HYPERTENSION THERAPEUTIC GOAL ATTAINMENT IN PATIENTS WITH DUAL DIAGNOSES OF HYPERTENSION AND DIABETES

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ABSTRACT

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The purpose of this study was to evaluate the adequacy of blood pressure control and utilization patterns of antihypertensive agents among patients with dual diagnoses of hypertension and Diabetes Mellitus type 2 seen in a primary care clinic during the calendar year 2008. Adequacy of blood pressure control was determined per recommendations of JNC7 antihypertension guidelines, which state that diabetics with hypertension need to have blood pressures controlled to less than 130/80.

Demographic results showed that 68% of patients were over the age of 65, 30% were between the ages of 50 and 64 and 2% were between the ages of 20-49. The sample was primarily male (99%), of white race (97%), and married (69%). Forty-two percent of the participants met JNC7 criteria and had both systolic and diastolic blood pressure measurements controlled to less than 130/80 mm Hg. Forty percent of participants had either the systolic or the diastolic measurement controlled. Eighteen percent had neither systolic or diastolic measurements controlled. Most commonly utilized antihypertensive medications in order of their frequency were ACE/ARBs (70%), beta blockers (59%), calcium channel blockers (38%), thiazide diuretics (36%), loop diuretics (28%) alpha blockers (27%) combination antihypertensives (6%) and miscellaneous agents (5%). Body mass index (BMI) showed the participants were morbidly obese (11%), obese (52%), overweight (30%), normal weight (7%), and below normal weight (4%). Only 44% of patients had a microalbuminuria test documented during the year. In summation, only 42% had blood pressures controlled to the criteria specified for diabetic hypertension per JNC7

antihypertensive guidelines. ACE/ARB medication use was the highest utilized antihypertensive medication (70%), which was expected as this class of medication is recommended for diabetics; however, thiazide diuretics which are indicated as a first line therapy were only prescribed to 36% of the sample. Lifestyle modifications especially need to be emphazised by providers to control blood pressure and diabetes as obesity and overweight rates were very high. Further recommendations include obtaining a microalbuminuria laboratory test annually.

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CHAPTER I

BACKGROUND AND SIGNIFICANCE

Introduction and Problem Statement

The treatment and prevention of cardiovascular disease are important goals of medical care systems globally. Cardiovascular disease refers to the class of diseases that involves the heart or blood vessels. Hypertension is not the only risk factor for cardiovascular disease; however, it is the most important one (Cutler et al., 2008). Hypertension contributes to approximately one-half of coronary heart disease cases and two-thirds of cerebrovascular disease cases (Cutler et al., 2008). Hypertension affects 29% of adults in the United States (Hajjar & Kotchen, 2003). According to Rose, Berlowitz, Orner, and Kressin (2007) there has been a strong effort to improve the treatment of hypertension, but only 64% of hypertension patients in the United States who were treated in 2003 and 2004 had controlled blood pressure per clinical guidelines as set forth by *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC7).

Diabetes mellitus type 2 is also a major medical problem in the United States and globally. According to Bell, O'Keefe Jr., and Bakris (2006) there are 21 million cases in the United States and 150 million cases worldwide and the problem continues to grow. Haffner, Lehto, Ronnemaa, Pyorala, and Laakso (1998) noted that the combination of diabetes and hypertension significantly increases the risk of cardiovascular disease. Patients with dual diagnoses of diabetes and hypertension need to attain blood pressures of less than 130/80 as compared to those patients with hypertension alone, for which the blood pressure goal is less than 140/90 per clinical guidelines of JNC7. Hypertension can

be especially difficult to control in the diabetic population (McLean, 2008). Having diabetes mellitus may be equal to established coronary artery disease, as diabetic patients have the same risk for a heart disease episode as nondiabetic patients who have already had heart attacks (McLean, 2008). Diabetic hypertension is caused by genetic factors of sympathetic nervous system overactivity, a heightened renin-aldosterone system and endothelial dysfunction. These factors create an increased vascular reactivity which causes retention of salt and water and can lead to atherosclerosis and increased workload for the heart (Bell et al., 2006).

JNC 7 guidelines emphasize the need to assess and treat overall risk for cardiovascular disease through the concomitant management of risk factors. My study seeks to ascertain hypertension treatment patterns and attainment of therapeutic goals in patients with dual diagnoses of hypertension and diabetes mellitus type 2 at a midwestern Veteran's Affairs (VA) facility. Improvement in the management of hypertension in the type 2 diabetic population will require an understanding of the current level of hypertension control and treatment. Improving hypertension care and control is a national priority, both inside and outside the VA (Chobanian, 2001). JNC 7 hypertension clinical guidelines are used as a guide to ascertain the level of therapeutic goal attainment in the management of hypertension in the diabetic population.

The study is important to nurse practitioners and other medical providers because the data collected will provide feedback on how well providers are treating hypertension in the diabetic population at one midwestern VA. At the close of 2008, there were 69 health care providers responsible for primary care at this site. Out of the 69 primary care providers, 40 were physicians, 16 were physician assistants and 13 were nurse

practitioners. According to Borzecki, Wong, Hickey, Ash, and Berlowitz (2003) hypertension is among the most common reasons for patient office visits in the United States. Hypertension has serious long term ramifications when we consider morbidity and mortality associated with cardiovascular disease. Additional information regarding antihypertensive medication utilization patterns may focus attention on the need for clinical providers to attain therapeutic goals in the management of hypertension.

Purpose of the Study

The purpose of the study was to evaluate the adequacy of blood pressure control and the utilization patterns of antihypertensive agents among patients with dual diagnoses of hypertension and diabetes mellitus type 2.

Background and Significance

Recent clinical guidelines noted by Chobanian et al. (2003), the National High Blood Pressure Education Program Coordinating Committee (2003), and JNC 7 emphasized the need to assess and treat hypertension to attain systolic blood pressure (SBP) goals of less than 140 mm hg and diastolic blood pressure (DBP) goals of less than 90 mm Hg in order to lower the risk for cardiovascular disease as a guideline for treating hypertension. The JNC 7 hypertension guidelines recommend that patients with hypertension and co-morbidities of diabetes and renal disease attain goals of less than 130/80 mm Hg blood pressure. Sutton-Tyrell, Wildman, Newman, and Kuller (2003) found that in people older than 55, a systolic blood pressure greater than 140 was more significant than a diastolic value of greater than 90. Systolic hypertension in the elderly is likely results from arteriosclerotic changes in large vessels and the aorta. Over time these changes result in a loss of elastic fibers which can lead to stiffening in the arteries and can

causes elevated systolic blood pressure without a corresponding rise in diastolic blood pressure (Sutton-Tyrrel et al., 2003). For those patients under the age of 65 who have progressive increases in blood pressure, there is a corresponding risk of suffering a stroke or heart attack (Kannel, 2000).

Hypertension is now thought of as a commonly treated disease; however, in reality, it has been only in the past 50 years or less, that the role hypertension plays in causing hospitalization and death has been recognized (Perkovic, Huxley, Wu, Prabhakaran, & MacMahon, 2007). Recognition of the morbidity and mortality caused by hypertension sparked the development of medications to treat hypertension. The era of the 1960s was the first time that safe and effective antihypertensive agents were made and widely used (Perkovic et al., 2007). These researchers found that there was a big difference between higher and lower income countries and how hypertension was treated in each economic category. Lower income countries are still treating patients like the United States did in the 1950s before the development of diuretics and beta blockers. Many lower income countries have instead focused on treating infectious diseases such as AIDS which has a higher prevalence. The World Health Organization has provided education in lower income countries on the impact that hypertension has on mortality, morbidity, social, and economic levels.

CHAPTER II

LITERATURE REVIEW AND STUDY FRAMEWORK

The JNC 7 clinical guidelines for hypertension in 2003 described a new stage of blood pressure called prehypertension. Prehypertension was defined as systolic blood pressure of 120-139 mm Hg or diastolic blood pressure of 80-89 mm Hg. The recommendation was for individuals in this stage to have close follow-up and possible non-pharmacological intervention due to an increased risk for cardiovascular disease (Chobanian et al., 2003). Kshirsager, Carpenter, Bang, Wyatt, and Colindres (2006) raised concerns that the addition of the new category of hypertension would significantly increase the number of people who may need evaluation and treatment of hypertension. These researchers felt that the increase would strain access to providers and have cost implications for our health care system. Patients in the prehypertension category may vary greatly in their risk profiles with some of them not even needing treatment and evaluating them, could lead to unnecessary pharmacologic treatment (Kshirsager et al., 2006). These researchers thought that the implications might explain why there seems to be a reluctance of providers to fully implement the JNC 7 guidelines.

Federman et al. (2008) described a clear need for improvement in the identification and treatment of hypertension, noting that hypertension is underdiagnosed and undertreated. They focused on what they called "clinical inertia" and explored if there was a difference in the likelihood of intensifying antihypertensive medication therapy by three provider types: attending physicians, resident physicians in training and midlevel practitioners (which they defined as nurse practitioners or physician assistants). Clinical inertia is defined as failure to initiate or intensify therapy when treatment is appropriate.

Their study setting was conducted at two major academic Veteran's Affairs facilities in Connecticut. They found that resident physicians were less likely to have "clinical inertia" than the other two provider types when seeing patients with elevated blood pressures. Their findings disputed prior studies by Federman, Krishnamurthy, Kancir, Goulet, and Justice (2005) which found that patients of the resident physicians were *less* likely to attain their blood pressure goal than patients of either attending physicians or midlevel practitioners.

Although there is evidence that intensive treatment of hypertension in diabetic patients reduces the incidence of heart disease, stroke, and heart failure, and reduces the progression of nephropathy and retinopathy, too often hypertension is not well controlled in this population. Berlowitz et al. (2003) found that diabetics actually had worse blood pressure control than nondiabetic patients and they were less likely to receive increases in their antihypertensive drug therapy.

There are differing opinions regarding the JNC 7 clinical guideline's recommendations for aggressive treatment of hypertension. Felicetta (2008) disputed the notion that patients with artificially lowered blood pressures have the same cardiovascular risk as those with naturally normal blood pressures, because there are physiologic reasons for elevated blood pressures. Felicetta also felt that artificially lowering one's blood pressure did not equalize cardiovascular risk because patients whose blood pressures are controlled with medications are not necessarily at the same risk as those patients who naturally have normal blood pressures. There are many physiologic factors that cause blood pressure to become elevated. In other words, just because blood pressure has been lowered with medications does not mean the factors behind the elevation have been decreased or

eliminated. Controlling blood pressure with diet and weight loss would be considered natural disease prevention interventions (Pender, 2006).

There is more than one reason why hypertension is not well controlled. The failure to intensify medication, also known as "clinical inertia", is associated with poor blood pressure control. According to Heisler et al. (2008) clinicians may be concentrating too much on increasing or changing the dose or adding another class of antihypertensive agent. According to these researchers, clinicians need to focus on intensification, but also need to ask their patients about medication adherence because 50% of the time, this is the reason behind treatment failures. Heisler et al. (2008) quoted U.S. Surgeon General Everett Koop as saying, "Drugs don't work in people who don't take them" (p. 2884). The possibility of medication adherence needs to be brought up and discussed with patients in a tactful way, if providers are going to be successful in assisting them to achieve therapeutic goals for control of hypertension.

Another possible explanation for the increased prevalence of hypertension in the United States may be the significant increase in obesity and body mass index (Hajjar & Kotchen, 2003). Blood pressure control could be improved through a concentrated effort by a number of disciplines. Walsh et al. (2006) found that giving some of the responsibility for blood pressure control to medical professionals other than the patient's physician deserves further evaluation. Nurses, pharmacists and dieticians should also be considered an integral part of the team.

In another VA study, Johnson, Pietz, Battleman, and Beyth (2006) found that although most patients were receiving medical therapy for hypertension, a substantial number were not, and more than half of all patients failed to attain therapeutic goals.

Diabetic patients with diagnoses of hypertension and dyslipidemia were even less likely to achieve therapeutic blood pressure goals.

The JNC 7 hypertension guidelines also noted that blood pressures were better controlled if patients were motivated. Patients who are motivated by empathy, trust, and good experiences with their clinician were more likely to achieve target goals.

Johnson and Singh (2005) conducted a study of 9,975 patients with diabetes and hypertension in a VA outpatient clinic in Houston, Texas. They found that patterns of antihypertensive therapy were consistent with the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 6) practice guidelines, the latest edition at the time of the study. The authors found that overall blood pressure control (<130/80) was 25.2%, and the control rate did not vary much across regimens. There was a relatively high use of alpha blockers thought to be due to the high proportion of males in the veteran population and the co-existence of benign prostatic hypertrophy. There is room for improvement in drug utilization and a critical need for better blood pressure control, especially in the group (19% of the study subjects) that was not on any antihypertensive therapies. The authors recommended that further research be done to understand poor blood pressure control despite good pharmacological treatment and include specific patient and provider factors that may be associated with blood pressure control.

Montgomery, Harding, and Fahey (2001) conducted an observational study that demonstrated the impact of individual values regarding the benefits and risks of blood pressure treatment. Decision analysis was used to evaluate patient preference measured by the standard gamble method in interviews of 52 hypertensive patients. Decision analysis is

a shared decision-making aid that has an impact on whether patients would be recommended to take antihypertensive medication. The researchers felt that further research was needed on using decision analysis as a tool to decide which patients to put on blood pressure medication. Decision analysis can be used in policy making and to assist patients in understanding benefits and harm in the treatment of hypertension. JNC 7 guidelines (Chobanian et al., 2003) assert that patients' blood pressure control will not improve unless they are motivated and have trust in their clinicians.

In a recent study of the use of hypertension guidelines and their limitations, Hegemeister et al. (2001) found that the impact of hypertension guidelines on actual medical knowledge is modest. Since the impact was only modest, the authors felt that the guidelines needed to be improved and tailored to the needs of physicians in clinical practice in order to actually improve patient care. This study had a sample size of 24,529 physician participants and demonstrated the need for the JNC 7 hypertension guidelines to be rewritten (Chobanian et al., 2003). The current guidelines need to be improved to meet the needs of clinical providers in order to improve patient care.

In a review of barriers to hypertension control, Borzecki et al. (2005) concluded that the most important provider-related barriers to adherence to practice guidelines is clinical inertia and lack of provider agreement with the guidelines, especially regarding management of systolic hypertension. Clinical inertia is likely due to clinicians overestimating the aggressiveness of the care that they actually provided. The authors also suspected, but could not prove, that there was a lack of provider knowledge about how to attain blood pressure levels consistent with JNC7 guidelines for their patients. Several other barriers were described, including the ability to access the healthcare system,

communication problems between patients and providers, and inadequate time and resources for providers to be able to adhere to the guidelines and provide the necessary patient education and counseling.

Baker (2001) asked the question, "Is it time to review the idea of compliance with guidelines" (p. 452)? He also felt that guidelines need to be of genuine help to both the patient and the provider, and that employers would have to support the provider with enough time to discuss treatment options. Baker also advocated assisted decision making between the provider and the patient and felt that guidelines should enable patients to decide what level of risk to accept and how to reach target blood pressure levels.

Wang (2004) explored physician-related barriers to hypertension management. He found that most physicians are familiar with hypertension guidelines but that implementation of these guidelines is inadequate. Wang discovered that most physicians thought that pharmacological therapy should be initiated at a blood pressure of 155/95 mm Hg. The physicians in the study felt that lifestyle modifications were important; however, only 21.4% routinely provided advice on dietary modification of low salt intake, regular physical exercise, and weight reduction. These physicians felt that patients' compliance was a major barrier and was often due to either the patients' financial constraints or the patients' concerns regarding the possible adverse side effects of the medications.

Phillips et al. (2001) performed an analysis of physician behavior and found that management of chronic disease is often limited due to "clinical inertia," defined as the failure of healthcare providers to initiate or intensify therapy, when indicated. The inertia is due to three causes: an overestimation by the provider of the care provided, use of "soft" reasons to avoid intensification of therapy, and lack of education, training and practice

aimed at achieving therapeutic goals. Examples of "soft" reasons include the perception that control was improving, dietary noncompliance, and concern about whether results from large studies in a research trial environment can legitimately guide decisions in the traditional clinic setting.

Carter (2004) explored the implementation of the JNC 7 guidelines. The author found that most patients are not at goal and that the greater challenge is to effectively treat patients with chronic kidney disease and diabetes because their target goals are lower than for patients without these conditions. The study was carried out at five VA facilities and resulted in a significant increase in the number of patients receiving beta blocker therapy, thiazide diuretics and angiotension-converting enzymes inhibitors. The author used the clinical pharmacist in an expanded role to consult with physicians about medications, design effective formularies and to be a co-manager of therapy. The goal was to improve physician awareness of important prescribing guidelines. The study intervention included pharmacists providing lectures, provider profiling, educational materials, and personal meetings between pharmacists and providers. The result after the intervention was a decrease in the proportion of patients receiving calcium channel blockers, from 43% to 38%, while the proportion of patients receiving beta blocker therapy or thiazide diuretics increased from 58% to 64%. In the hypertensive diabetic population, the proportion receiving an ACE inhibitor or ARB increased from 72% to 76%.

Seroussi, Bouaud, and Chatellier (2005) noted that despite the proliferation of clinical guidelines, physician compliance remains low. There was no research found that would indicate the level of compliance of nurse practitioner providers. Clinical situations of individual patients can be difficult to match to specific guidelines, because few clinical

situations actually present as clearly as the guidelines depict. The authors proposed a guideline knowledge two-level decision tree, wherein one level would represent clinical situation descriptions and the other level would represent treatment strategies. The authors would develop a software program into which the physician could enter the patient's past history and circumstances into the guideline decision tree and then be able to ascertain the next recommended step of therapy.

Framework

Betty Neuman, Ph.D, RN developed the Neuman Systems Model in 1970 at the University of California, Los Angeles. Neuman's model provides a holistic view of five client variables that are found in human beings. These variables are physiological, psychological, socio-cultural, developmental and spiritual aspects. The model is not a full theory, but instead is a conceptual framework or visual framework in which to view human beings in their interactions.

The model portrays the individual as a layered, multidimensional whole who is in continuous dynamic interaction with the environment. The layers represented in the model are akin to various levels of defense that protect the core being. The two major components of the model are the stress reactions and systemic feedback loops. The individual will react to stress with lines of defense and resistance and there are constant feedback loops that modify the lines of defense in order to achieve stability (Neuman, 1995). The individual is in continual, dynamic interaction with the environment, with each influencing the other. The goal of this model is to obtain maximum system balance.

The layers of the model are represented by circles that consist of a central core, resistance lines, normal defense lines and flexible defense lines. The core is comprised of

survival mechanisms which include temperature, organ function, genetic makeup, response patterns, ego and what Neuman calls "knowns" and "commonalities." The lines of resistance and the two lines of defense protect the core. The "person" in the model could be an individual, a family, a group, or a community. The "person" is an open system that interacts with the environment in a reciprocal exchange.

Neuman's model is frequently used in research and in nursing practice because its concentric layers help to classify the severity of a problem. To Neuman, health is equated with wellness, and this is portrayed on a wellness-illness continuum. People's positions on the continuum depend on their interaction with the variables and stressors they experience. They move toward death or illness on the continuum and this process is ever changing. The closer to death people move, the less energy they have than they actually need. The closer to wellness they move, the more energy they have than they actually need.

Neuman's model is well suited for the nursing profession, as nurses interact with people who are usually experiencing at least one stressor in their lives (often physical) who quite often are experiencing many stressors at the same time. The nurse's role is to interact to affect people by using primary, secondary, and tertiary prevention strategies to restore or maintain system stability.

Stressors can be either positive or negative, but ultimately they have an effect on system stability. People can have various responses to stressors at different times. Neuman believes that prevention is the primary nursing intervention and can provide protection for people.

The model provides nurses a tool to use as they treat and educate patients with hypertension and diabetes. These are two common chronic diseases and recognition of the

many aspects that contribute to how well patients are able to control their disease is important. Prevention of disease, and disease progression or sequelae, requires nurses to recognize that the best patient care will occur when a team effort is put forth. Treatment of hypertension in patients with diabetes may be delivered using Neuman's Model, as it provides a holistic view that can be used to educate and treat patients. The model bases care on physiological, psychological, socio-cultural, developmental, and spiritual needs. The most effective way to prevent and manage chronic disease is to address all of these aspects.

Research Questions

1. What percentages of patients who have hypertension and diabetes mellitus type 2 have attained goal blood pressure as per recommendations of the JNC 7 clinical guidelines?
2. What are the most common medications used in antihypertensive therapy for patients with hypertension and diabetes mellitus type 2?
3. Is urinalysis for microalbuminuria done at the time of diagnosis and annually thereafter?

Conceptual and Operational Definitions

Conceptual Definitions

Antihypertensive Agents: Class of medications used to treat high blood pressure

Hypertension: Chronic medical condition of elevated blood pressure

Patient: Individual receiving healthcare services.

Second Blood Pressure Measurement: Second to last blood pressure measurement taken during this research study timeframe.

Operational Definitions:

Agent Orange: Herbicide containing trace amounts of the toxic contaminant dioxin that was used in the Vietnam War to defoliate areas of forest.

Current Blood Pressure Measurement: Latest blood pressure measurement taken during this research study timeframe.

Other Antihypertensive Category: Clonidine HCL, Hydralazine, Methlydopa, Minoxidil.

Patient: Individual receiving care at the Veteran's Administration Primary Care Clinic in the upper midwest.

Second Blood Pressure Measurement: Second to last blood pressure measurement taken during this research study.

CHAPTER III

METHODOLOGY

Design

The study was a retrospective descriptive cohort study of hypertension management of patients with known dual diagnoses of hypertension and diabetes mellitus type 2. Data were collected from the electronic medical record system at the research site. The data were collected by a VA data support specialist from the data warehouse.

Protection of Human Rights

Prior to data collection, Institutional Review Board approvals were obtained from North Dakota State University (Appendix A) and the University of South Dakota (Appendix B), which was the delegated Institutional Review Board for the VA. Approval from the Research and Development Committee of the VA was also obtained. No information that could identify study participants was collected.

Sample

Data collection included the variables age, gender, race, body mass index, estimated glomerular filtration rate, microalbuminuria results, the last two recorded systolic and diastolic blood pressure measurements, and classes of antihypertensive medications used which were categorized according to the electronic data support system. The following classes of antihypertensive medications were studied: ACE inhibitors including ARBs (angiotensin II receptor blockers), alpha blockers, beta blockers, calcium channel blockers, thiazide diuretics, loop diuretics and a category including all other antihypertensive agents. The sample included all veterans seen in outpatient clinics of a midwestern VA during the

calendar year 2008 with ICD-9 dual diagnoses of medical codes of 401.1 and 401.9 for hypertension and 250.00 for diabetes mellitus type 2.

In order to better study the use of the class of ACE/ARB antihypertensive medications (which are specifically recommended in the treatment of hypertensive diabetic patients), patients who also had diagnoses of congestive heart failure (CHF) were excluded from the study. Adequacy of blood pressure control in the diabetic population was measured by comparing patient blood pressure values with target values for hypertension in the presence of diabetes mellitus for which the standard was less than 130/80 per JNC 7 hypertension guideline recommendations.

Variables Data Analyses

All data analyses were done on site at the VA, and all research data were stored on a secure password-protected database per VA protocol. Analyses were done using statistical analysis software (SAS).

CHAPTER IV

RESULTS

A total of 4,234 subjects met the inclusion criteria for this study. These subjects were veterans seeking medical care at a midwestern VA primary care clinic. They were veterans who had dual diagnoses of hypertension and diabetes mellitus type 2 during the calendar year 2008.

The age demographic was stratified into age ranges. A high percentage (68%) of the study population was greater than 65 years of age. The next highest percentage (30%) was in the 50 to 64 years of age. A low percentage (2%) was between the ages of 20 to 49. They were primarily male (99%) with females making up just one percent of the population. Demographic data reflecting the age and gender of the study population is displayed in Tables 1 and 2.

Table 1. *Demographics: Age*

Age	Number (%)
20-49	81 (2)
50-64	1262 (30)
> 65	2891 (68)

Table 2. *Demographics: Gender*

Gender	Number (%)
Female	59 (1)
Male	4175 (99)

Other demographic variables included marital status and race. The majority of the participants in the study were married (69%). A distant second were those who were

divorced (14%). Those who were widowed, never married, separated or whose status was unknown made up a minority of the population. These findings are depicted in Table 3.

Table 3. *Demographics: Marital Status*

Marital Status	Number (%)
Married	2927 (69)
Divorced	589 (14)
Widowed	370 (9)
Never Married	294 (7)
Separated	50 (1)
Unknown	4

Ninety-seven percent of the population was white. Two percent of the population did not have race data available and one percent of the population was American Indian. Other race categories were black and Hispanic but amounted to less than one percent. These findings are listed in Table 4.

Table 4. *Demographics: Race*

Race	Number (%)
White	4130 (97)
Unknown	69 (2)
American Indian	30 (1)
Black	1
Hispanic	4

Military service data were also collected with the majority of the participants having served in the Vietnam era (44%). The second highest category was the Korean veterans (23%) with World War II, Post-Korean, Persian Gulf War, and Vietnam War era with the next highest numbers, respectively. These findings are shown in Table 5.

Table 5. *Demographics: Service Era*

Service Era	Number (%)
Vietnam Era	1842 (44)
Korean War	992 (23)
World War II	672 (16)
Post-Korean	481 (11)
Persian Gulf War	111 (3)
Post-Vietnam	109 (3)
Pre-Korean	19
Other or None	5
Merchant Marine	2
Air Force-Active Duty	1

Health Specific Factors

There are other health factors that may influence blood pressure control such as tobacco use, body mass index, exposure to Agent Orange, and the use of non-steroidal anti-inflammatory (NSAID) medications. Data were collected to determine what effect these factors may play in management of hypertension. NSAID use is compared to blood systolic blood pressure values. Tables 6 through 9 highlight these factors.

Table 6. *Health Factors: Smoking Status*

Smoking Status	Number (%)
Lifetime Nonsmoker	3801 (90)
Current Smoker	405 (10)
Previous Smoker	28

Table 7. *Health Factors: Body Mass Index*

Body Mass Index	Number (%)
< 18.5	4
18.5 – 24.9	305 (7)
25. – 29.9	1252 (30)
30.0 -39.9	2222 (52)
> 40	451 (11)

Table 8. *Health Factors: Agent Orange*

Exposure to Agent Orange	Number (%)
No	3488 (82)
Yes	394 (10)
Unknown	352 (8)

Table 9. *Health Factors: NSAID Use Comparison to Systolic Blood Pressure*

NSAID Use and Systolic Blood Pressure (SBP)	Number (%)
No SBP < 130	1579 (37)
No SBP > 130	1292 (30)
Yes SBP < 130	660 (15)
Yes SBP > 130	512 (14)
Unknown	191 (4)

Laboratory Data

Informational data collected in this study included the laboratory tests of glycated hemoglobin also known as hemoglobin A1C and estimated glomerular filtration rate (EGFR). These tests were obtained to gain further insight into the health status of veterans with hypertension and diabetes mellitus co-morbidities. Data regarding laboratory tests of microalbuminuria were collected to answer research question number three.

The hemoglobin A1C assay reflects the average level of glucose to which red blood cells have been exposed to within the 120 day life span of the red blood cell. It is used to assess effectiveness of diabetes treatment and management. For most adults, the goal is to attain an A1C below 7 to prevent microvascular disease. Higher A1C levels correlate with higher blood glucose levels being present over the past three months which is the life of the red blood cell (Nathan et al., 2008).

Overall, diabetics' control of their disease was less than optimal with less than half (41%) of the veterans demonstrating good control of their diabetes as evidenced by hemoglobin A1Cs of less than seven. Twenty-eight percent of the participants did not have

a hemoglobin A1C laboratory test checked during the past year. I was unable to ascertain what level of control these veterans have of their diabetes; I only know that they have not had their hemoglobin A1C checked in our laboratory. Some veterans may have had their hemoglobin A1C checked at a laboratory in the private sector rather than at the VA laboratory.

Another reason why it is important to control blood pressures to the levels recommended by the JNC 7 hypertension guidelines is because high blood pressure (as well as poor diabetic control) can affect kidney function. The laboratory test, estimated glomerular filtration rate (EGFR), depicts what is known about the stage of kidney disease within the diabetic hypertensive population at the VA during the year 2008. Twenty-eight percent of veterans did not have their estimated glomerular filtration rate checked at all during the year or had it checked at a facility in the private sector rather than at the VA.

The EGFR correlates with the present stage of kidney disease. Fifty percent of the study population had EGFRs greater than 60, indicating that their renal function was relatively well preserved. However, a significant percentage (19%) had stage 3 kidney disease as indicated by EGFRs of 30.0 -59.9, which presents an important opportunity to preserve and prevent progression of the disease. I did not know the status of the renal function of a large segment of the participants since the EGFR has not been obtained in the VA laboratory during the past year. Some of these veterans may have had an EGFR checked in a laboratory outside of the VA. Tables 10 and 11 illustrate hemoglobin A1C and EGFR findings.

Table 10. *Laboratory Test: Hemoglobin A1C*

Hemoglobin AIC Value	Number (%)
< 6.9	1726 (41)
7.0 - 7.9	766 (18)
8.0 - 8.9	310 (08)
9.0 – 9.9	141 (3)
10.0 – 10.9	52 (1)
11.0 – 11.9	30 (1)
> 12.0	21
A1C not checked	1188 (28)

Table 11. *Laboratory Test: Estimated Glomerular Filtration Rate (EGFR)*

Estimated Glomerular Filtration Rate (EGFR)	Number (%)
>/=14.9	19 (1)
15.0 – 29.9	67 (2)
30.0 -59.9	820 (19)
>/= 60	2125 (50)
EGFR not checked	1203 (28)

Research Question 1

What percentages of patients with hypertension and diabetes mellitus type 2 have attained goal blood pressure as per recommendations of the JNC 7 clinical guidelines?

Blood pressure measurements for the last two clinic visits were collected during the calendar year 2008. In order to meet JNC 7 guidelines *both* the systolic and diastolic blood pressures must be controlled. The number of veterans who achieved blood pressure control per JNC 7 guidelines by the time of their last clinic visit was 1,773 or 42%. There were 748 (18%) veterans who did not document either diastolic or systolic control. Another 1,713 (40%) of these veterans achieved only partial control, of either their diastolic or systolic value. Table 12 illustrates current blood pressure measurements.

Table 12. *Current Systolic (SBP) and Diastolic (DBP) Blood Pressures*

Current Systolic (SBP) and Diastolic (DBP) Blood Pressures	Number (%)
SBP </= 130 and DBP </= 80	1773 (42)
SBP > 130 and DBP > 80	748 (18)
Attained only SBP Control or DBP Control	1713 (40)

Examination of the second to last blood pressure measurements, taken earlier in the year, showed that 1,083 (26%) veterans had achieved both systolic and diastolic control. At the time of these measurements, 478 (11%) veterans did not achieve either systolic or diastolic blood pressure control. A large number of veterans, 2,673 (63%), attained only systolic or diastolic control. In the middle-aged and elderly population, it is usually the systolic blood pressure that is not controlled (Franklin, Jacobs, Wong, L'Italien, & Lapuerta, 2001). Table 13 illustrates blood pressure measurements for the second to last blood pressure.

Table 13. *Second to Last Systolic (SBP) and Diastolic (DBP) Blood Pressures*

Second to Last Systolic and Diastolic Blood Pressures	Number (%)
SBP </= 130 and DBP </= 80	1083 (26)
SBP > 130 and DBP > 80	478 (11)
Attained only SBP Control or DBP Control	2673 (63)

Research Question 2

What are the most common medications used in antihypertensive therapy for patients with hypertension and diabetes mellitus type 2?

Patterns of antihypertensive medication use were studied in these patients with diabetes and hypertension, without congestive heart failure, to evaluate whether they were consistent with evidence-based practice guidelines. Due to the method of data extraction and its limitations, it was not possible to determine how many patients were receiving

monotherapy and how many were receiving multidrug regimes and in what combinations. However, there were 11,369 antihypertensive medications prescribed to this study population of 4,234 patients. These statistics indicate that these patients are receiving an average of 2.6 antihypertensive medications.

Seventy percent of the 4,234 patients were taking ACE or ARB medications. The high use of these medications is expected, especially in a diabetic population. However, thiazide diuretics were prescribed to only 36% of these patients, making them the fourth highest utilized medication, far behind ACE/ARB as well as beta blockers. (Thiazide therapy is a first line recommendation per JNC 7 hypertension guidelines.) Table 14 illustrates the utilization patterns of antihypertensive medications.

Table 14. *Frequency of Antihypertensive Medications*

Frequency of Antihypertensive Medications	Number (%)
ACE/ARBS	2958 (70)
Beta Blockers	2475 (59)
Calcium Channel Blockers	1626 (38)
Thiazide Diuretics	1527 (36)
Loop Diuretics	1196 (28)
Alpha Blockers	1145 (27)
Combination Antihypertensive	239 (6)
Other Antihypertensive	203 (5)

Research Question 3

Is urinalysis for microalbuminuria done at time of diagnosis and annually thereafter? The data results demonstrate that over half of the time, microalbuminuria has not been checked over the course of the whole year. Table 15 illustrates these findings.

Table 15. *Microalbuminuria*

Microalbuminuria	Number (%)
No	2353 (56)
Yes	1881 (44)

CHAPTER V

DISCUSSION AND CONCLUSIONS

There were 4,234 patients who met the inclusion criteria for hypertension and type 2 diabetes and who did not have chronic heart failure. The demographics indicate that the largest share of the participants in this study were over the age of 65 (68%) and were predominantly male (99%).

Health Specific Factors

Health specific factors were also collected as they were available from the data set. Only 10% had a documented exposure to Agent Orange; however, this is not a mandatory field to be input at clinic visits, so it is not consistently documented. There may be documentation of Agent Orange exposure elsewhere in service records, which do not include the medical records. These limitations with regard to Agent Orange exposure data collection have been discussed under study limitations.

Another health specific factor that may influence blood pressure control was whether or not the patient was taking a nonsteroidal anti-inflammatory (NSAID) agent for pain control. Theoretically, NSAID use has the potential to increase blood pressure by altering prostaglandin homeostasis, although nonnarcotic analgesics effects on hypertension have not been well studied (Forman, Rimm, & Curhan, 2007). Nonnarcotic analgesics include acetaminophen, aspirin, and nonsteroidal anti-inflammatory agents.

In this study, the data indicated that nearly 30% of veterans were taking an NSAID. The frequency with which they are taking these is unknown. These patients would likely benefit from education on the effect these medications may have on water retention, kidney function, and blood pressure control.

Nationally, as well as globally, people are becoming increasingly obese (Ogden, Yanovski, Carroll, & Flegal, 2007). The effect of obesity on chronic disease states, especially hypertension and diabetes can be tremendous. Unfortunately, the veteran population was no exception to this trend. The obese category as measured by BMI (30.0 to 30.9) was exceptionally high at 52%, indicating that there was a need for education and dietary intervention to assist veterans in making lifestyle changes. The second highest category was the overweight category (25.0 to 29.9) at 30%. The morbidly obese (> 40) made up 11% of the population. The normal weight (18.5 to 24.9) veterans made up only 7% of the population.

Smoking is also associated with higher blood pressure and increased complications for those with diabetes, peripheral vascular disease and chronic obstructive pulmonary disease. For the US military, smoking is a significant problem affecting veterans' health (Brown, 2010). According to Bastian and Sherman (2010), smoking rates in the US declined significantly (50%) between 1965 and 2005; however, current smokers still make up 21% of the US population. Iraq and Afghanistan veterans are smoking at high rates which are comparable to those seen in the general population in the 1960s, with current prevalence up to 40% higher for veterans than nonveterans (Bastian & Sherman, 2010).

In comparing these figures to this study, 90% of veterans were lifetime non-smokers, with current smokers making up only 10% of the population. Data were not collected to determine a breakdown of smoking by age group for this study, so the data cannot be compared directly to other studies. One explanation for the lower smoking rates in my study may be that many of the veterans who were smokers are now deceased.

Brown (2010) noted that low smoking prevalence among older veterans could reflect smoking-related mortality.

Another reason for the lower reported smoking rates in this study may be that the smoking status is obtained by nurses prior to office visits with the data being self-reported, so it may be that patients do not admit to smoking. Possibly, they may do this in order to avoid what they may consider a lecture, since there is so much emphasis today on counseling patients to stop smoking. Another possibility is that they may have quit smoking a long time ago and had responded that they have never smoked as it is an easier response. The question about whether or not a patient is smoking could be clarified if nurses were careful to follow up a negative answer with a question asking the patient if they have *ever* smoked.

Laboratory Data

Informational laboratory data were also collected to provide a clearer picture of the disease states of diabetes and hypertension in our veterans. The hemoglobin A1C laboratory test provides an average of what blood glucose readings have been over the past two to three months. The veterans demonstrated good control of their diabetes with the greatest percentage (57%) having an A1C of less than seven. The next highest percentage (25%) was in the 7.0 to 7.9 hemoglobin A1C range. According to these values, it appears that veterans and their medical providers have been fairly successful in controlling their diabetes. This will lessen the chances for sequelae of retinopathy, neuropathy, and nephropathy in these patients.

The estimated glomerular filtration rate (EGFR) is another laboratory blood test that is routinely checked during clinic visits to monitor the status of kidney function. Blood

pressure control is very important to preserving kidney function. In the veteran population with diabetes and hypertension co-morbidities, most of the kidney disease was classified in the Stage 3 level (27%). Stage 3 is comprised of a wide range of filtration rates, from 30.0 to 59.9, and is the stage where oftentimes specific interventions can be made to prevent disease progression. One of the specific interventions is striving to achieve optimal hypertension management. Another intervention would be to ensure that veterans with dual diagnoses of hypertension and diabetes mellitus type 2 are taking an ACE inhibitor or ARB antihypertensive agent, which will lower blood pressure and have the added benefit of preventing or decreasing microalbuminuria.

Research Question 1: What percentages of patients with hypertension and diabetes mellitus type 2 have attained goal blood pressure as per recommendations of the JNC 7 clinical guidelines?

Levels of blood pressure control found in this study were quite low and demonstrate the need for improvement in hypertensive management. If I take into account the percentage of veterans who have attained either systolic or diastolic control, but not both, hypertension management success would appear better; however, JNC 7 specifically addresses the need for *both* systolic and diastolic control. In the group showing that they had attained either the systolic or diastolic goals, unfortunately, we do not know which measurement is controlled. However, we do know that they have not achieved control as recommended by JNC 7 guidelines since they have achieved only *one* of the measurements. Optimal control needs to occur at the levels specified in the JNC 7 guidelines in order to attempt to prevent both macro-vascular and microvascular complications.

A study of family practice patients at the Health Science Center at St. John's, Newfoundland found that only 65% of patients had achieved a blood pressure level of less than 140/90 mm Hg (Godwin, Pike, Kirby, Jewer, & Murphy, 2008). These researchers noted that if they had based their study on the blood pressure value of less than 130/80 mm Hg, as would be the standard for diabetics, the percentage of patients who had achieved control would be even less than 65%. These results compare to this study's 42% achievement of target blood pressure. If the blood pressure target goals had been lower in that study such as the target goals as in this study were, then the percentage of veterans who achieved blood pressure control for that study would likely be lower than 65% and perhaps more comparable to the 42% attained in this study.

Borzecki, Wong, Hickey, Ash, and Berlowitz (2003) also did a study on hypertension control in military veterans. They found that blood pressure control in diabetics was similar to those without diabetes as 60% of diabetics had blood pressures over 140/90. Blood pressure control was comparable to this study's findings considering that would leave 40% in their study who had blood pressures less than 140/90. However, my study showed that 42% had blood pressures less than 130/80, which suggested that hypertension management at my research site may be better than the hypertensive management in the researchers' study.

Research Question 2: What are the most common medications used in antihypertensive therapy for patients with hypertension and diabetes mellitus type 2?

The most common antihypertensive medications in order of their frequency of use were ACE/ARB medications, beta blockers, calcium channel blockers, thiazide diuretics, and loop diuretics. The result was expected as ACE/ARB medications are indicated for

kidney protection in the diabetic population. A surprising finding was that the frequency of use for both classes of diuretics was fourth and fifth in comparison to the use of ACE/ARB medications, beta blockers and calcium channel blockers, respectively. An increased use of thiazide diuretics would be indicated to attain improved blood pressure control.

Seventy percent of the 4,234 patients in the study were taking either an ACE inhibitor or an ARB antihypertensive agent. These findings were similar to the findings of Carter (2004) in a study which was also conducted at VA facilities. The study utilized the clinical pharmacist in an expanded role in consultation with physicians and to be a co-manager of therapy. The results showed that the proportion of patients receiving an ACE inhibitor or an ARB increased from 72% to 76% which was statistically significant. Since the percentage of participants received ACE/ARB in this study was 70%, it may also be possible to increase the use of ACE/ARB medications at this midwestern VA facility. There is an opportunity for nurse practitioners as well as other healthcare providers here to lead the way in changing and improving hypertension management.

Johnson and Singh (2005) conducted a study of antihypertensive therapy among patients with diabetes at VA facilities and found that 83.5% were using an ACE or ARB therapy. These findings were significantly higher than the results found in this study or in the study by Carter (2004). The second highest drug utilization category in the Johnson and Singh study was diuretic use at 62.8%. These findings are consistent with evidence-based practice JNC7 guidelines for treating hypertension in patients with diabetes.

Diuretics, especially thiazides, have been well established to offer both cardiovascular and renal protection (Maitland-van der Zee et al., 2005). There has been evidence that lower blood pressures have been mostly achieved by using thiazide diuretics

(Sawicki & McGauran, 2006). There has also been controversy regarding the use of thiazide diuretics as a first line agent in the treatment of hypertension. The controversy was the reason that the large hypertension study, Antihypertensive and Lipid-Lowering treatment to prevent Heart Attack Trial (ALLHAT) was conducted. There was concern because thiazide diuretics may have the potential to cause metabolic side effects such as an increase in cholesterol and potassium, and a slight increase in blood glucose levels. Maitland-van der Zee et al., (2005) conducted further research on patients using thiazide diuretics to look for any significant changes in their glucose, lipids and potassium levels. They concluded that thiazide diuretics may be responsible for only very small changes in lipids and glucose levels. They recommended maintaining normal potassium while using thiazides to prevent thiazide induced hyperglycemia.

Only 38 percent of the participants in the study that I have conducted received a thiazide diuretic, which was slightly below calcium channel blockers which were prescribed to 40% of the participants. Loop diuretics were prescribed for 30% of the participants. Godwin, Pike, Kirby, Jewer, & Murphy (2008) had nearly similar results in their study in a family practice population that included everyone with hypertension, not only diabetics. They found that only 35% of hypertensive patients were using thiazides, even though these medications are inexpensive, effective and have few side effects when used at low doses. The researchers did not offer any possible explanations.

Race may also play a role in choice of therapy; whereas, in this study participants were predominantly white, participants in other studies conducted at VA clinics had a higher percentage of other races including blacks. The ALLHAT trial had more than

15,000 blacks and found that ACE inhibitors were less effective in lowering blood pressure than either thiazide diuretics or calcium channel blockers.

Beta blocker antihypertensive agents in my study were highly utilized with 61% of the population receiving them making them the second mostly highly utilized therapy. There is nearly a 20 % gap between utilization of the beta blockers to the third most highly utilized class which was the calcium channel blockers. The high use of beta blockers in the study population may be due to the high number of elderly patients who may have coronary artery disease. ACE/ARB medications are likely being frequently used in conjunction with beta blocker medications.

Research Question 3: Is urinalysis for microalbuminuria done at time of diagnosis and annually thereafter?

This is a highly overlooked area, as 56% of participants did not have a microalbuminuria test done during the 2008 calendar year. There is a need for providers to practice diligence in obtaining this test to identify chronic kidney disease and preserve and prevent progression of the disease. According to Tuttle (2007), whenever there is increased microalbuminuria or loss of protein through the urine, a treatment goal for clinicians should be to identify and prevent progression of kidney disease. Eijkelkamp et al. (2007) recommended that clinicians who treat hypertensive diabetics who also have nephropathy consider having two important goals. One goal should be to reduce systolic blood pressure and while the other should be to reduce albuminuria. Prevention of progression of chronic kidney disease depends on achieving lower systolic blood pressures; however, patients also must have albuminuria reduced to achieve desired renal outcomes.

Of the 44% of participants in this study who had the microalbuminuria test 58% were in the normal range of less than 30 33% were in the 30-300 range indicating some evidence of nephropathy and 9% were in the greater than 300 range, indicating a greater concern for the presence of progressive kidney disease. These findings argue for the need to attain blood pressure control to less than 130/80 mm Hg.

Limitations

Interpretation of the results must be considered along with recognition of several limitations of the study. First, the study is retrospective and conducted at one primary care center. In addition, because of the predominantly male gender and white race of the sample, the results cannot be generalized to women or to those who are not of the white race.

Since the Decision Support System (DSS) software was able to extract only prescriptions that were filled within the VA system there was no way to determine if subjects had prescriptions filled in the private sector. The rates of withdrawal of ACE medications due to adverse effects or patient choice should be considered. Finally, as in all studies of the prevalence of pharmaceutical use based on computerized dispensing records, the estimates presented are a balance of provider prescribing intent reflected in the actual fill patterns of patients.

The method of data collection is also a limitation of the study. Decision Support System is a primarily a managerial cost accounting system that is based on a commercial software called Eclipsys. The VA made changes to this software to make it possible to interact with VA national databases to populate the data elements for cost accounting

purposes. The DSS data files are composed of specific clinical data and cost accounting data and are able to measure care quality, clinical, and financial outcomes.

While the use of DSS provided a large quantity of records (n = 4234) for review; its accuracy depended on the utilization data (Barnett & Rodgers, 1999). Barnett and Rodgers also noted that an important limitation to using this collection method for research was the difficulty in accessing data. Accessing and extraction of data can be difficult because data is decentralized, and it is recorded across many different databases. Data extraction was difficult in this study with regard to the retrieval of medication usage. Specific questions relating to whether or not a patient was using or not using any medication, monotherapy, or using a multi-drug regime would have been especially informative.

Heynes, Perrin, Rappaport, Stevens, and Demarkis (2004) also evaluated informatics resources within the VA, including DSS. These researchers felt that the involvement of clinical and research personnel in DSS use would ensure clinical integrity and relevance. DSS requires a good working knowledge of its capabilities and limitations. Clinical researchers should first determine what DSS data fields are mandatory input fields by clinicians, and if the data can be easily and accurately extracted. In this study, the data for Agent Orange exposure was not a mandatory input field for use in this database. Consequently, the dataset likely does not indicate the full number of veterans who have Agent Orange exposure.

The VA has many different databases at both the national and local levels. These databases are kept at the Austin Automation Center in Austin, Texas. Maynard and Chapko (2004) provided an overview of databases maintained by the VA and their relevance to researchers involved in epidemiological, clinical and health system research.

Their analysis was that value of these databases would become more important as communications and database management capabilities improve. Overall, the sentiment expressed by clinical researchers was that VA databases have great potential; however, they need to be much more integrative and their use less cumbersome.

Another area of limitation with this particular electronic data collection is that it is unable to capture lab values or prescriptions that may be obtained or prescribed outside of the VA. These veterans are a segment called "co-managed." Co-managed veterans are typically seen by their primary care provider at the VA once per year at which time they are requested to bring in copies of their progress notes including lab values and a medication list from their outside provider. VA providers are to designate these veterans as co-managed in the medical record. The VA provider may make treatment changes and obtain lab work at the time they see the veteran for their annual visit, or may advise the patient to follow-up with their own primary care provider outside of the VA setting. The veteran decides who is to be the primary manger of care, the VA provider or a provider outside of the VA facility. The VA providers do not have much control over how these veterans are managed if they choose to be managed by someone in the private sector. VA facilities and providers want to be the veteran's first choice for healthcare. Choice of provider in the past has mainly been a function of clinic access because of the long distance veterans lived from the VA facility. These veterans often preferred to be managed by an outside provider who was located closer to where they live. Within recent years the VA has added community based outpatient clinics in remote areas and this will likely have an impact on how many veterans are managed primarily by their VA providers.

Another limitation was that some fields of data were not mandatory to be input into this particular database. For example, Agent Orange exposure was not a mandatory field to enter. Consequently, the dataset likely does not indicate the full number of veterans who have had Agent Orange exposure. It was also not possible to specifically obtain the number of medications taken per patient and which classes of antihypertensive medications that patients were taking concurrently.

Implications for Nursing Practice

The results of this study indicate that our healthcare providers are doing a good job controlling blood glucose levels; however, there is room for improvement in the management of hypertension. One non-pharmacological way to improve the management of hypertension is weight loss through diet and exercise. The study found that a large number of veterans who were obese. Obesity makes it much more difficult to control both hypertension and diabetes. Although obese patients need to make lifestyle changes, there are many barriers to doing so. Nursing professionals need to encourage veterans to implement these changes. Nurses need to provide succinct, easy to understand educational material on diet and exercise to veterans. If this information is presented in nonthreatening manner, the veterans may then start to ask questions and initiate a discussion about lifestyle changes. Nurse practitioners need to approach the obesity problem by implementing an interdisciplinary approach that would include dieticians. Having a dietician in an office nearby where patients are seen and having them available for walk in consultations may be helpful.

Provider profiling by management as a quality assurance process is a common practice in many clinics today. The VA has not adopted this practice yet; however, it may

at some time in the future. Because of provider profiling, some providers are concerned that they will be asked to treat a number instead of the patient. Nurse practitioners and other providers will need to be diligent in justifying and documenting their reasons for not choosing a particular medication or treatment. There may be contraindications to using certain medications for particular patients and providers must keep in mind that patients also have the right to refuse any treatment. Nurse practitioners have the benefit of their nursing knowledge, skills and experience to draw upon to educate patients on the best treatment of hypertension (Way, Jones, Baskerville, & Busing, 2001). However, they also need the patient's partnership and cooperation in order to provide proactive, preventative healthcare. If patients are able to keep the same practitioner as a provider for a number of years, they will likely develop a higher level of comfort and trust with their provider and will be more likely to discuss their healthcare concerns.

Nurse practitioners and nurses need to continue to assess patients for smoking; however, they may need to be more proactive in assisting veterans to quit. If the veteran is interested, they can make sure that he has had an opportunity to try both pharmacological and non-pharmacological measures to quit smoking.

Recommendations for Further Research

There are no published studies regarding how well nurse practitioner providers are treating hypertension as indicated by the goals recommended in the JNC 7 clinical guidelines. Seroussi, Bouaud, and Chatellier (2005) noted physician compliance remains low; however, I could not find any research to indicate the level of compliance of nurse practitioner providers. Further research into nurse practitioner practice in the treatment of hypertension would be highly recommended.

There is a need to determine why microalbuminuria tests are not being obtained for 100% of diabetic patients. Could it be that providers ordering these tests and patients are not completing them? How does the diabetes educator fit into the treatment plan? Providers need to educate patients on why it is important to have a urine test. It is possible that some patients may think that the provider is looking for an infection rather than looking for indications that diabetes and hypertension may be affecting their kidneys.

Further research is needed to explore the idea of establishing diabetic clinics to specialize in the treatment of diabetes as well as the prevention of diabetes related complications. These specialized diabetes clinics could implement a one-stop type of approach where patients could be seen by groups of four or five rotating specialists at each visit such as nurses, podiatrists, dieticians, optometrists, diabetic educators, dentists, psychologists, and healthcare providers. Visits with these specialists could be alternated or arranged according to patients' individual needs. Group visits may also be another way to enhance education and provide care. There could be a checklist that the nurse goes through to make sure all the diabetic tests and recommendations were being addressed. A checklist should improve the rate of obtaining microalbuminuria tests.

Further research is needed to determine how medication utilization and hypertension control rates compare in settings outside of the VA. It is important that research is continued on why poor blood pressure control still remains an issue despite good pharmacological treatment. Further research needs to be done on other factors as well, such as obesity, which affect both hypertension and diabetes. Research into changing attitudes and habits relating to food is needed, including how to prevent children from becoming overweight. There is also a need for research in the public health arena on what

can be done to eliminate barriers and encourage people to exercise, lose weight and follow a nutritious diet.

Manual review of electronic charts may also be useful to examine how many veterans with diabetes and hypertension were not on any medications, how many were on monotherapy, as well as on two or three antihypertensive medications concurrently. This study was not able to extract data to this amount of detail, as it focused more on utilization of certain classes of antihypertensive medications.

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APPENDIX A

NDSU IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

Institutional Review Board
Office of the Vice President for Research, Creative Activities and Technology Transfer
NDSU Dept. 4000
1735 NDSU Research Park Drive
Research 1, P.O. Box 6050
Fargo, ND 58108-6050

701.231.8995
Fax 701.231.8098

Federalwide Assurance #FWA00002439
Expires April 24, 2011

June 25, 2009

Dr. Dean Gross
Dept. of Nursing
Sudro Hall 136

Re: IRB Certification of Human Research Project:

"Hypertension Therapeutic Goal Attainment in Patients with Dual Diagnoses of Hypertension and Diabetes"
Protocol **#PH09281**

Co-investigator(s) and research team: **Susan M. Harris and Byron Danielson**

Study site(s): **VA Medical Center** Funding: **n/a**

It has been determined that this human subjects research project qualifies for exempt status (category # 4) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, *Protection of Human Subjects*). This determination is based on the protocol form received 6/25/2009.

Please also note the following:

- This determination of exemption expires 3 years from this date. If you wish to continue the research after 6/24/2009, submit a new protocol several weeks prior to this date.
- The project must be conducted as described in the approved protocol. If you wish to make changes, pre-approval is to be obtained from the IRB, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. A *Protocol Amendment Request Form* is available on the IRB website.
- Prompt, written notification must be made to the IRB of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Any significant new findings that may affect the risks and benefits to participation will be reported in writing to the participants and the IRB.
- Research records may be subject to a random or directed audit at any time to verify compliance with IRB policies.

Thank you for complying with NDSU IRB procedures; best wishes for success with your project.

[redacted]
Kristy Shirley
Research Compliance Administrator

APPENDIX B

NDSU IRB AMENDMENT APPROVAL

Institutional Review Board ...for the protection of human participants in research

North Dakota State University
Sponsored Programs Administration
1735 NDSU Research Park Drive
NDSU Dept #4000
PO Box 6050
Fargo, ND 58108-6050 231-8995(ph) 231-8098(fax)

Protocol Amendment Request Form

Changes to approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants. Reference: SOP 7.5 Protocol Amendments.

Examples of changes requiring IRB review include, but are not limited to changes in: investigators or research team members, purpose/scope of research, recruitment procedures, compensation scheme, participant population, research setting, interventions involving participants, data collection procedures, or surveys, measures or other data forms.

Protocol Information:

Protocol #: **PH09281** Title: **Hypertension Therapeutic Goal Attainment in Patients with Dual Diagnoses of Hypertension and Diabetes**

Review category: ☒ Exempt ☐ Expedited ☐ Full board

Principal investigator: **Dr. Dean Gross** Email address: [redacted]
Dept: **Nursing**

Co-investigator: **Susan M. Harris and Byron Danielson** Email address: [redacted]
Dept: **Nursing**

Principal investigator signature, Date: [redacted]

Description of proposed changes:

1. Date of proposed implementation of change(s)*: **As soon as approved by IRB board**
   * *Cannot be implemented prior to IRB approval unless the IRB Chair has determined that the change is necessary to eliminate apparent immediate hazards to participants.*

2. Describe proposed change(s), including justification:
We would like to add additional variables, consisting of the following:
1. Marital status
2. Smoking data (smoker or not)
3. Co-managed status (yes or no)
4. Number of times someone was seen in primary care clinic during the study period
5. Positive for Agent Orange Exposure (yes or no)
6. NSAID prescriptions through VA during the study period. (Non-VA data not available)
7. Last two blood pressure readings of the study period (instead of one reading)

3. Will the change involve a change in principal or co- investigator?
   ☒ No
   ☐ Yes: *Include an Investigator's Assurance (last page of protocol form), signed by the new PI or co-investigator.*

   Note: If the change is limited to addition/change in research team members, skip the rest of this form.

4. Will the change(s) increase any risks, or present new risks *(physical, economic, psychological, or sociological)* to participants?
   ☒ No
   ☐ Yes: *In the appropriate section of the protocol form, describe new or altered risks and how they will be minimized.*

5. Does the proposed change involve the addition of a vulnerable group of participants?
   Children: ☒ no ☐ yes – include the *Children in Research* attachment form
   Prisoners: ☒ no ☐ yes – include the *Prisoners in Research* attachment form
   Cognitively impaired individuals: ☒ no ☐ yes*
   Economically or educationally disadvantaged individuals: ☒ no ☐ yes*

   **Provide additional information where applicable in the revised protocol form.*

6. Does the proposed change involve a request to waive some or all the elements of informed consent or documentation of consent?
   ☒ no
   ☐ yes – include the *Informed Consent Waiver or Alteration Request* attachment form

7. Does the proposed change involve a new research site?
   ☒ no
   ☐ yes – include a letter of permission/cooperation, IRB approval, or grant application or contract

Attach a copy of the approved protocol, with highlighted change(s) incorporated within the relevant section(s).

Impact for Participants (future, current, or prior):

1. Will the change(s) alter information on previously approved versions of the recruitment materials, informed consent, or other documents, or require new documents?
   ☒ No
   ☐ Yes - attach revised/new document(s)

2. Could the change(s) affect the willingness of *currently* enrolled participants to continue in the research?
   ☒ No
   ☐ Yes - describe procedures that will be used to inform current participants, and re-consent, if necessary:

3. Will the change(s) have any impact to *previously* enrolled participants?
   ☒ No
   ☐ Yes - describe impact, and any procedures that will be taken to protect the rights and welfare of participants:

---------- FOR IRB OFFICE USE ONLY ----------

Request is: ☒ **Approved** ☐ **Not Approved**	
Review: ☒ **Exempt, category#:** 4 ☐ **Expedited method, category #** ____ ☐ **Convened meeting, date:** ____	
IRB Signatur [redacted]	**Date:** 8/20/2009
Comments:	

Protocols previously declared exempt: (Allow 5 working days) If the proposed change does not alter the exemption status, the change may be administratively reviewed by qualified IRB staff, chair, or designee. If the change(s) would alter this status, Expedited or Full Board review will be required.

Protocols previously reviewed by the expedited method: (Allow 10 working days) Most changes may also be reviewed by the expedited method, unless the change would increase risks to more than minimal, and/or alter the eligibility of the project for expedited review.

Protocols previously reviewed by the full board: Minor changes (not involving more than minimal risks, or not significantly altering the research goals or design) may be reviewed by the expedited method (allow 10 working days). Those changes determined by the IRB to be more than minor will require review by the full board (due 10 working days prior to next scheduled meeting).

APPENDIX C

USD IRB APPROVAL

The University of South Dakota.

Office of Human Subjects Protection
(605) 677-6184
(605) 677-3134 fax

March 23, 2009

Byron Danielson, MD
VAMC/Research Service
2101 Elm Street N.
Fargo, ND 58102

Project Title:	2009.073-Hypertension Therapeutic Goal Attainment in Paitents with Dual Diagnosis of Hypertension and Diabetes
PI: Byron Danielson, MD	**Student PI:** Susan Harris
Level of Review: Exempt 4	**Risk:** No More than Minimal
Date Approved: 3/23/2009	

The proposal referenced above has received an Exempt review and approval via the procedures of the University of South Dakota Institutional Review Board 02.

Veterans Administration (VA) research may not begin until R&D Committee approval is obtained.

Annual Continuing Review is not required for the above Exempt study. However, when this study is completed you must submit a Closure Form to the IRB. You may close your study when you no longer have contact with the subject.

Prior to initiation, promptly report to the IRB, any proposed changes or additions (e.g., protocol amendments/revised informed consents/ site changes, etc.) in previously approved human subject research activities.

The forms to assist you in filing your: project closure, continuation, adverse/unanticipated event, project updates /amendments, etc. can be accessed at http://www.usd.edu/oorsch/compliance/applicationforms.cfm.

If you have any questions, please contact: [redacted] or [redacted].

[redacted]
Lisa Korcuska
Director-Office of Human Subjects Protection
University of South Dakota
Institutional Review Boards

The University of South Dakota IRBs operate in compliance with federal regulations and applicable laws and are registered with the Office for Human Subject Protections (OHRP) under FWA # 00002421.
Full AAHRPP Accreditation since 2005

APPENDIX D

USD IRB AMENDMENT APPROVAL

The University of South Dakota.

July 21, 2009

Byron Danielson, MD
VAMC/Research Service
[redacted]

PI: Byron Danielson **Student PI:** Susan Harris
Project: 2009.073 - Hypertension Therapeutic Goal Attainment in Patients with Dual Diagnosis of Hypertension and Diabetes
Review Level: Exempt 4 **Risk:** No More than Minimal Risk
USD IRB: 02
Amendment Approved: 7/20/2009
Veterans Administration (VA) research may not begin until R&D Committee approval is obtained.
Amendment: Amendment approved to add seven additional variables

The University of South Dakota Institutional Review Board (IRB) has received and reviewed your amendment. The University of South Dakota IRB 02 has approved the amendment and the information has been added to the file. Thank you for keeping the IRB informed of project changes.

This amendment did not require the consent form to be revised.

Prior to initiation, promptly report to the IRB, any proposed project updates / amendments (e. g., protocol amendments/revised informed consents) in previously approved human subject research activities.

Any research-related injuries (physical or psychological), adverse side effects or other unexpected problems encountered during the conduct of this research study needs to be reported to the IRB within 72 hours of notification of the occurrence.

The forms to assist you in filing your: project closure, continuation, adverse/unanticipated event, project updates /amendments, etc. can be accessed at http://www.usd.edu/oorsch/compliance/applicationforms.cfm.

If you have any questions, please contact: [redacted].

Sincerely,

[redacted]

Lisa Korcuska
Director- Office of Human Subjects Protection
University of South Dakota
Institutional Review Boards
[redacted]