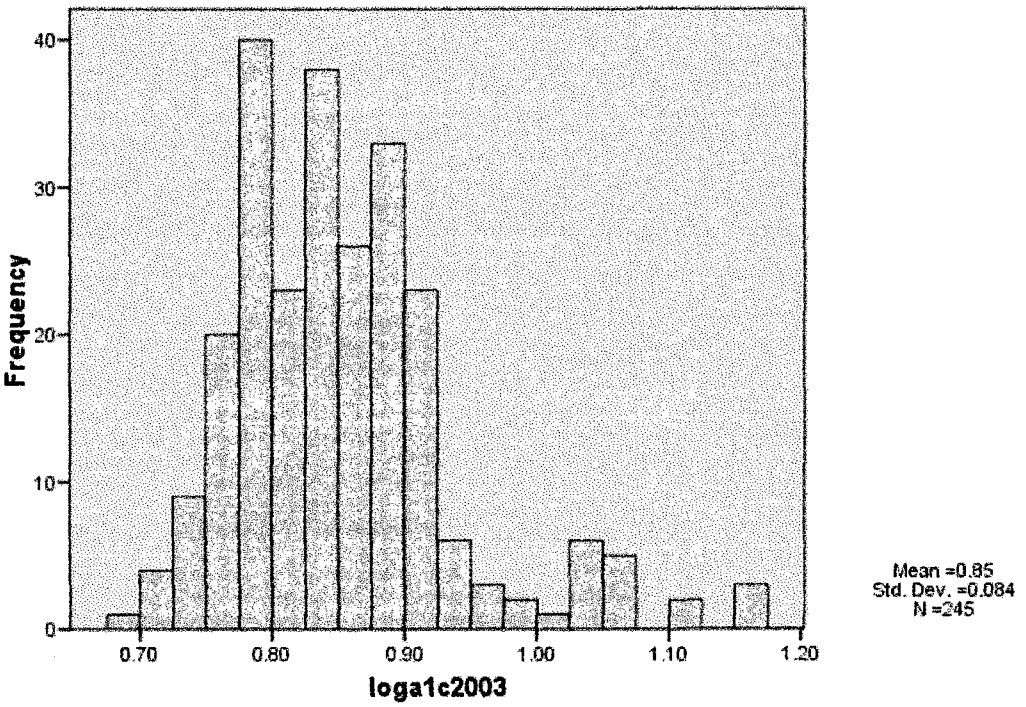
Patients deemed high risk with elevated LDL and HbA1c were more likely to participate in goal-setting and patient education and had more frequent appointments as their health care provider worked with them to reduce their risk. Body mass index was not impacted by patient-provider goal-setting or educational class attendance. Sustained weight loss required a great deal more effort and motivation on the part of patients. This study found that patient adherence was influenced by increasing patient age, employment frequent visit intervals, type of provider, and prescribing of cholesterol lowering medications.

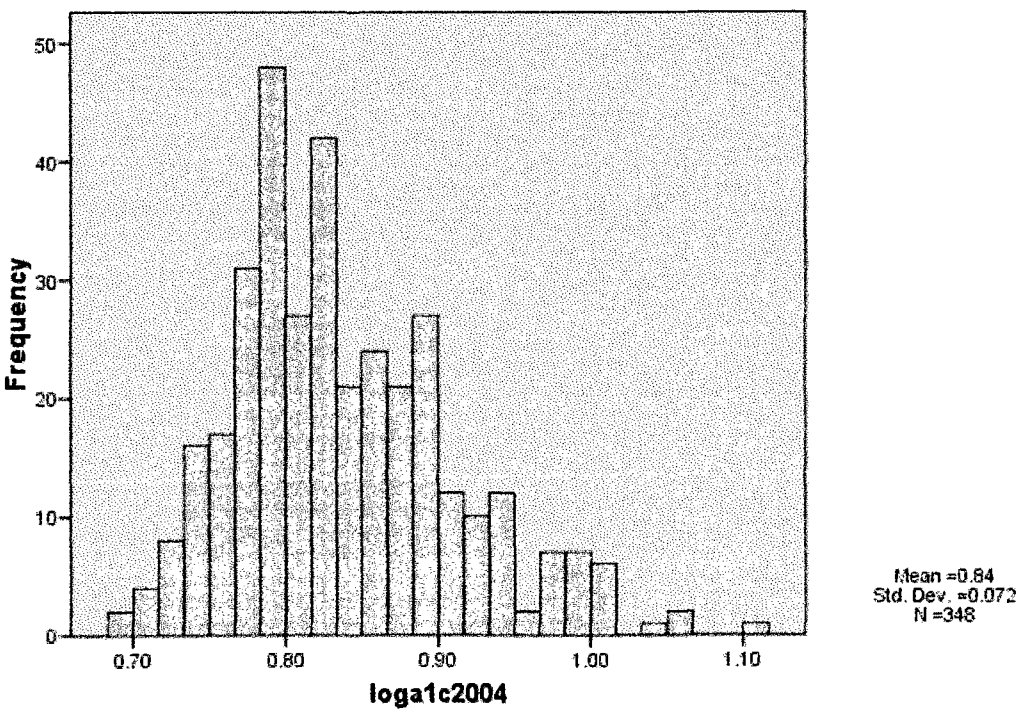
Promotion of patient adherence to current health guidelines is essential in reduction of cardiovascular disease risk and is a component of the Andersen behavioral model. In this study, almost half of the high risk participants were involved in patient-provider goal-setting with improvement in their biological outcomes. It was through this

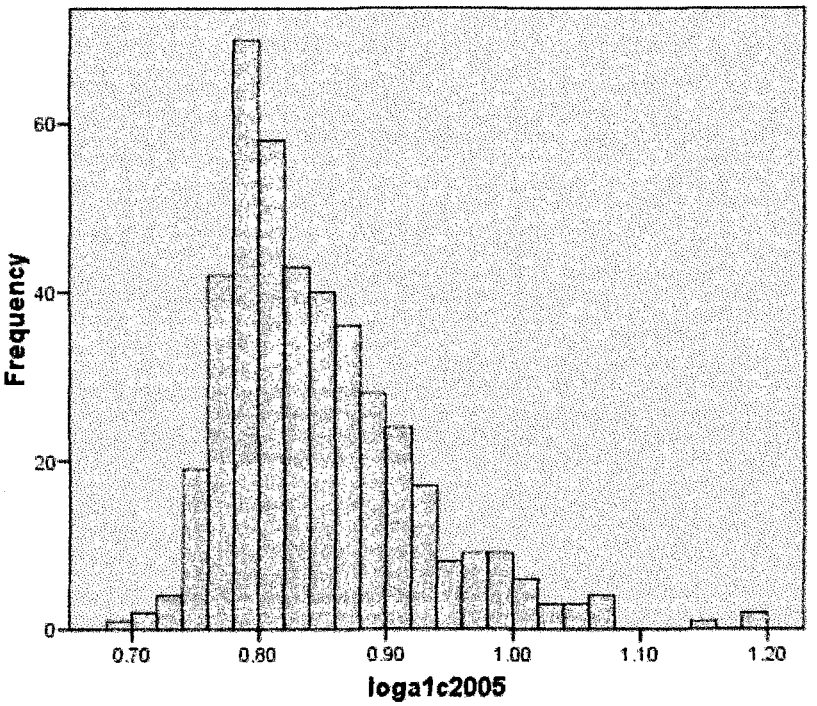
alliance that patient adherence to health recommendations was promoted and the outcome measure of LDL improved over a 5 year period. The incorporation of patient-provider goal-setting and decision support and the move toward collaborative decision making is an important first step in promoting cardiovascular health and developing programs to meet the needs of the veteran population.

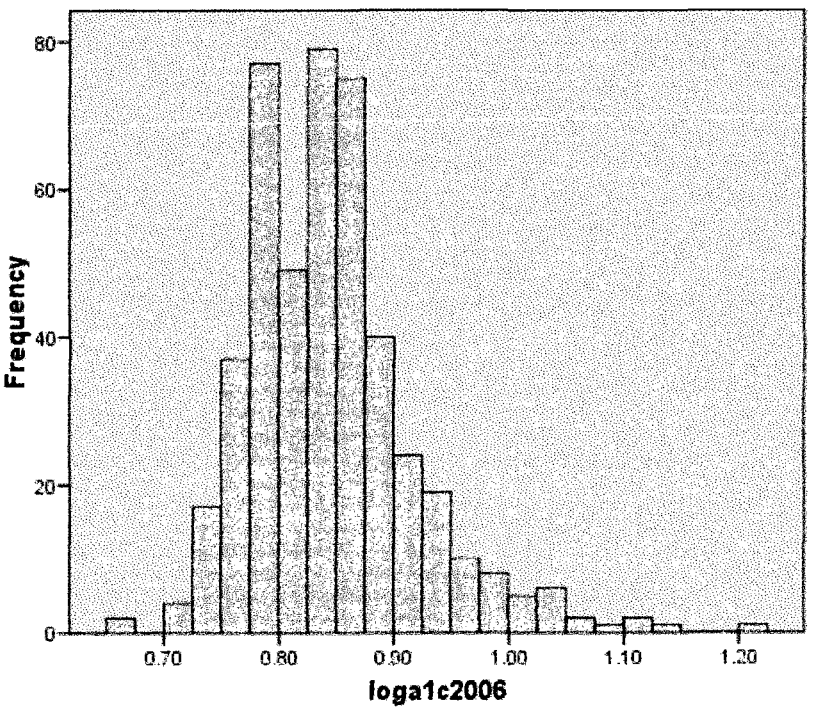
Appendix

Appendix A. Histograms of dependent variables of LDL, log HbA1C, and log BMI for years 2003-2007






Frequency
60
40
20
0
0.70
0.80
0.90
1.00
1.10
1.20
loga1c2005
Mean =0.85
Std. Dev. =0.075
N =429


Frequency
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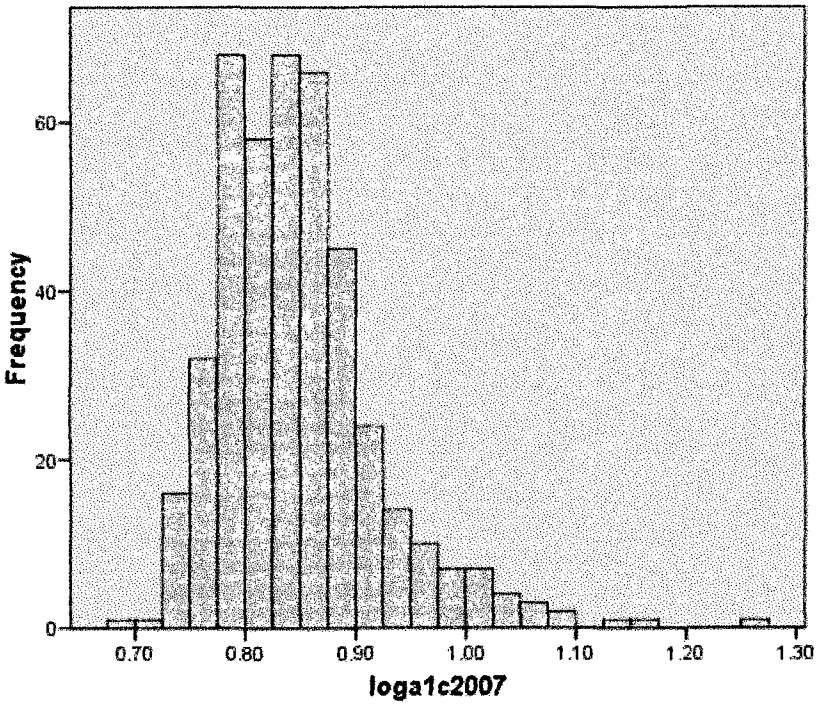
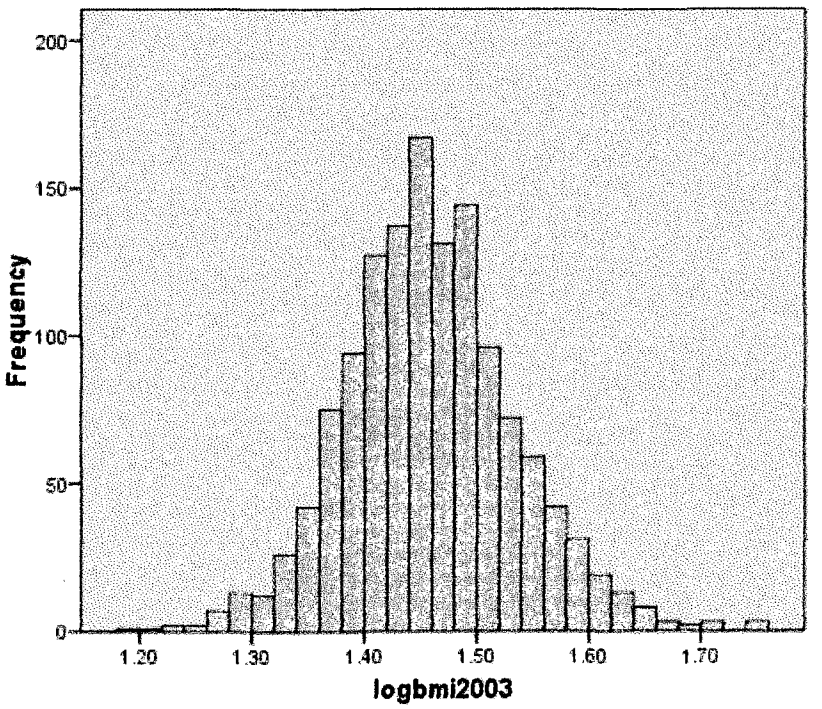
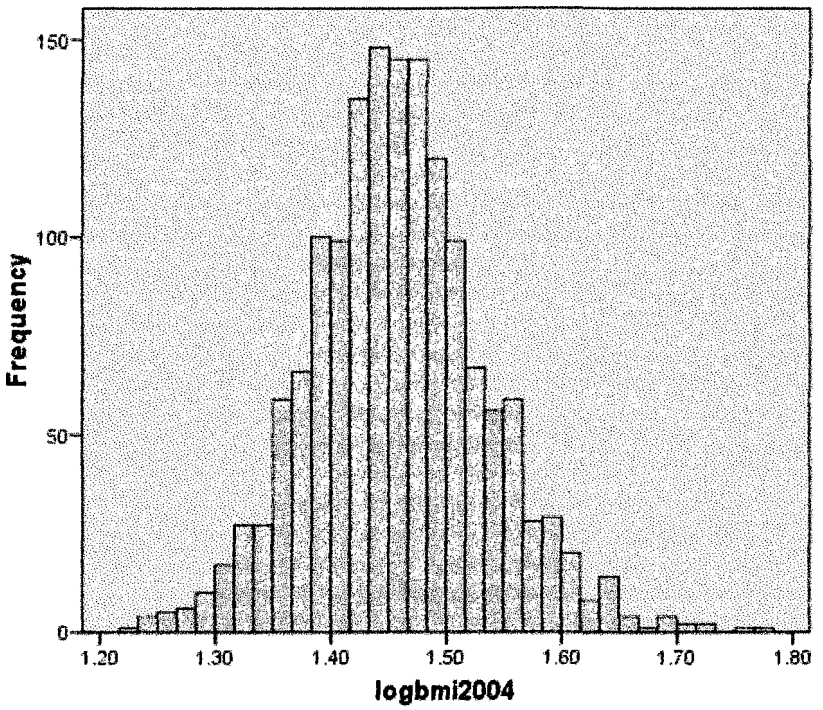
60
40
20
0
0.70
0.80
0.90
1.00
1.10
1.20
loga1c2006
Mean =0.84
Std. Dev. =0.072
N =459


Frequency
60
40
20
0
0.70
0.80
0.90
1.00
1.10
1.20
1.30
loga1c2007
Mean =0.85
Std. Dev. =0.072
N =429


Frequency
200
150
100
50
0
1.20
1.30
1.40
1.50
1.60
1.70
logbmi2003
Mean =1.46
Std. Dev. =0.076
N =1,332


Frequency
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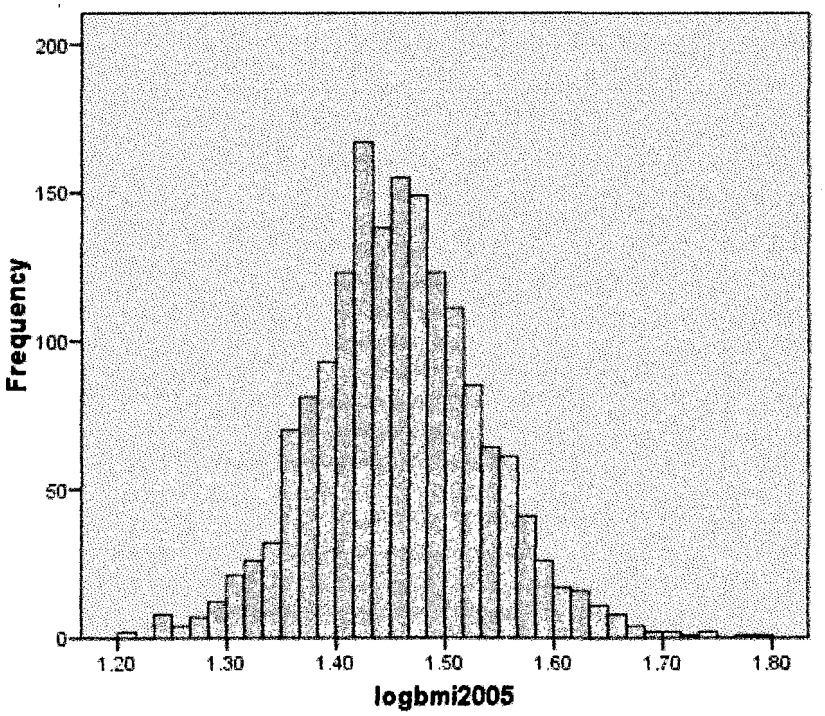
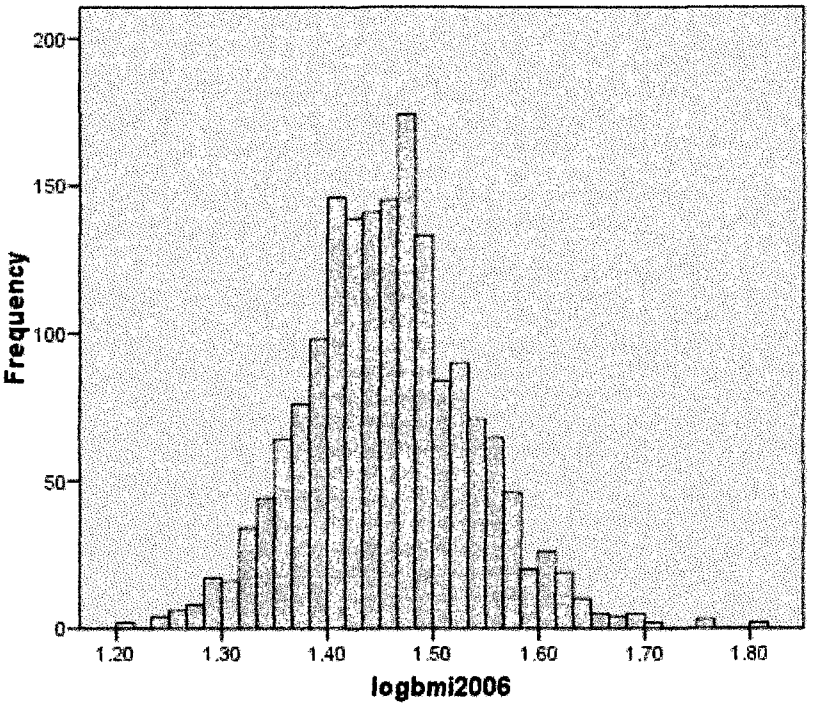
100
50
0
1.20
1.30
1.40
1.50
1.60
1.70
1.80
logbmi2004
Mean =1.46
Std. Dev. =0.076
N =1,509


Frequency
200
150
100
50
0
1.20
1.30
1.40
1.50
1.60
1.70
1.80
logbmi2005
Mean =1.46
Std. Dev. =0.078
N =1,664


Frequency
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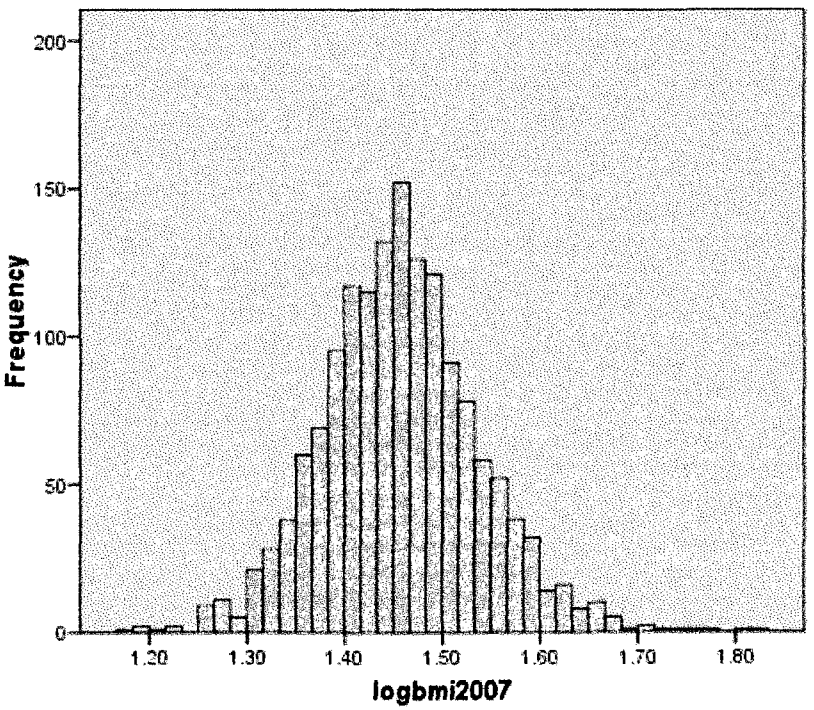
150
100
50
0
1.20
1.30
1.40
1.50
1.60
1.70
1.80
logbmi2006
Mean =1.46
Std. Dev. =0.079
N =1,699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1.70
1.80
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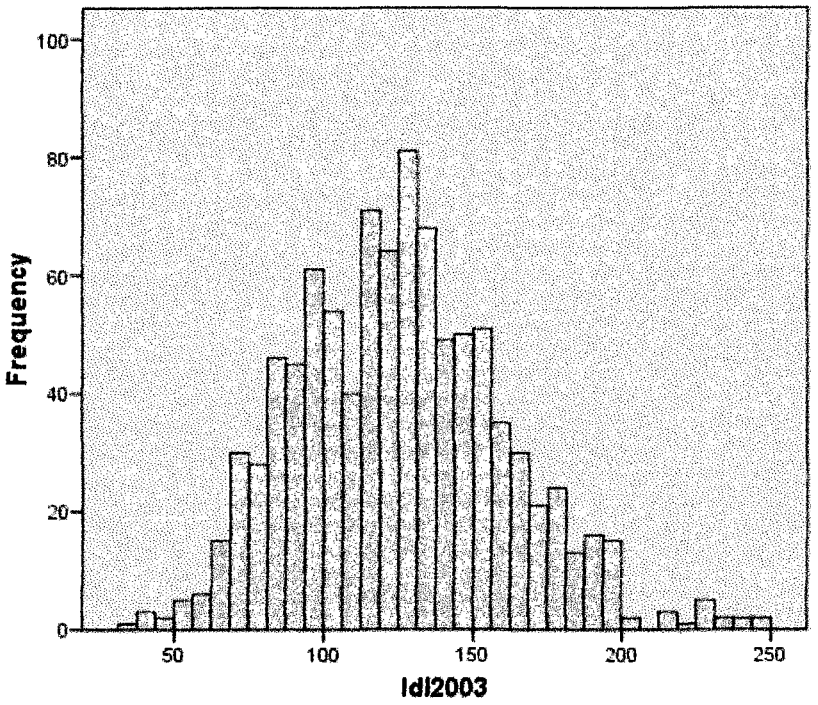
N =1,516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100
150
200
250
Idl2003
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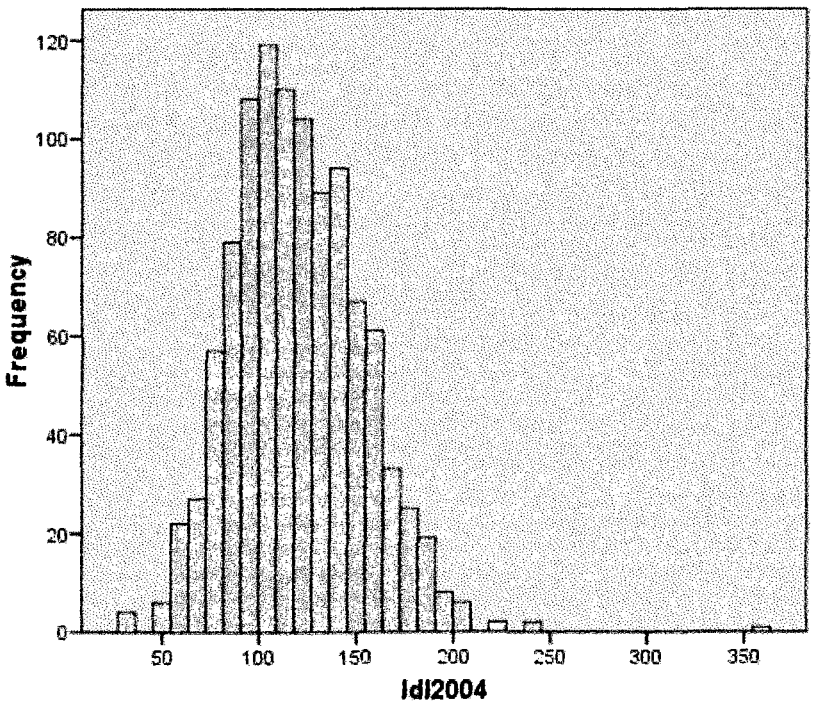
Std. Dev. =35.287
N =941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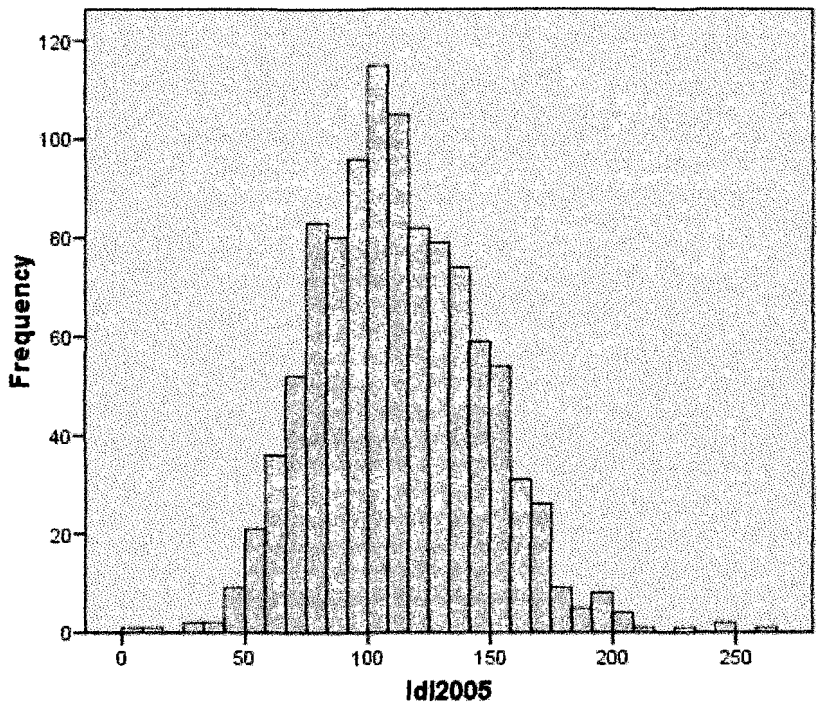
150
200
250
300
350
Idl2004
Mean =120.13
Std. Dev. =33.146
N =1,043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200
250
ldl2005
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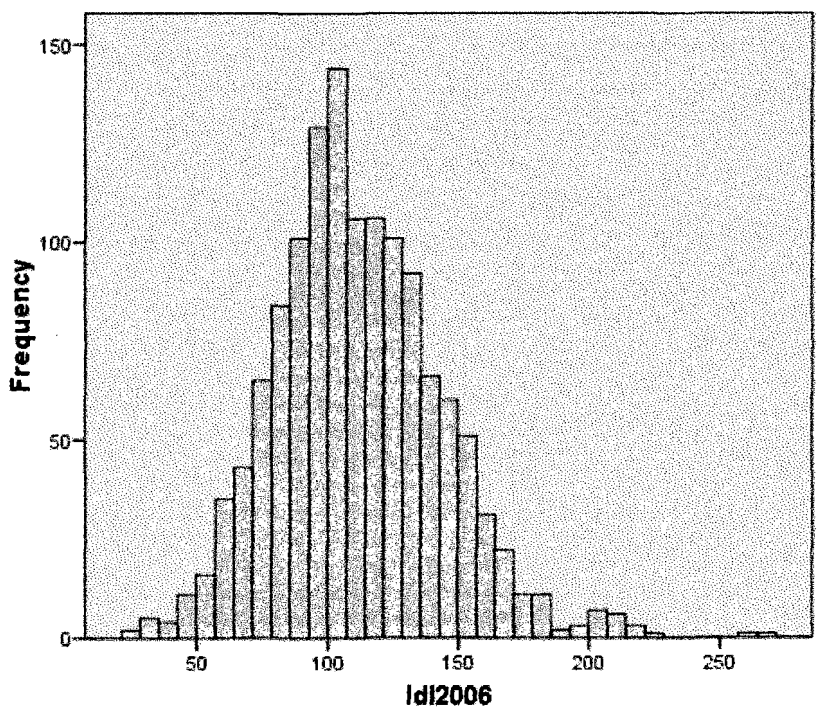
Std. Dev. =33.321
N =1,039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ldl2006
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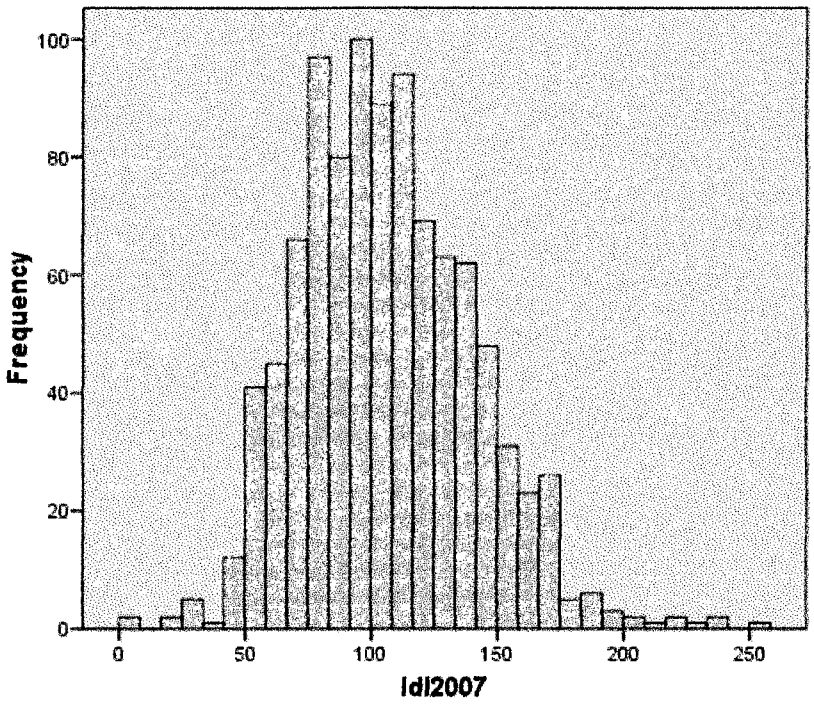
N =1,320


Frequency
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0
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50
100
150
200
250
ldl2007
Mean =106.27
Std. Dev. =34.438
N =979

Appendix B. Body Mass Index 2003-2007 (n= 1,865)

	n	%
BMI 2003		
16-20	41	2.2
21-30	885	47.5
31-40	369	19.8
41-50	34	1.8
50+	3	0.2
Missing data*	533	28.5
Total	1865	100.0
BMI 2004		
16-20	49	2.6
21-30	879	47.1
31-40	398	21.3
41-50	38	2.0
50+	6	0.3
Missing data*	495	26.7
Total	1865	100.0
BMI 2005		
16-20	61	3.3
21-30	1084	58.1
31-40	458	24.6
41-50	42	2.3
50+	6	0.3
Missing data*	214	11.4
Total		100.0
BMI 2006		
16-20	57	3.1
21-30	1106	59.3
31-40	460	24.7
41-50	49	2.63
50+	7	0.38
Missing data*	186	9.9
Total	1865	100.0
BMI 2007		
16-20	53	2.8
21-30	982	52.8
31-40	416	22.4
41-50	43	2.3
50+	7	0.38
Missing data*	364	19.5
Total	1865	100.0

**no height and/or weight recorded. ** No patients had a BMI under 16*

Appendix C

Ethnicity by high and low risk by year, 2003-2007

Variable/Year	n	% of Ethnic Group
Caucasian low risk 2003	66	8.3
Caucasian high risk 2003	730	91.7
African American low risk 2003	18	10.3
African American high risk 2003	157	89.7
Total missing data 2003	833	---
Caucasian low risk 2004	54	6.8
Caucasian high risk 2004	742	93.2
African American low risk 2004	14	8.0
African American high risk 2004	161	92.0
Total missing data 2004	833	---
Caucasian low risk 2005	54	6.8
Caucasian high risk 2005	742	93.2
African American low risk 2005	16	9.1
African American high risk 2005	159	90.9
Total missing data 2005	833	---

Appendix C (Continued).

Ethnicity by high and low risk by year, 2003-2007

Variable/Year	N	%
Caucasian low risk 2006	52	6.5
Caucasian high risk 2006	744	93.5
African American low risk 2006	10	5.7
African American high risk 2006	165	94.3
Total missing data 2006	833	---
Caucasian low risk 2007	58	7.3
Caucasian high risk 2007	738	92.7
African American low risk 2007	11	6.3
African American high risk 2007	164	93.7
Total missing data 2007	833	---

Note: The 11 participants who were not Caucasian or African American were not included.

Appendix D
2003-2007 Employment, and Number of Visits According to Patient Risk Group.

Variable	Low Risk		High Risk	
	Freq.	Valid %	Freq.	Valid %
Employment 2003				
Employed	14	66.7	261	33.0
Unemployed or retired	7	33.3	531	67.0
Missing/not reported	12	---	165	
Employment 2004				
Employed	10	71.4	311	31.9
Unemployed or retired	4	28.6	664	68.1
Missing/not reported	5	---	88	---
Employment 2005				
Employed	22	71.0	347	33.2
Unemployed or retired	9	26.5	697	66.8
Missing/not reported	3	---	54	---
Employment 2006				
Employed	31	62.0	391	32.0
Unemployed or retired	19	38.0	831	70.0
Missing/not reported	3	---	79	---
Employment 2007				
Employed	17	60.7	291	29.4
Unemployed or retired	11	39.3	699	70.6
Missing/not reported	4	---	66	---

Appendix D (Continued).

2003-2007 Employment, and Number of Visits According to Patient Risk Group.

Variable	Low Risk		High Risk	
	Freq.	Valid %	Freq.	Valid %
Annual visits 2003				
0 visits	10	30.3	142	14.8
1-2 visits	20	60.6	269	28.1
3-5 visits	3	9.1	441	46.1
6 or more visits	---	---	105	11.0
Annual visits 2004				
0 visits	4	21.1	53	5.0
1-2 visits	12	63.2	341	32.1
3-5 visits	3	15.8	549	51.7
6 or more visits	---	---	118	11.1
Missing/not reported	---	---	2	---
Annual visits 2005				
0 visits	1	2.9	18	1.6
1-2 visits	28	82.4	346	31.5
3-5 visits	5	14.7	594	54.1
6 or more visits	---	---	140	12.8
Missing/not reported	---	---	---	---

Note. Freq. = Frequency; Valid % = percentage of reported counts (excludes missing data).

Appendix D (Continued).

2003-2007 Employment, and Number of Visits According to Patient Risk Group

Variable	Low Risk		High Risk	
	Freq.	Valid %	Freq.	Valid %
Annual visits 2006				
0 visits	0	0.0	3	0.2
1-2 visits	40	75.5	418	32.2
3-5 visits	12	22.6	725	55.8
6 or more visits	1	1.9	154	11.8
Missing/not reported	---	---	1	---
Annual visits 2007				
0 visits	1	3.1	8	0.8
1-2 visits	23	71.9	295	28.0
3-5 visits	8	25.0	616	58.6
6 or more visits	---	---	133	12.6
Missing/not reported	---	---	4	---

Note: Freq. = Frequency; Valid % = percentage of reported counts (excludes missing data).

Appendix E.

IRB Approval Letters from the Department of Veterans Affairs Medical Center and the University of Hawai'i at Mānoa

UNIVERSITY OF HAWAI'I

Committee on Human Studios

MEMORANDUM

December 11,2008

TO: Shannon Cohen
Principal Investigator Department of Nursing

FROM: William H. Dendle

SUBJECT: CHS #16680- "Adherence, Goal-Setting, and Cardiovascular Risk Reduction Among the Veteran Population"

Your project identified above was reviewed and has been determined to be exempt from Department of Health and Human Services (DHHS) regulations, 45 CFR Part 46. Specifically, the authority for this exemption is section 46.101 (b)(4). Your certificate of exemption (Optional Form 310) is enclosed. This certificate is your record of CHS review of this study and will be effective as of the date shown on the certificate.

An exempt status signifies that you will not be required to submit renewal applications for full Committee review as long as that portion of your project involving human subjects remains unchanged. If, during the course of your project, you intend to make changes which may significantly affect the human subjects involved, you should contact this office for guidance prior to implementing these changes.

Any unanticipated problems related to your use of human subjects in this project must be promptly reported to the CHS through this office. This is required so that the CHS can institute or update protective measures for human subjects as may be necessary. In addition, under the University's Assurance with the U.S. Department of Health and Human Services, the University must report certain situations to the federal government Examples of these reportable situations include deaths, injuries, adverse reactions or unforeseen risks to human subjects. These reports must be made regardless of the source funding or exempt status of your project.

University policy requires you to maintain as an essential part of your project records, any documents pertaining to the use of humans as subjects in your research. This includes any information or materials conveyed to, and received from, the subjects, as well as any executed consent forms, data and analysis results. These records must be maintained for at least three years after project completion or termination. If this is a funded project, you should

be aware that these records are subject to inspection and review by authorized representatives of the University, State and Federal governments.

Please notify this office when your project is completed. We may ask that you provide information regarding your experiences with human subjects and with the CHS review process. Upon notification, we will close our files pertaining to your project. Any subsequent reactivation of the project will require a new CHS application. Please be aware that unless we are notified otherwise, this will automatically expire 5 years from the approval date.

Please do not hesitate to contact me if you have any questions or require assistance. I will be happy to assist you in any way I can.

Thank you for your cooperation and efforts throughout this review process. I wish you success in this endeavor.

Mali Way, Spalding 253, Honolulu, Hawai'i 96622-2303
Telephone: (808) 956-5007, facsimile: (808) 956-8683
An Equal Opportunity/Affirmative Action Institution

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

PROJECT/PROGRAM TITLE:
Adherence, Goal-Setting, and Cardiovascular Risk Reduction among the Veteran Population

PRINCIPAL INVESTIGATOR:
David Buyck, Ph.D.

VAMC: SALEM

IRB REVIEW DATE: 2/2/09

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills. ☐ YES ☐ NO ☑ NA

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. ☐ YES ☐ NO ☑ NA

3. Every effort has been made to decrease risk to subject(s)? ☑ YES ☐ NO ☐ NA

4. The potential research benefits justify the risk to subject(s)? ☑ YES ☐ NO ☐ NA

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met; a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, they will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described. ☐ YES ☐ NO ☑ NA

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. ☐ YES ☐ NO ☑ NA

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. ☑ YES ☐ NO ☐ NA

8. Comments: **Protocol-Related Materials Include:** Expedited Review Checklist; Request for waiver of informed consent; Request for full waiver of authorization for research; Financial Conflict of Interest statements;

If applicable, Waiver of Authorization (Full or Partial) approved by: ( ) Full Review (X) Expedited Review

Recommendation: (X) **Study Approved by:** ( ) Full Review (X) Expedited Review ( ) Exempted
( ) **Study Disapproved**

IRB Protocol #: DB0051

SIGNATURE OF CHAIRMAN	DATE
KIM G. RAGSDALE, PH.D. Kim G. Ragsdale PhD	2/2/09

VA FORM OCR 1995(R) **10-1223** Rev. 2/15/08

Department of Veterans Affairs

Memorandum

Date: March 9, 2009

From: Chair, Research and Development Committee (151)

Subject: Approval of New Expedited Protocol

To: David Buyck, Ph.D. (116B2)

1. The Research and Development Committee reviewed and approved the new expedited protocol DB 0001, **"Adherence, Goal-Setting, and Cardiovascular Risk Reduction among the Veteran Population"** on Monday, March 9, 2009. This includes: protocol; expedited review checklist; request for full waiver of authorization for research; request for waiver of informed consent; financial conflict of interest statement. This protocol was also reviewed and approved by the IRB Chair on Monday, February 2, 2009. The IRB approval is valid through February 1, 2010.

2. You must notify the R&D Office (ext. 2029) of the date when any research activity begins on this study. A Research Progress Report must be submitted annually and at the completion of this protocol.

3. Any modification or amendment to the research protocol, including the informed consent form (if applicable), must be approved by the IRB prior to implementation.

4. All adverse events and safety reports must be submitted to the IRB according to the guidelines outlined in the standard operating procedures.

STEPHANIE E. NAGY-AGREN, M.D.

3-20-09
DATE

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