

FACTORS INFLUENCING ANTIHYPERTENSIVE MEDICATION ADHERENCE IN  
VETERANS WITH HYPERTENSION AND VETERANS WITH HYPERTENSION  
AND POST-TRAUMATIC STRESS DISORDER

by

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## ABSTRACT

Hypertension is a common diagnosis for American veterans. Despite years of research investigating how to improve antihypertensive medication adherence, suboptimal adherence still results in uncontrolled blood pressure leading to hospitalizations and complications. Connelly's model of Self-Care in Chronic Illness was used to compare veterans with hypertension, with and without post-traumatic stress disorder (PTSD) for health motivation, perceptions of the seriousness of illness, psychological status, and social support. Alcohol intake was added due to previous research suggesting it influences medication adherence in veterans with PTSD.

A cross-sectional design was conducted among 428 veterans. 1,199 surveys were mailed with good response ( $n=428$ , 35.7%). The sample was comprised of 417 (97.4%) males and 11 (2.6%) females. Mean age was 76 years for participants with HTN and 66.7 years for participants with both HTN and PTSD ( $p<.01$ ). Veterans with PTSD had higher rates of divorce or separation (28.8%), and higher mean blood pressure readings of 94.04 ( $p=.01$ ). Medication adherence was very high in both groups with means of 7.14 ( $SD=1.30$ ) and 6.48 ( $SD=1.97$ ), respectively, for veterans with HTN and veterans with PTSD.

Path analysis was used to evaluate associations of variables with medication adherence. However, the data did not fit the proposed model, thus modification indices were used with improved model fit. Among veterans with PTSD, less alcohol intake ( $\beta =$

-15), less health distress ( $\beta = -.36$ ), and more social support ( $\beta = .27$ ) were indirectly associated with medication adherence. Among veterans without PTSD the degree of comorbidity ( $\beta = -.15$ ), less health distress ( $\beta = -.27$ ), and more social support ( $\beta = .26$ ), were indirectly associated with medication adherence. The path model explained a very small amount of the variance on medication adherence therefore nurses caring for veterans with HTN should assess for these variables but also be alert to other issues that may impact antihypertensive medication adherence. Future studies on antihypertensive medication adherence should recruit less adherent participants, and include more female veterans and other military subgroups at risk for PTSD to enhance the cardiovascular health of those who have served and protected our country.

In memory of  
Victor George Chaplik  
and  
Severin John Severson

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## CHAPTER 1

### INTRODUCTION

An estimated 78 million American adults were diagnosed with hypertension (HTN) between 2007 and 2010 (Go et al., 2013). Because it is a major risk factor for cardiovascular and stroke complications, it is a significant public health issue. While improvements over the last four decades have resulted in a decline in mortality of 31% from cardiovascular complications and 22.8% from stroke (Go et al., 2013), one American still dies of stroke every 4 minutes, and it is the leading cause of disability in the United States (Go et al., 2013; Roger, et al., 2012)

In veterans, HTN is one of the most common diagnoses among veterans, with an approximate 15,000 veterans hospitalized yearly for stroke, costing an estimated \$111 million (U.S. Department of Veterans Affairs, 2014). The U.S. Department of Veterans Affairs (2014) is working to enhance stroke care through improving hospital management, focusing on prevention strategies, and expanding patient and system-level data. The goals of the department are to improve blood pressure control and prevent strokes among veterans.

### Hypertension and Post-Traumatic Stress Disorder

Veterans who have been exposed to a previous traumatic event find that it impacts their daily lives (Boscarino, 2008; McFarlane, 2010). Any sudden onset of memory about the event increases stress responses that include higher heart rates, higher level of caution, inability to concentrate, insomnia, and desire to avoid other people (Lockwood, Steinke, & Botts, 2009; McFarlane, 2010). Moreover, Kibler, Joshi, and Ma (2008) reported that younger civilian men and women with a history of post-traumatic stress disorder (PTSD) had higher rates of HTN. In combat veterans, newly reported HTN was found in those who had exposure to trauma through multiple episodes of warfare in Iraq and Afghanistan (Granado et al., 2009). Consequently, these veterans are a vulnerable population at risk for potential complications from HTN.

### Description of Study

The overall aim of this study was to describe differences related to antihypertensive medication adherence between veterans with HTN and veterans with both HTN and PTSD. The study was guided by Connelly's (1987) Model of Self-Care in Chronic Illness, an extension of the Health Belief Model developed in the 1950s. That study sought to better understand poor participation in health promotion programs through patients' perceptions of the seriousness of their illness, benefits, and costs of treatment (Glanz, Rimer, & Viswanath, 2008). Connelly (1993) integrated this model with an added dimension of self-care behaviors focused on outcomes of adherence to treatment dependent on predisposing factors which engaged patients in self-care behaviors, and enabling factors which assisted or obstructed self-care behaviors.

The predisposing factors of patients' health motivation and perception of the seriousness of their HTN, and enabling factors of patients' well-being and social support system were reported to be associated with self-care behaviors in chronic illness (Connelly, 1993). These predisposing and enabling factors were selected to be assessed in antihypertensive medication adherence. Three factors from previous literature, degree of comorbidity, alcohol intake, and patient perception of involvement in care (patient and primary-care provider) were also examined for their association with antihypertensive medication adherence (Bryson et al., 2007; Fix et al., 2013; Ren, Kazis, Lee, Zhang, & Miller, 2002).

Despite multiple medical diagnoses, the focus of this study was on veterans with HTN and veterans with both HTN and PTSD. Moreover, differences between these two groups of veterans provided an understanding of how care for veterans with PTSD was different than for those without this additional diagnosis in primary-care clinics. The findings contributed to patients' clinical treatment.

#### Medication Adherence

In this study, medication adherence was defined as taking prescribed medications consistently as prescribed by their primary care healthcare provider (Siegel, Lopez, & Meier, 2007). Approximately 95% of hypertensive cases are essential HTN without secondary causes as part of the diagnosis (Carretero & Oparil, 2000). Antihypertensive medications are prescribed to control HTN when preventive modalities of diet and exercise are not effective. However, antihypertensive medication adherence may be suboptimal due to disruptions in peoples' schedules, the number of pills required,

unpleasant side effects, and length of time taking medications (Eisen, Miller, Woodward, Spitznagel, & Przybeck, 1990; Fix et al., 2013; Munger, Tassell, & LaFleur, 2007; Proulx, Leduc, Vandelac, Grégoire, & Collin, 2007). One long standing reason for nonadherence has been presumed to be that the condition is asymptomatic. When no symptoms exist, treatment may be suboptimal which may lead to uncontrolled blood pressure.

### Methods

Approval was through two Institutional Boards from the University of Utah and the Veterans Administration (VA) Connecticut (CT) Healthcare System. The International Classification of Diseases (ICD-9) was used to query the number of veterans with essential HTN, and with the additional diagnosis of PTSD. Veterans were recruited from the VA CT Healthcare System through a mailed survey about their antihypertensive medication adherence.

The survey included additional questions about other factors which impacted their antihypertensive medication adherence. Enhanced participation was encouraged through the use of an incentive to guide the proposed data collection for survey responses (Dillman, Smyth, & Christian, 2009). Identical surveys were sent to both groups of veterans.

### Analysis

Descriptive analyses, Chi-square tests, independent *t*-tests, Pearson product moment correlations, and analysis of variance, were used to analyze data. Due to the number of analyses conducted, the alpha was adjusted to 0.01. Analyses were conducted

on demographic data (age, gender, race, ethnicity, marital status, years of education, occupational status), length of time diagnosed with HTN and PTSD, number of medications, and adherence to clinic visits. In addition, validation of the self-report in antihypertensive medication adherence was through pharmacy and blood pressure data.

Path analysis was used to test a model derived from Connelly's (1987, 1993) Model of Self-Care in Chronic Illness. The variables in the path analysis were veterans' health motivation, perceptions of the seriousness of HTN, well-being, social support, degree of comorbidity, alcohol intake, and perception of involvement in care (between patient and primary-care provider). Direct and indirect effects on antihypertensive medication adherence were examined for two groups of veterans (Pett & Clayton, 2010). Statistical significance (alpha) was set at 0.05.

### Specific Aims and Research Questions

The primary purpose of this study was to compare differences between veterans with HTN and veterans with HTN and PTSD. Data from mailed surveys and the patients' electronic medical records were examined for the relationships among variables and medication adherence.

#### Specific Aim 1

To describe the demographics of veterans (age, gender, race, ethnicity, marital status, years of education, occupational status), number of years each diagnosed with HTN and PTSD, number of medications, adherence with clinic visits, and reasons for potential omission of antihypertensive medications comparing veterans with HTN and



veterans with both HTN and PTSD.

#### Research Question 1.1

What are the differences in reported demographics of veterans (age, gender, race, ethnicity, marital status, years of education, occupational status), number of years diagnosed with HTN, number of medications, and adherence with clinic visits between two diagnostic groups of veterans?

#### Research Question 1.2

What is the self reported number of years veterans have been diagnosed with PTSD?

#### Research Question 1.3

What are the reasons veterans in both groups give for potentially omitting antihypertensive medications?

#### Specific Aim 2

To assess indicators of medication adherence: self-report, pharmacy refill records, and clinical indicators.

#### Research Question 2.1

What is the relationship between antihypertensive medication adherence self-report and pharmacy refill data in both diagnostic groups of veterans?

### Research Question 2.2

Do the two diagnostic groups of veterans differ from each other with regard to their blood pressures?

### Specific Aim 3

To identify the extent to which the degree of comorbidity, alcohol intake, and social support are directly and/or indirectly associated with the veterans' well-being and antihypertensive medication adherence in veterans with HTN, and veterans with both HTN and PTSD.

### Research Question 3.1

To what extent are the degree of comorbidity, alcohol intake, and social support directly and/or indirectly associated with veterans' well-being and antihypertensive medication adherence in both diagnostic groups of veterans?

### Specific Aim 4

To identify the extent to which health motivation, veterans' well-being, and veterans' perceived involvement in hypertensive treatment (patient and primary-care provider interaction) are directly associated with antihypertensive medication adherence in veterans with HTN, and veterans with both HTN and PTSD.

#### Research Question 4.1

To what extent are veterans' health motivation, well-being, and perceived involvement in hypertensive treatment (patient and primary care provider interaction) directly associated with antihypertensive medication adherence in both diagnostic groups of veterans?

#### Research Question 4.2

To what extent is veterans' well-being directly associated with health motivation and perceived involvement in hypertensive treatment in both diagnostic groups of veterans?

#### Specific Aim 5

To identify the direct and indirect effects of veterans' perceptions of the seriousness of HTN and veterans' perceived involvement in hypertensive treatment (patient and primary-care provider interaction) and antihypertensive medication adherence in veterans with HTN and in veterans with both HTN and PTSD.

#### Research Question 5.1

To identify the extent to which veterans' perceptions of the seriousness of HTN are directly and/or indirectly associated with veterans' perceived involvement in hypertensive treatment and antihypertensive medication adherence in both diagnostic groups of veterans?

### Research Question 5.2

To identify the extent to which veterans' perceived involvement in hypertensive treatment was directly associated with antihypertensive medication adherence in both diagnostic groups of veterans?

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## CHAPTER 2

### MEDICATION ADHERENCE IN HYPERTENSION IN VETERANS:

### AN INTEGRATIVE REVIEW<sup>1</sup>

#### Medication Adherence in Veterans

#### Key words

Veterans, hypertension, post-traumatic stress disorder, antihypertensive medication adherence.

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### Conflict of Interest

The authors have no conflicts of interest to disclose.

### Abstract

#### Purpose

To develop a conceptual model based on theory from 3 decades of research regarding antihypertensive medication adherence.

#### Methods

An integrative literature review was conducted on HTN in both civilians and veterans, and medication adherence from 1984 to 2014. The review was guided by the theoretical framework from Connelly's (1987) Model of Self-Care in Chronic Illness.

#### Findings

Thirty-eight studies were identified. Extensive scientific evidence on HTN concluded that medication nonadherence leads to uncontrolled HTN, potential complications, and remains as a significant problem. A prevalent mental health problem for veterans is PTSD, and the literature suggests this mental health diagnosis is linked to HTN. However, little is known about the antihypertensive medication adherence in the specific population of veterans with both HTN and PTSD.



### Conclusion

Connelly's (1987) theory posits a circular relationship between predisposing factors and enabling factors of self-care behaviors and adherence to treatment. Two predisposing factors (health motivation and patients' perceptions of the seriousness of the illness) and two enabling factors (well-being and social support) were associated with self-care behaviors (Connelly, 1993). Additional factors associated with HTN in veterans were their perceived involvement in their hypertensive treatment (Ren, Skinner, Lee, & Kazis, 2002), alcohol consumption (Bryson et al., 2008), and degree of comorbidity (Fix, et al., 2014).

### Clinical Relevance

Identifying whether there are differences in antihypertensive medication adherence between veterans with HTN and veterans with both HTN and PTSD in primary care will provide further evidence for the need to develop nursing assessment strategies, suggesting that hypertensive management for veterans with PTSD may be different than for civilians with hypertension.

### Problem Identification

Hypertension (HTN) is an international public health issue because uncontrolled blood pressure leads to serious complications (Roger et al., 2012). Unfortunately, HTN causes no symptoms, so victims can be unaware they are affected. A common complication is stroke. Complications from stroke alone caused an estimated 9.4 million deaths internationally in 2008 (World Health Organization, 2013).

The number of persons with hypertension is staggering. In the United States, an estimated 76 million Americans were diagnosed with HTN in 2008, with a prediction of 103 million nationally by the year 2030 (Roger et al., 2012). In the Veterans Administration, approximately 5.5 million veterans were diagnosed in 2006 (Furmaga et al., 2008).

A diagnosis of HTN reflects a systolic blood pressure greater than 140 and diastolic blood pressure greater than 90 (Roger et al., 2012). However, patients do not always consider a diagnosis of HTN as one of chronic illness or particularly as one of consequence; they fail to seek appropriate treatment, to reduce their risk factors, and to take other proactive measures in addressing the disease.

The National Health and Nutrition Examination Surveys from 2005 to 2008 reported that HTN affects both genders (as cited in Roger et al., 2012). Males have a higher prevalence of HTN than females over 44 years of age; as age increases, rates of female HTN increases at a similar rate as male HTN due to a decline in control of blood pressure because of postmenopausal hormone replacement, lack of exercise, and alcohol consumption (Bailey, Grossardt, & Graves, 2008; Roger et al., 2012). Prevention is crucial in decreasing the risk of complications and disabilities caused by HTN (World Health Organization, 2013).

Even though treatment for HTN has improved and more education is available to the public, it remains a major health problem (Ostechegea, Yoon, Hughes, & Louis, 2008). Improvement in HTN management has occurred since the 1990s, but from 2007 to 2010 almost half of the United States civilian population still had uncontrolled HTN (Centers for Disease Control, 2011). Veterans showed better blood pressure control over 10 years

and across 15 Veterans Administration (VA) hospitals from 2000 to 2007, but declined slightly in the 3 years from 2007 to 2010 (Flechter et al., 2012).

Despite years of research in how to control HTN, complications and associated deaths continue to occur in vast numbers. HTN contributes to cardiovascular, renal, visual, and neurological complications (National Institute of Health, 2004). Overall deaths in the United States from stroke, a major complication of HTN, occur approximately every 40 seconds (Roger et al., 2012). Every year an estimated 795,000 Americans has a stroke, and it is predicted there will be another 4 million by 2030 (Roger et al., 2012). According to the VA National Stroke Quality Enhancement Research Initiative (QUERI) Coordinating Center (2013), every year more than 15,000 veterans are admitted to the hospital with a stroke; approximately 40% of these result in physical disabilities.

Older Veterans and civilians who are non-Hispanic Blacks have the highest rate of HTN in the United States, with a higher risk of strokes and mortality from strokes (Allen et al., 2010; Roger et al., 2012). HTN increases the risk of stroke for those with HTN (Ostchega, Yoon, Hughes & Louis 2008), even though it is the most modifiable risk factor for stroke. In veterans, the annual costs of stroke are approximately \$111 million for acute care, with another estimated \$88 million for rehabilitation care in the first few months after a stroke (QUERI, Fact sheet, 2013).

### Literature Review

The primary purpose of this review is to identify problems related to lack of medication adherence for persons taking antihypertensive medication in the literature for

HTN. Selected literature was examined from 2011 to 2014, due to the vast amount of articles found relating to antihypertensive medication adherence. Inclusion criteria used to identify articles from 1984 to 2014 included adults aged 21 and older, a minimum of 20 participants, published studies, and selected theoretical variables from the Model of Self-Care in Chronic Illness (health motivation, perceptions of seriousness of the illness, well-being and social support). Databases included the Cumulative Index to Nursing and Allied Health Literature, the Medical Literature Analysis and Retrieval System Online, the Psychology and Behavior Sciences Collection, and the Psychological Information Database.

### Medication Adherence

The issue of medication nonadherence continues to be a challenge. Significant findings in early studies showed veterans who were prescribed HTN medication with electronic pill dispensers and less frequency of pills were associated with better medication adherence and improved blood pressure control (Eisen, Miller, Woodward, Spitznagel, & Przybeck, 1990; Eisen, Woodward, Miller, Spitznagel, & Windham, 1987). However, there is inconsistency among studies about whether HTN patients will be more or less adherent when more medications are prescribed (Bailey et al, 2009; Ren, Kazis, Lee, Zhang, & Miller, 2002). Diuretics were more commonly associated with nonadherence in the veteran population, whereas calcium channel blockers, angiotensin-converting enzyme inhibitors, or angiotensin II receptor blockers were more commonly associated with higher adherence (Siegel, Lopez, & Meirer, 2007; Wannemacher, Schepers, & Townsend, 2002).

Medication nonadherence may be either intentional or unintentional, but the result is the same: regardless of intention, it leads to uncontrolled blood pressure (Lowry, Dudley, Oddone, & Bosworth, 2005). If medications had more than five side effects—including frequent urination, syncope, wheezing, and fast heart rate—both veterans and civilians intentionally did not take the medication (Lowry et al., 2005). Unpleasant side effects are not the only reason for nonadherence; another study showed that distractions in daily life caused unintentional medication nonadherence among civilians (Proulx, Leduc, Vandelac, Gregoire, & Collin, 2007).

#### Post-Traumatic Stress Disorder

Veterans with a diagnosis of PTSD were found to have a physiologic response that releases higher levels of norepinephrine and epinephrine from the sympathetic nervous system, causing increased heart rate and diastolic blood pressure (Muraoka, Carlson, & Chemtob 1998; Paulus et al., 2013). Veterans diagnosed with post-traumatic stress disorder (PTSD) were associated with an increased risk for HTN (Paulus, Argo, & Egge, 2013). As such, veterans comprise a unique population when considering how to manage HTN. Between 2001 and 2005, PTSD was found to be a common diagnosis in veterans who served in Iraq and Afghanistan, and were identified either in the VA primary care clinic or a hospital admission, several months after their discharge from the service (Milliken, Auchterlonie, & Hoge, 2007; Seal, Bertenthal, Miner, Sen, & Marmar, 2007).

Magruder and colleagues (2005) reported few differences were found between veterans with PTSD and veterans without PTSD in their choice of receiving care in

primary-care clinics and in their visits to urgent-care clinics. Findings showed veterans with PTSD seen in primary-care clinics were younger than 65 years of age, lacked a college education, had been exposed to combat, and were unemployed (Magruder et al., 2005). Despite availability of mental-health services, many veterans instead chose to be evaluated in primary-care clinics (Wilson, 2007). The challenge of an additional diagnosis of PTSD is important when considering its association with medication adherence and how to prevent potential complications in the primary care setting.

### Theoretical Framework

The theoretical framework for self-care in chronic illness suggests how to assess and support patients with their self-care behaviors to improve health and medication adherence (Connelly 1987). The appearance of patients in a clinic visit does not always reflect consistency with their medications or indicate that they are managing their chronic disease effectively (Connelly, 1987). Therefore, Connelly (1987) reported that nurses are facilitators of patients' performing self-care behaviors and their treatment adherence to improve their outcomes.

Connelly's (1987, 1993) Model of Self-Care in Chronic Illness expanded on aspects in the health belief model of patients' self-care behaviors with a model that included factors that predisposed patients through their engagement of self-care behaviors, in addition to factors that enabled patients such as support or hindrance of self-care behaviors. These factors signify a holistic approach that assists patients with chronic illnesses to perform self-care behaviors (Connelly 1987, 1993).

The predisposing factors of health motivation and veterans' perceptions of the

seriousness of the illness, as well as the enabling factors of well-being and social support were examined by Connelly (1993) in a sample size of 181 retired and active veterans. The veterans were recruited from the primary-care clinics in a military hospital. Psychological well-being and health motivation were found to be positively associated with general self-care behaviors, but social support was negatively correlated with general self-care health behaviors (Connelly, 1993). However, the findings showed that veterans still followed treatment for their chronic illness without social support or if social support was negative (Connelly, 1993). Well-being and seriousness of the illness were positively associated with medication self-care (Connelly, 1993). The Model of Self-Care in Chronic Illness (Connelly 1987) was used in research for heart failure patients in ambulatory care and psychological well-being was also found associated with medication adherence (Schnell-Hoehn, Naimark, & Tate, 2009).

### Health Motivation

Medication adherence was found to be dependent on patients' health motivation and how they perceived control of their health (Connelly, 1993). Hess, Emery, and Neupert (2011) found in a longitudinal study that 332 older adults who had a decline in mental and physical health also had decreased self-motivation with their physical and cognitive functioning. Even if patients felt motivated about their health, they were vulnerable to omission of their medications for several reasons, including an occasional missed dose due to forgetfulness, the belief that HTN was short term, and fear caused by taking numerous prescribed medications (found in a qualitative study with 27 civilians) (Proulx et al., 2007). One important finding was when patients were asymptomatic, their

motivation to adhere to antihypertensive medications declined—without symptoms, they doubted the diagnosis and treatment and found it difficult to take medications (Proulx et al., 2007).

### Well-Being

Connelly (1993) reported psychological status as a positive correlation with medication self-care. Schnell-Hoehn, Naimark, and Tate (2009) reported well-being was positively associated with self-care behaviors in 65 patients with heart failure. An earlier study on well-being in a sample size of 794 hypertensive adults showed subjective factors of their perceived seriousness of their illness was associated with their ability to care for themselves (McDonald-Miszczak, Wister, & Gutman, 2001). The findings showed the hypertensive patients who rated themselves with poor well-being participated more with their self-care behaviors (McDonald-Miszczak et al., 2001).

Emotional support from family members was positively associated with well-being in a sample of 1,146 adults ages 65 and older (Merz & Huxhold, 2010). The overall quality of relationships from family was positively associated with well-being (Merz & Huxhold, 2010). In another study of older adults, Friedman and Ryff (2011), found the number of chronic illnesses were associated with psychological well-being but not with respondents' assessment of their purpose in life and social support system.

### Patients' Perceptions of the Seriousness of HTN

Patients' perceptions of the seriousness of chronic illness impacted positively on their adherence to treatment (Connelly, 1987). However, adults with HTN did not rate



their condition serious in comparison to patients with arthritis and heart problems because of the lack of symptoms (McDonald-Miszczak et al., 2001). Similar findings were also reported in a qualitative study of 48 veterans who rated HTN as low priority in comparison to cancer, diabetes or human immunodeficiency virus (Fix et al., 2014). In contrast, it was found that participants who felt at risk with their disease continued their antihypertensive medication treatment (Proulx et al., 2007).

The seriousness of chronic illness causes distress in individuals; Hamer, Batty, Stamatakis, and Kivimaki (2010) found a positive association between psychological distress and HTN in 33,105 adults. The diagnosis of HTN versus calling it high blood pressure increased the risk of distress because of the label (Hamer et al., 2010). Elderly adults with psychological distress were reported to be less involved in preventive care, and how identification of emotional distress should be considered as part of routine visits (Thorpe, Kalinowski, Patterson, & Sleath, 2006).

### Social Support

Marital status was found to have a positive association with antihypertensive medication adherence in 636 patients from primary care clinics (Trivedi et al., 2008). In addition, hypertensive civilians symptomatic of depression who were adherent to hypertensive medications had stronger social support in comparison to those who were nonadherent (Maguire, Hughes, & McElnay, 2008). In a secondary analysis of 1,146 older adult participants, social support also showed a positive association to emotional well-being among those involved with family and friends (Merz and Huxhold, 2010).

Veterans with PTSD were shown to be less symptomatic when they had social

support—when they were married, lived with family and extended families, and had friends who were also veterans (Laffaye, Cavella, Drescher, & Rosen, 2008; Ren, Skinner, Lee, & Kazis, 1999). Veterans who discussed their feelings with family and friends had decreased PTSD symptoms, whereas those who were unable to discuss their feelings because of unsupportive family and friends had an increase of PTSD symptoms (Fontana, Rosenheck, & Horvath, 1997). Findings show that a positive support system may make a difference in veterans with PTSD adhering to antihypertensive medication treatment.

#### Degree of Comorbidity

Participants diagnosed with one or more comorbid conditions had difficulty in separating out the differences between their HTN and their other illnesses in addition to their medication for HTN (Fix et al., 2014). In a national longitudinal study of 998 participants, higher numbers of chronic medical diagnoses were found to be negatively correlated with middle-aged and older adults' well-being and happiness with their life (Friedman & Ryff, 2012). Veterans 55 to 64 years of age who had an average of seven medical diagnoses—including two or more chronic conditions—had higher mortality rates if the diagnoses included HTN (Lee et al., 2007). Furthermore, a higher 5-year mortality rate occurred in the veteran population with HTN, ischemic heart disease, diabetes, and stroke added as a fourth illness in a disease cluster (Lee et al., 2007).

The Charlson comorbidity index is a calculation of medical diagnoses that are weighted to predict 1-year mortality rate (Quan et al., 2011). In a sample size of 1,079 subjects, researchers found older non-Hispanic Black veterans, who were diagnosed with

HTN and suffered a cerebrovascular accident had a Charlson comorbidity index greater than 2 (Ellis, Woodward, Miller, Spitznagel & Windham, 2009). In addition, this sample of veterans had higher mortality rates in comparison to non-Hispanic White veterans in a sample of 2,004 veterans (Ellis et al., 2009).

#### Patients' Perceived Involvement in HTN Treatment

Veterans' perceptions of greater participation in their treatment with their primary care provider demonstrate a positive relationship to antihypertensive medication adherence (Ren et al., 2002; Roumie et al., 2011). However, there was inconsistency in the literature; in one study ratings by veterans of their primary-care provider were higher when participating in decision-making during their clinical visits, but were not associated with antihypertensive medication adherence or improvement with their blood pressure control (Cho, Voils, Yancy, Oddone, & Bosworth, 2007). Veterans and their primary-care providers both rated clinical skills as most important, but the veterans rated their discussions with their primary-care providers as the second most important factor in out-patient care after clinical competence (Roumie et al., 2011).

#### Self-Care Behavior and Alcohol Intake

Adherence to antihypertensive medications was found in civilians who exercised, did not smoke, and restricted salt in their diets (Warren-Findlow, Seymour, & Huber, 2012). However, findings showed that study participants did not relate alcohol intake as a self-care behavior affecting HTN (Warren-Findlow et al., 2012). Alcohol misuse was found to have a negative association with antihypertensive medication adherence in both

civilians and veterans (Braithwaite et al., 2007; Bryson et al., 2008; Wang et al., 2004). An increased risk of alcohol misuse was found among Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) veterans who were 55 years or younger and required alcohol referrals and in veterans diagnosed with PTSD (Eisen et al., 2012; Hawkins, Lapham, Kivlahan, & Bradley, 2010).

### Summary

The literature review showed a link between the diagnosis of PTSD and the risk of HTN in veterans (Paulus et al., 2013). Veterans with decreased psychological well-being (an enabling factor) were associated with increased alcohol consumption which was found to decrease antihypertensive medication adherence (Bryson et al., 2008). The degree of comorbidity was associated with veterans experiencing difficulties in managing their HTN (Fix et al., 2014). However, veterans' psychological well-being was positively associated with both general self-care and medication self-care behaviors (Connelly, 1993).

Veterans' and civilians' perceptions of being diagnosed with HTN (a predisposing factor) did not always consider HTN as serious because of their lack of symptoms and it was a low priority in comparison to other illnesses (Fix et al., 2014; McDonald-Miszczak, Wister, & Gutman, 2001). Social support (an enabling factor) was found to be associated with increased well-being and medication adherence, in addition to decreased PTSD symptom (Fontana, Rosenheck, & Horvath, 1997; Laffaye, Cavella, Drescher, & Rosen, 2008; Merz & Huxhold, 2010; Ren, Skinner, Lee, & Kazis, 1999). Blood pressure control was found in veterans who perceived higher involvement with their physician which

included information exchange during their clinic visits (Ren et al., 2002).

Connelly's research findings were to assist nurses in their assessments of self-care behaviors in primary-care patients. Despite improvements in blood pressure among veterans, adherence to antihypertensive medications is crucial to prevent poor blood pressure control and complications. This evidence could potentially lead to strategies in how to evaluate antihypertensive medication adherence in these two groups of patients. Recommendations for practice include assessing veterans' alcohol consumption and their understanding of the effects of it on their blood pressure. Another area also to evaluate is the veterans' perceptions of the seriousness of their illness because hypertension is an asymptomatic illness which makes it more difficult to adhere to medications. Lastly, it would be important to assess the veterans' social support system in adhering to the treatment of hypertension.

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## CHAPTER 3

### RESEARCH DESIGN AND METHODS

#### Purpose and Design

The purpose of this study was to further understand factors contributing to antihypertensive medication adherence among two groups of veterans: those with hypertension (HTN) and no post-traumatic stress disorder (PTSD) diagnosis and those with both HTN and PTSD. An adherent patient was defined in this study as one who took prescribed antihypertensive medications as directed on a consistent basis of 80% to 100% (Cramer et al., 2007), as measured by the medication possession ratio and medication self-report.

A cross-sectional design was used to examine predisposing and enabling factors derived from Connelly's (1987, 1993) theoretical framework of self-care behaviors in chronic illness. For this study, selected predisposing factors were health motivation and the patient's perception of the seriousness of the illness; the enabling factors of well-being and social support were chosen because the literature suggested an association was found with both medication adherence self-care behaviors and general self-care behaviors. In addition, other variables—including degree of comorbidity, alcohol intake, and patients' perceived involvement in their care (patient and primary care provider interaction)—were evaluated because these variables have also been found to

have an association with hypertension (Bryson et al., 2007; Fix et al., 2014; Ren, Kazis, Lee, Zhang, & Miller, 2002). Table 3.1 indicates the theoretical concepts and associated measures.

The integrative review using a theoretical framework of self-care in chronic illness for HTN and the additional diagnosis of PTSD led to a development of a conceptual model. This model shows potential factors associated with the chronic illness of HTN and antihypertensive medication adherence in the veteran population. The proposed conceptual model (Figure 3.1) shows seven independent variables and the dependent variable of medication adherence. The solid arrows are paths between two variables, and this model can be examined for direct and indirect effects on antihypertensive medication adherence and whether there are significant associations. The proposed conceptual model derived from theory could predict differences between veterans with HTN and veterans who have the additional diagnosis of PTSD and are evaluated in primary care clinics.

#### Specific Aims and Research Questions

The primary purpose of this study was to compare differences between veterans with HTN and veterans with HTN and PTSD. Data from mailed surveys and the patients' electronic medical records were examined for the relationships among variables and medication adherence.

### Specific Aim 1

To describe the demographics of veterans (age, gender, race, ethnicity, marital status, years of education, occupational status), number of years each diagnosed with HTN and PTSD, number of medications, adherence with clinic visits, and reasons for potential omission of antihypertensive medications comparing veterans with HTN and veterans with both HTN and PTSD.

#### Research Question 1.1

What are the differences in reported demographics of veterans (age, gender, race, ethnicity, marital status, years of education, occupational status), number of years diagnosed with HTN, number of medications, and adherence with clinic visits between two diagnostic groups of veterans?

#### Research Question 1.2

What is the self reported number of years veterans have been diagnosed with PTSD?

#### Research Question 1.3

What are the reasons veterans in both groups give for potentially omitting antihypertensive medications?

### Specific Aim 2

To assess indicators of medication adherence: self-report, pharmacy refill records, and clinical indicators.

#### Research Question 2.1

What is the relationship between antihypertensive medication adherence self-report and pharmacy refill data in both diagnostic groups of veterans?

#### Research Question 2.2

Do the two diagnostic groups of veterans differ from each other with regard to their blood pressures?

### Specific Aim 3

To identify the extent to which the degree of comorbidity, alcohol intake, and social support are directly and/or indirectly associated with the veterans' well-being and antihypertensive medication adherence in veterans with HTN, and veterans with both HTN and PTSD.

#### Research Question 3.1

To what extent are the degree of comorbidity, alcohol intake, and social support directly and/or indirectly associated with veterans' well-being and antihypertensive medication adherence in both diagnostic groups of veterans?

#### Specific Aim 4

To identify the extent to which health motivation, veterans' well-being, and veterans' perceived involvement in hypertensive treatment (patient and primary-care provider interaction) are directly associated with antihypertensive medication adherence in veterans with HTN, and veterans with both HTN and PTSD.

#### Research Question 4.1

To what extent are veterans' health motivation, well-being, and perceived involvement in hypertensive treatment (patient and primary care provider interaction) directly associated with antihypertensive medication adherence in both diagnostic groups of veterans?

#### Research Question 4.2

To what extent is veterans' well-being directly associated with health motivation and perceived involvement in hypertensive treatment in both diagnostic groups of veterans?

#### Specific Aim 5

To identify the direct and indirect effects of veterans' perceptions of the seriousness of HTN and veterans' perceived involvement in hypertensive treatment (patient and primary-care provider interaction) and antihypertensive medication adherence in veterans with HTN and in veterans with both HTN and PTSD.

### Research Question 5.1

To identify the extent to which veterans' perceptions of the seriousness of HTN are directly and/or indirectly associated with veterans' perceived involvement in hypertensive treatment and antihypertensive medication adherence in both diagnostic groups of veterans?

### Research Question 5.2

To identify the extent to which veterans' perceived involvement in hypertensive treatment was directly associated with antihypertensive medication adherence in both diagnostic groups of veterans?

## Sample and Setting

### Background

The target population for this study was military veterans who were recruited from the Veterans Administration New England Healthcare System at the VA CT Healthcare System. This medical center is university affiliated and consists of in-patient units, out-patient clinics, and six community-based outpatient clinics throughout Connecticut. It is also a national center for the treatment of PTSD. Out-patient clinics, in which approximately 55,000 veterans are treated, are referred to as Primary Care.

More than 200,000 veterans live in Connecticut, including approximately 167,800 wartime veterans from World War II, the Korean conflict, the Vietnam era, the Gulf War, and Operation Enduring Freedom and Operation Iraqi Freedom (Department of Veterans' Affairs, 2014). In preparation for this proposal, a query of the primary care database was



conducted by the administrative officer for Primary Clinics at the VA Connecticut Healthcare System which identified 11,554 veterans who were diagnosed with HTN without PTSD; 2,232 veterans who were diagnosed with PTSD; and 1,207 who were diagnosed with both HTN and PTSD.

#### Inclusion and Exclusion Criteria

Inclusion criteria included the ability to speak English, an age of 21 years or older, assigned to a primary-care provider in at VA Connecticut Healthcare System, and diagnosis of HTN and/or both HTN and PTSD for 12 or more months. Participants were not considered eligible if they had a history of traumatic brain injury, drug addiction, or major psychiatric diagnoses of psychosis or schizophrenia disorders, since all of these factors may disable cognitive functioning and the ability to provide valid self reported data (Bowie, Reichenberg, Patterson, Heaton, & Harvey, 2006; Jorge, 2005).

#### Recruitment and Retention Procedures

Names of potential participants and home addresses were acquired through the administrative officer of Primary Care Clinics at the VA Connecticut Healthcare System. An introduction letter (Appendix A) from the chief of Primary Care at the VA Connecticut Healthcare System was sent to veterans as required by the VA research protocol. The introductory letter provided an explanation of the study, specified that participation was voluntary, and listed criteria for participant eligibility.

Included in the letter was a request to review the veteran's electronic medical record for 1) length of time of HTN treatment, 2) number of medical diagnoses, 3) blood

pressure measurements at office visits, 4) medications, and 5) medication refills at the VA Connecticut Healthcare System. In addition, the veterans were thanked in advance for their participation and told that if they returned the survey they would be mailed a \$20 gift card. Veterans were requested to return the survey booklet within 2 weeks.

Mailed surveys were chosen in order to reach a larger number of veterans despite known barriers. The benefit of mailed surveys is that potential participants are usually comfortable opening mail in the privacy and convenience of their own home. Barriers to mailed surveys include cost and multiple reminders to increase the response rate; in addition, participants who have less education may not always respond to mailed surveys (Dillman, Smyth, & Christian, 2009). Other barriers include fear of disclosure of private information on a website (Dillman et al., 2009). We decided that the potential for greater recruitment outweighed these barriers.

Packets were created with copies of introductory letters, survey booklets with a demographic data form, and postage paid envelopes addressed to the veterans. Return of the survey constituted consent for participation in the study. Instructions were provided with the booklet that explained how to answer questions in the survey. The surveys were written in Times New Roman 11-point font on white paper for easier reading and enhancement of response rates (Dillman et al., 2009). The packets were mailed from a local post office with postage paid return envelopes addressed to the VA Connecticut Healthcare System along with the co-investigator's name and department number. In addition, the supervisor of the mailroom was alerted to the large volume of expected returned mail. A reminder postcard was planned to be sent 2 weeks after the packets were mailed.

Veterans indicated on the demographics form where they obtained their antihypertensive medications—whether at the Veterans Administration pharmacy or a local pharmacy. Since we could not know in advance whether the veterans used the Veterans Administration pharmacy, we mailed the gift card to each participant who returned the survey. A total of 1,199 packets were mailed; we conservatively estimated a response rate of 20% for veterans as opposed to the reported 30% to 45% when selecting how many packets to mail (Dillman et al., 2009; Shih & Fan, 2008).

#### Protection of Human Subjects

Approval was sought from both the University of Utah and VA Connecticut Healthcare System Institutional Review Boards (IRB). Per VA requirements, the site primary investigator was required to be the Chief of Primary Clinics, Christopher Ruser, MD. Due to the vulnerable population of veterans diagnosed with PTSD, the Institutional Review Board procedure at the VA required an initial review by a psychiatrist. Suggested revisions were made, and then the study proposal was submitted to the Institutional Review Boards (Appendix A).

Office space that included a computer and a locking file cabinet for secured confidential files was located at the VA Connecticut Healthcare System in the Education Service area. The mailbox for incoming research packets was checked daily. When questionnaires were returned, each survey booklet had a unique identification number written on it which linked the de-identified data to the participant's name in the VA computer database for future electronic review. The de-identified surveys were stored in a locked cabinet. Only the co-investigator had access to identified data, all of which were

maintained in a password-protected computer

There were two databases for this study. One contained the patient's name, age, gender, address, diagnosis of HTN or HTN and PTSD. A second database had all personal identifiers removed and was entered into Research Electronic Data Capture (REDCap; Harris, et al., 2009) through the University of Utah for analyses. Medical diagnoses, medications, blood pressures, pharmacy refills (medication possession ratio), and clinic visits were entered into REDCap on a data extraction form. Data were entered by the co-principal investigator. The research assistant, who was approved by the IRB at VA CT Healthcare System, assisted with re-entry of survey data using de-identified data for future comparisons to ensure accuracy. After completion of data double entry, data entry errors were compared between the two datasets. Discrepancies were resolved by reviewing the surveys for the correct information.

### Instrumentation

#### Psychometrics

Internal consistency was evaluated for all instruments and subscales using Cronbach's alpha. Internal consistency evaluates the extent to which the items in a scale measure the same concept (Munro, 2005). Cronbach's alpha is one indicator of the amount of measurement error in a survey (Tavakol & Dennick, 2011). If the scale measures more than one concept, then the Cronbach's alpha would be calculated for each concept (Tavakol & Dennick, 2011). The instruments referred to in this chapter are found in Appendix B.

Demographics. The National Institutes of Health (NIH) demographic form was

adapted in this study with additional questions about HTN. The NIH data form included age, gender, race, ethnicity, marital status, level of education, and occupational status. Three additional questions were added for this study: 1) the number of years diagnosed with HTN; 2) whether veterans obtained antihypertensive medication at the VA pharmacy or at a non-VA pharmacy; and 3) reasons why they might skip doses of antihypertensive medications.

A total of eight measures were initially piloted with one 87-year-old veteran and two nonveterans (66 and 58 years of age). Questionnaires were completed in approximately 20 minutes for all three participants.

Degree of comorbidity. Previous research has showed that more comorbid conditions are associated with increased mortality rates and medication nonadherence (Fix et al., 2014; Lee et al., 2007). Veterans with a Charlson Comorbidity Index value indicated more than two comorbid conditions were associated with higher mortality rates (Ellis, Zhao, & Egede, 2009; Roger et al., 2012). The numbers and types of clinical diagnoses in this study were measured with the Charlson Comorbidity Index.

Alcohol intake. Self-care behaviors were identified in the seventh report of the Joint National Committee on Prevention, Evaluation, and Treatment of Hypertension (National Institutes of Health, 2004). For this study, moderate or no alcohol intake was chosen to indicate self-care behavior. The range of scores for this screening tool was from 0 to 12, higher scores indicated alcohol misuse. Bush, Kivlahan, McDonnell, and Fihn (1998) reported the three-item Alcohol Use Disorders Identification Tool was valid and it positively identified alcohol misuse in a sample size of 393 veterans. Reliability was demonstrated with test-retest reliabilities over 3 months in 264 veterans, with

correlations which ranged from 0.65 to 0.85 (Bradley, McDonell, Bush, Kivlahan, Diehr, & Fihn 1998). Bryson and colleagues (2008) measured alcohol misuse with the tool in 35,725 veterans from seven national Veterans Administration medical centers who were enrolled in the Ambulatory Care Quality Improvement Project; they found that increased scores were associated with decreased antihypertensive medication adherence.

Social support. Previous research has shown social support to be positively associated with medication adherence (Maguire, Hughes, & McElnay, 2008; Trivedi, Ayotte, Edelman, & Bosworth, 2008) in contrast to Connelly (1993), who found a negative association between self-care behaviors and social support. The Multidimensional Scale of Perceived Social Support (MSPSS) is designed to measure social support of family, friends, and significant others. It has 12 items with a 7-point Likert-type scale (1=very strongly disagree, 7=very strongly agree), with possible scores of 12 to 84 (Zimet, Powell, Farley, Werkman, & Berkof, 1990). Subscale means (significant other, family, and friends) are added and divided by 12 for a total score with higher scores indicated stronger social support (Zimet et al., 1990).

Previous research demonstrates good reliability of the MSPSS using Cronbach's alpha. Reliability ranged from 0.84 to 0.94 in three different studies from Zimet and colleagues (1990) with three different groups for a total of 394 participants; Dahlem, Zimet and Walker (1991) used 170 participants from diverse backgrounds; and Jackson (2009) used 301 participants with chronic illness. Validity of relationships between the independent variable of marital status and the subscales of family, friends, and significant other supported the researchers' hypothesis in multivariate analysis of variance (Zimet et al., 1990). The results indicated that married participants had greater support from their

significant other in comparison to single participants in a sample size of 55 pediatric residents (Zimet et al., 1990).

Patients' perceptions of the seriousness of HTN. The Health Distress Scale was used to evaluate the predisposing variable of patients' perceptions of the seriousness of illness. The original health distress version was a six-item scale from the Medical Outcomes Study and adapted to a four-item scale from an interventional study for a possible range of 0 to 20 (Lorig et al., 1999). The scale has four items each with a 5-point Likert-type scale (0=none of the time, 5 all of the time), with a Cronbach's alpha of 0.87 (Stanford School of Medicine, 2012). The scale is scored using a mean of the four items (Stanford School of Medicine, 2012). Higher mean scores indicate more distress about a diagnosis—defined in this study as a diagnosis of HTN. Previous research evaluated differences between treatment and control groups of patients who had arthritis, heart disease, or lung disease, finding that health distress decreased when health behaviors improved in 839 patients who were 40 years and older (Lorig et al., 1999). Lorig et al. (1999) referred to the Cronbach's alpha cited in previous research of 1,130 adults (Lorig et al., 1996, p. 25) of 0.87 for the health distress scale.

Health motivation. Motivation was measured with the Health Motivation Scale. The scale has eight items with a 7-point Likert-type scale (1=strongly disagree, 7=strongly agree) with a scoring of 7 to 56 (Labig, Zantow, & Peterson, 2005; Moorman & Matulich, 1993). The scale has previous acceptable internal consistency when administered to older adults from lower and higher income households (Cronbach's alpha 0.82; Moorman & Matulich, 1993). Higher scores indicate higher health motivation associated with one's health behaviors (Moorman & Matulich, 1993). Moorman and

Matulich (1993) hypothesized that a higher level of motivation was associated with individuals to perform healthy behaviors, and had significant findings in a sample of 404 participants ranging from young to elderly participants. Previous research has demonstrated that health motivation is associated with preventive healthcare behaviors in 175 patients from a primary care clinic (Cronbach's alpha 0.78; Jayanti & Burns, 1998). Connelly's (1987) model of Self-Care in Chronic Illness was an extension of the health belief model, and both are based on motivational theory

Patient's well-being. In Connelly's (1993) model, patient well-being is a predictor of enabling patients to perform self-care activities for themselves. The short form (SF)-12 was used to assess physical and psychological well-being. Ware, Kosinski, and Keller (1996) obtained data from the Medical Outcomes Study and National Survey of Functional Health Status and determined the shorter version of the SF-12 was comparable to the SF-36. The SF-12 showed 90% and greater variances on the SF-36 physical and mental health subscales in a sample of 2,333 adults. Previously, Ware and colleagues (1996) demonstrated test-retest reliability of 0.89 and 0.76 in the physical and mental component summary subscales, respectively, and a pilot study demonstrated the SF-12 could be completed within 2 minutes.

Larson, Schlundt, Patel, Beard, and Hargreaves (2008) conducted a study with a sample size of 1,721 using the SF-12 with a Cronbach's alpha of 0.80 and 0.78 for the physical and mental component subscales, respectively. Larson et al. (2008) reported convergent and discriminant validity of the subscales with scales used in a previous study and found no significant ceiling or floor effects, which suggested scores did not cluster near the higher or the lower scores (Shadish, Cook, & Campbell, 2002).



Patients' perceived involvement in hypertensive treatment. Lerman and colleagues (1990) developed the Patient Involvement in Care Scale (PICS) to determine patients' perception of the interaction between themselves and their provider in relation to their participation in their chronic disease treatment. The original 25-item scale resulted from observations by Lerman and colleagues (1990) with analyses of patient and primary-care provider communications in routine clinic visits. The final scale version is a 13-item scale using a dichotomous response format (0= disagree, 1=agree) with a possible total score of 0 to 13. Higher summation scores indicated a higher level of perceived involvement in care (Lerman et al., 1990; Rodriguez, Appelt, Switzer, Sonel, & Arnold, 2008). Cronbach's alpha was reported as 0.73 in 131 patients for the 25-item PICS instrument (Lerman et al., 1990). A modified version of the scale in 87 patients with breast cancer and persistent pain had a Cronbach's alpha range of 0.79 to 0.89 for the subscales (Smith, Winkel, Egert, Diaz-Wionczek, & DuHamel, 2006). Construct validity was evaluated using exploratory factor analysis with findings of three independent subscales: doctor facilitation, patient-physician information exchange, and patient decision-making (Lerman et al., 1990).

Antihypertensive medication adherence. The Morisky Medication Adherence Scale is a self-report instrument; originally a four-item scale, it had been redesigned to an eight-item scale for high, medium, and low adherence (Morisky, Ang, Krousel-Wood, & Ward, 2008). The eight-item scale had seven items with a dichotomous response format (yes=0, no=1); and the eighth item consists of a 5-point Likert-type response (0=never/rarely, 4=all the time; Morisky et al., 2008). Concurrent validity of the eight-item scale correlated (0.64;  $p < 0.05$ ) with the validated four-item self-report scale

(Morisky et al., 2008). The eight-item scale was administered to 1,367 participants ages greater than 18 years of age and from diverse backgrounds who took antihypertensive medications in outpatient settings, demonstrated a Cronbach's alpha of 0.83 (Morisky et al., 2008). High adherers of 15.9% had better blood pressure control in comparison to medium or low adherers.

The eight-item scale version was found to have a positive association with the pharmacy refill rate calculated by the medication possession ratio in 87 patients with a Cronbach's alpha of 0.83, as cited in Morisky et al., 2008 (Krousel-Wood et al., 2009). Gatti, Jacobson, Gazmararian, Schmotzer, and Kripalani (2009) used a dichotomous response formats for all eight items (yes=1, no=0) with higher scores indicating lower adherence, and used the previous validation from Morisky et al. (2008) Cronbach's alpha of 0.83. Following the precedent of Gatti et al. (2009), and in order for all eight items to be scored in a similar manner for the path analysis, item eight was scored as yes or no, with never/rarely as 0, and the other four items as 1. Substantiating this revision of item eight was a lack of response variability. Veterans answered they never/rarely/once in a while have difficulty remembering taking their medications, 94.9% and 91.2%, respectively, for veterans with HTN and PTSD. Scores for all eight items (yes=1, no=0) were summated as a continuous variable for path analysis and reverse-coded for ease of interpretation; higher scores reflected higher medication adherence.

Medication possession ratio. The medication possession ratio (MPR) of pharmacy refills was used to examine medication adherence. The calculation of medication adherence was defined as: the numerator as the sum of the total number of days' supply of refills minus the last refill, and the denominator as the difference between the first and

last refills (Krousel-Wood et al., 2009; Shah, Steiner, Vermeulen, Fleming, & Cory, 2007). A ratio between 0.8 and 1.0 was considered adherent (Krousel-Wood et al., 2009; Shah et al., 2007). If a patient was taking more than one class of antihypertensive medications, each classification of medications was calculated with the MPR and averaged for all classifications to allocate a single ratio (Krousel-Wood et al., 2009). The medication possession ratio was found to be positively associated with self-reported results from the Morisky Medication Adherence Scale (Krousel-Wood et al., 2009).

The Morisky Medication Adherence Scale was also found to be positively correlated with the medication electronic monitoring system (MEMS) (Braverman & Dedier, 2009). From a large randomized clinical trial, findings of MEMS data on 70 participants correlated significantly with the systolic blood pressure and self-reported medication adherence with the Morisky survey (Braverman & Dedier, 2009). The self-report provided an accurate estimate of medication adherence with the pharmacy refills as a validation.

For pharmacy data, it was not possible to know in advance whether veterans purchased their medications outside of the Veterans Administration. Veterans may choose another pharmacy if they are able to purchase their medications less expensively. Veterans who completed their surveys received the incentive, but data for those who used non-VA pharmacies were excluded ( $n=126$ ) in the analysis because we did not have access to non-VA pharmacy refill information.

### Approach to Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) 17.0 (IBM, 2013) was used to generate the descriptive statistics, Chi-square, Pearson product correlation coefficient, independent *t*-test, and analysis of variance. A path analysis was conducted using Analysis of Moment Structures (AMOS; IBM, 2013; version 22). AMOS was chosen because comparison between AMOS and linear structural relations (LISREL) demonstrated minimal differences in results, and AMOS was found to be more user-friendly for less experienced users (Clayton & Pett, 2008).

Demographic characteristics of veterans (age, gender, race, ethnicity, marital status, level of education, and occupational status) were evaluated with percentages, Chi-square, and independent *t*-test. Means and standard deviations were conducted to assess the number of years diagnosed with HTN and PTSD. Independent *t*-tests for comparison of the survey means between the diagnostic groups. Evidence of medication adherence was evaluated using Pearson product moment correlation using self-reported antihypertensive medication adherence and pharmacy refill data. Pharmacy refill data were calculated using the medication possession ratio, demonstrated veterans' adherence to refilling their prescriptions. Blood pressure data were analyzed using the independent *t*-test to assess mean differences between the veterans with HTN only and those with both HTN and PTSD. Path analysis, a statistical subset of structural equation modeling and an extension of multiple regression, was used to measure direct and indirect effects on the outcome of antihypertensive medication adherence (Clayton & Pett, 2008; Lei & Wu, 2007; Pett & Clayton, 2010).

### Path Analysis

The path analysis model was designed to examine the predisposing factors (health motivation and veterans' perception of the seriousness of illness) and enabling factors (well-being and social support) on medication adherence. In addition, three variables from the literature—degree of comorbidity, alcohol intake, and veterans' perceived involvement in hypertensive-treatment were also examined for their relationship with medication adherence. Using a path analysis we tested the magnitude and direction of standardized path coefficients among observed variables on the outcome variable within a theoretical framework derived from the self-care chronic illness model (Connelly 1987, 1993).

The squared absolute values of coefficients indicate how much variance in the outcome variable is directly shared with the predictor variable (Pett & Clayton, 2010). The range of standardized paths is +1.0 to -1.0 in path analysis and shows the direction of the relationship, positive or negative. A positive relationship between two variables indicates that a higher score on one variable is associated with a higher score on the other variable. A negative path coefficient indicates an inverse relationship: in other words, a higher score on one variable is associated with a lower score on the other variable.

Path analysis model. A path analysis model begins with specification that is creating a statement about the parameters and drawing a hypothesized model from theory (Clayton & Pett, 2010; Kenny, 2011). The observed variables included: 1) degree of comorbidity, 2) alcohol intake, 3) social support, 4) health motivation, 5) veterans' well-being, 6) veterans' perceived involvement in hypertensive care (patient and primary-care provider interaction), 7) veterans' perception of the seriousness of HTN, and 8) the outcome variable of antihypertensive medication adherence. The observed variables were

assessed and analyzed for their direct and indirect effects on antihypertensive medication adherence in a population of veterans with HTN only and those with HTN and PTSD.

Exogenous and endogenous variables. Exogenous variables, also called predictors, have direct paths leading away from them to the endogenous variables with error terms, because every measurement has an error associated with it (Clayton & Pett, 2008). The exogenous variables are degree of comorbidity, self-care behavior of alcohol intake, social support and veterans' perception of the seriousness of HTN. A path analysis model where all paths are in one direction is deemed recursive (Byrne, 2010). The endogenous variables were health motivation, veterans' well-being, perceived involvement in care, and medication adherence. Four of the variables selected from Connelly's (1987, 1993) model were health motivation, veterans' perception of the seriousness of HTN, veterans' well-being, and social support.

Path model, analysis, power, and sample size. The path model in this study had 28 parameters (unknowns) that included error terms (Clayton & Pett, 2008). Free parameters are estimated from the data (Kenny, 2012). In this study there were 6 curved paths (correlations), 10 paths, 4 exogenous variables, and 4 endogenous variables for a total of 24 free parameters. This model had eight variables calculated as  $[8*(8+1)/2] = 36$  sample moments, which were the maximum number of parameters to be estimated in this path model (Byrne, 2010).

The required sample size is 10 to 20 times the number of free parameters (Kline, 2011; Munro, 2005). The path model had 24 free parameters, which required a minimum sample size of 240, with 120 for each group. In the final group models, the HTN group had 241 veterans, and the HTN and PTSD group had 187 veterans. Given the number of

parameters for a medium effect size with power of 0.80, the probability was set at 0.05, with power (1-beta) at .80 for a medium effect (Kline, 2011, p. 34).

Assumptions. Path analysis is a linear model with an outcome variable measured on a continuous scale; observed variables were also measured on a continuous scale, but categorical scales were also used (Munro, 2005; Pett & Clayton, 2010). The model was recursive where the paths were in a straight path from one variable to another (Munro, 2005). The observations are independent of each other where a participant cannot be counted more than once (Pett & Clayton, 2010).

### Model Fit

Several methods were used to evaluate fit of the data to the proposed model. First, the Chi-square assessed the model fit between the hypothesized model and the study data (Byrne, 2010; Clayton & Pett, 2011). Second, the root mean square error of approximation (RMSEA) was used as a general fit index (Clayton & Pett, 2011). Third, the comparative fit index was used for accuracy of the fit with the sample size (Byrne, 2010). Fourth, Akaike information criterion (AIC) and the expected cross validation index (ECVI) were used as predictive indexes (Clayton & Pett, 2011). Because the data did not fit the initial model, modification indices were used.

Path coefficients. Standardized regression coefficients, also known as beta weights, were used to assess the direct and indirect effects of the exogenous variables paths on medication adherence (Pett & Clayton, 2010). The path coefficient divided by the standard error, also known as the critical ratio, provided a probability value (Pett & Clayton, 2010). If the value was less than the set probability value, then only significant

pathways were retained in the model (Clayton & Pett, 2011).

Model fit indices. The path analysis model was evaluated with the fit indices. First, the Chi-square was evaluated. When the Chi-square is not significant there is good model fit because the model fits the data; there is no significant difference between the data and model (Clayton & Pett, 2011). Second, the root mean square error of approximation (RSMEA) index was used to estimate fit of the model at less than 0.05. A confidence of 90% was used for this study (Clayton & Pett, 2011). Third, the comparative fit index (CFI), was evaluated compared to the hypothesized model to the independence model—also referred to as the null model with the index of .90 to .95 (Byrne, 2010; Kline, 2011). Lastly, AIC and ECVI indicated smaller values, which demonstrated a better fit of the data (Clayton & Pett, 2011).

### Missing Data

After data were double entered, discrepancies of missing values were analyzed. We attempted to recover missing data by telephoning participants, using a minimum of three calls at different hours of the day and evening. When the survey booklet had an entire page/pages missing, copies of the form/forms with the questions highlighted were mailed to the participants. A letter of appreciation was included to thank the participant for taking time to complete the missing questions. The participant was asked to return the form or forms in the enclosed prepaid envelope within 2 weeks. After recovery of the missing data, the data were again reviewed for missing values, including the distribution and patterns of missing data.

Patterns of missing data that show no systematic pattern are referred to as missing



completely at random (MCAR; Byrne, 2010). MCAR is when the nonresponse to an item has a low probability of being related to another variable and will not contribute to biased data (Byrne, 2010). Common reasons for missing data include the time availability of the participant, distraction of the participant while completing the survey, and procrastination that results in the participant hurrying through the survey (Dillman, Smyth, & Christian, 2009). In addition, Jerant, Chapman, Duberstein, and Franks (2009) found in a randomized sample of 415 participants tested in a model of personality traits that less missing data were associated with participants who had higher levels of being conscientious and agreeable.

There are many reasons for missing data that cannot always be controlled, but there are common methods to dealing with incomplete data (Byrne, 2010). The common methods include: 1) listwise deletion, which is deletion of missing values; 2) pairwise deletion is deletion of missing cases from particular analyses; 3) single imputation is insertion of estimated values for missing scores; 4) expectation-maximization is a two step method that is repeated until estimated values replace missing values (Byrne, 2010; Tabachnick & Fidell, 2007).

#### Methods for Managing Missing Data

Randomly missing data were imputed through the method of expectation-maximization (Tabachnick & Fidell, 2007). The first part of expectation uses regressions and each incomplete variable is regressed on the observed variable and a score is imputed (Kline, 2011). The second part, the imputed data are put through maximization likelihood an estimation process as if the data were added (Tabachnick & Fidell, 2007). These two

steps are repeated until the estimation of missing data is finalized and saved in the data set (Kline, 2011; Tabachnick & Fidell, 2007). An advantage is that expectation-maximization can be used in a cross-sectional design.

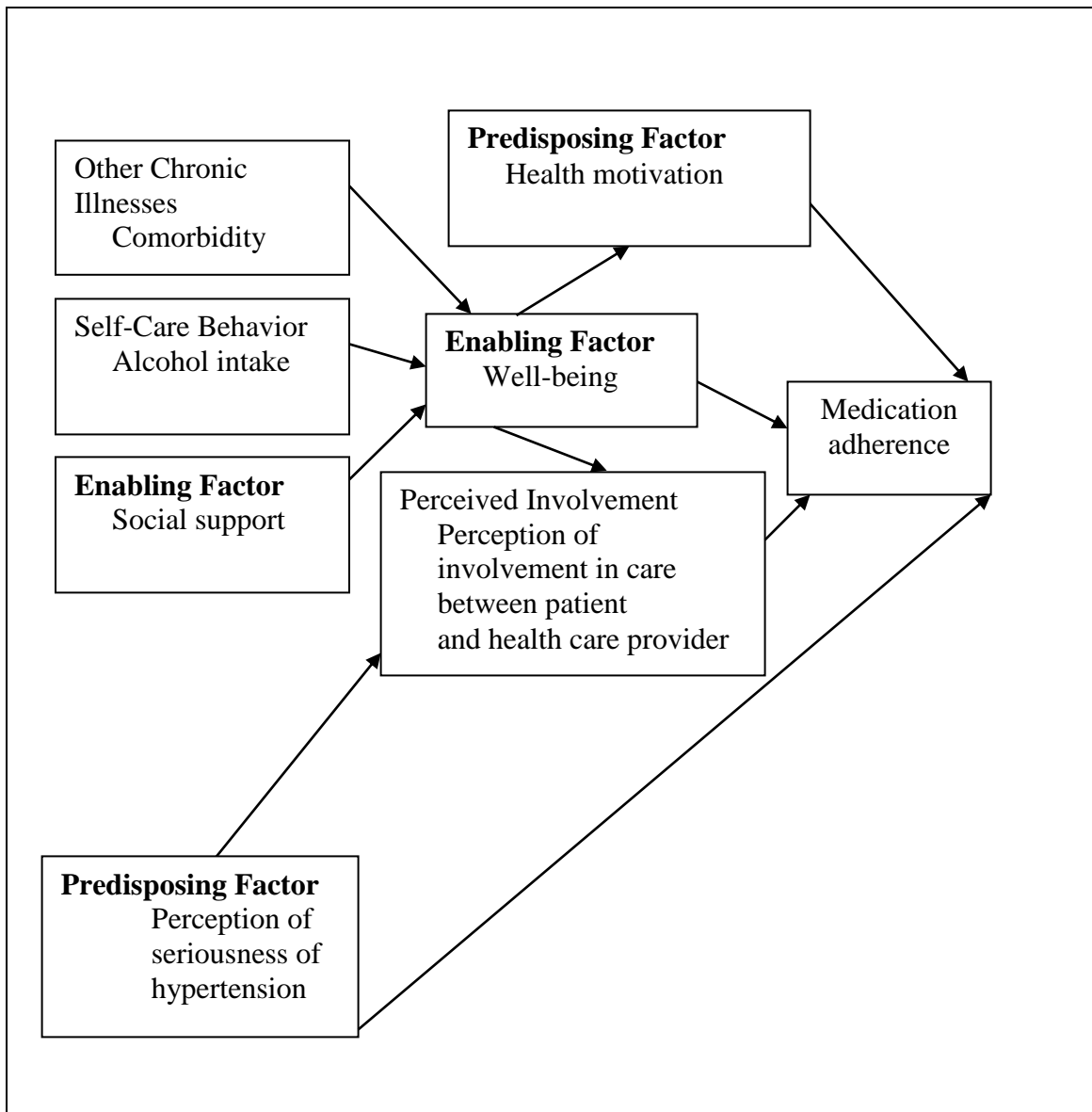
### Summary

This chapter described the purpose, design, aims, methods, sample, instrumentation, and the approach to the statistical analysis in this study. The variables and the instruments are defined in addition to the medical chart review in Table 3.1. The medical chart review was validation of the blood pressure data and prescription refills. The medication possession ratio was calculated to validate the refill adherence. The results of the analyses are presented in Chapter 4.

Table 3.1

## Measurements of Theoretical Concepts and Patient Data

Variables	Definition	Instruments
Demographics	Characteristics of veterans; years diagnosed with HTN; medication cost	National Institutes of Health Demographic Form
Predisposing Factors		
Health motivation	Patients' having self-directed goals for their health behaviors	Health Motivation Scale
Patients' perceptions of seriousness of HTN	Patients' level of perception of seriousness HTN	Health Distress Scale
Enabling Factors		
Well-Being	Mental and physical health	SF-12 Scale
Social Support	Patients' perceptions of support from family, friends and significant others	Multidimensional Scale of Perceived Social Support
Comorbidity	Degree of comorbidity	Charlson Comorbidity Index
Self-Care Behavior	Moderate or no alcohol intake	Alcohol Use Disorder Identification Test- Consumption
Alcohol intake		
Patient's perceived involvement in hypertensive treatment	Patient and primary care provider interaction	Perceived Involvement in Care Scale
Antihypertensive medication adherence	Self-report on antihypertensive medication adherence	Morisky Self-Report Medication Adherence Scale
Medical records		
Last clinic visit	Month, day, and year. Blood pressure data from clinic visit. If patient cancels appt without follow-up, considered nonadherent.	Computerized Patient Record System Data Extraction Form
Prescription refills	30, 60, or 90 days after medication prescribed as determined by prescription. If refills not ordered with time period, subject considered nonadherent.	Computerized Patient Record Data Extraction Form (Medication Possession Ratio)



*Figure 3.1* Proposed Conceptual Model of Factors Influencing Antihypertensive Medication Adherence. Adapted from Connelly's (1993) Model of Self-Care in Chronic Illness.

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## CHAPTER 4

# PREDICTORS OF ANTIHYPERTENSIVE MEDICATION ADHERENCE IN VETERANS WITH HYPERTENSION AND POST-TRAUMATIC STRESS DISORDER<sup>1</sup>

### Predictors of Medication Adherence in Veterans

#### Key words

Veterans, hypertension, post-traumatic stress disorder, medication adherence

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### Conflict of Interest

The authors have no conflicts of interest to disclose.

### Abstract

#### Background

In addition to being a national health problem, hypertension is a common medical diagnosis among U.S. military veterans. Suboptimal antihypertensive medication adherence continues to be a significant problem and is a precursor to poor blood pressure control. Post-traumatic stress disorder (PTSD) in veterans was found to be associated with increased blood pressure and heart rate and a greater risk of hypertension. The objective is to identify and compare factors influencing antihypertensive medication adherence among veterans with hypertension and veterans with both hypertension and PTSD.

#### Methods

Using a cross-sectional design, 428 veterans (241 veterans with hypertension and 187 veterans with hypertension and PTSD) participated in a mailed survey. Connelly's theoretical model of Self-Care in Chronic Illness was used to guide the choice of variables thought to be associated with antihypertensive medication adherence: patients' health motivation, perceptions of the seriousness of illness, psychological well-being, and social support. In addition, the survey sought information about degree of comorbidity, alcohol intake, and a veteran's perceived involvement in their care. Path analysis was used to examine and compare the direct and indirect effects of antihypertensive

medication adherence for veterans with hypertension and veterans with both hypertension and PTSD.

### Results

Evaluation of the final models evaluating medication adherence by diagnostic group (veterans with hypertension and veterans with hypertension and PTSD), used only the mental component summary scale of the SF-12, since the physical component summary scale was not a significant contributor to the models. Both final models showed significant paths from social support and health distress to well-being which was a moderator for medication adherence. Additional significant variables were alcohol intake for veterans with hypertension and PTSD, and the number of medical diagnoses for veterans with hypertension. However, in both groups, only a small portion of the variance on medication adherence was explained.

### Discussion

Although the variances were small, the significant paths provide clinical application. Practice implications for nurses in the primary care setting should include: teaching about the effects of high alcohol consumption on blood pressure; providing options of programs to decrease health distress in veterans with hypertension; and offering opportunities of a support group to those veterans who feeling isolated without a social support system. Strategizing interventions for veterans who are at risk for suboptimal adherence will lead to prevention of complications from poor blood pressure control.

### Problem Identification

Approximately 75 million adults in the United States who are diagnosed with hypertension (HTN) take antihypertensive medications. Failure to adhere to the prescribed regimen for antihypertensive medication leads to uncontrolled blood pressure, increasing the risk of complications, permanent disabilities, and high mortality rates (Roger et al., 2012). Despite the Healthy People 2020 national agenda for Americans recommending increased awareness of stroke symptoms and activation of the emergency medical system for timely treatment, stroke continues to be a leading cause of disabilities in the United States, with estimated treatment costs of \$73.4 billion (Centers for Disease Control and Prevention, 2012; Institute of Medicine, 2010). Among veterans, approximately 15,000 of those diagnosed with hypertension are hospitalized yearly for strokes, resulting in medical costs of more than \$100 million (Department of Veterans Affairs Health Services Research & Development Hypertension and Stroke, 2011).

Recently, research findings showed that veterans who were exposed to combat had a greater risk of developing HTN (Granado et al., 2009). Traumatic experiences are common among veterans because of the constant threat of harm experienced in combat. Bedi and Arora (2007) reported that over time the sympathetic nervous system is activated from traumatic memories, inducing a stress response and impacting health. Consequently, post-traumatic stress disorder (PTSD) was found to be associated with HTN because of increased sympathetic activity, including increased heart rate and blood pressure due to increased stress (Bedi & Arora, 2007; Kibler, Joshi, & Ma, 2008). Identifying factors that are associated with antihypertensive medication adherence among veterans with HTN and veterans with both HTN and PTSD will ultimately lead to

strategies that will enable us to identify suboptimal medication adherence and potentially prevent complications from uncontrolled blood pressure.

### Theoretical Framework

Connelly's (1993) Model of Self-Care in Chronic Illness is an extension of the Health Belief Model first developed by Hochbaum in the 1950s (as cited in Glanz, Rimer, & Viswanath, 2008). One focal point of the Health Belief Model is that individuals will take preventative measures if they understand the potential complications of their illness. Connelly's (1987) model added dimensions of self-care behaviors that focus on adherence to the treatment of chronic diseases in veterans. Connelly's extension depends on predisposing factors where patients choose to employ self-care behaviors and on enabling factors that either assist or obstruct the patients' behaviors. Two predisposing factors (the patient's health motivation and perceptions of the seriousness of the illness) and two enabling factors (the patient's psychological status and social support) are addressed in this study (Connelly, 1993). Other factors found to be associated with medication adherence in veterans were their perceived involvement in their hypertensive treatment (Ren, Skinner, Lee, & Kazis, 2002), alcohol consumption (Bryson et al., 2008), and degree of comorbidity (Fix, et al., 2014) were also examined (Figure 4.1).

Previous research has demonstrated that there are both positive and negative relationships among predisposing factors, enabling factors, and other variables. Multiple comorbid diagnoses and increased alcohol consumption were negatively associated with patients' psychological well-being (an enabling factor) and antihypertensive medication adherence (Braithwaite et al., 2005; Bryson et al., 2008; Friedman & Ryff, 2012).

Another study showed that older adult patients with decreased psychological well-being (an enabling factor) were found to have less motivation (a predisposing factor) related to their physical and cognitive activities (Hess, Emery, & Neupert, 2011). However, greater social support (an enabling factor) from patients' families, friends, and significant others were positively associated with psychological well-being, PTSD symptoms, and antihypertensive medication adherence (Fontana, Rosenheck, & Horvath, 1997; Laffaye, Cavella, Drescher, & Rosen, 2008; Merz & Huxhold, 2010; Ren, Skinner, Lee, & Kazis, 1999).

Even though HTN is a serious or even fatal illness with the potential of devastating complications, some patients do not consider it a serious illness (a predisposing factor) in comparison to symptomatic diseases (McDonald-Miszczak, Wister, & Gutman, 2001). If patients do not consider their HTN to be serious, they may not consult their healthcare provider often enough, and they may consequently develop multiple physical problems associated with uncontrolled HTN. Connelly (1987) described the importance of the relationship between the patient and his or her healthcare provider in improving the patient's participation in self-care. A positive association was found in blood pressure control in patients who perceived higher involvement with their physician, which included information exchange during their clinic visits (Cooper et al., 2011). Veterans who perceived that they were involved in their care had greater antihypertensive medication adherence (Ren, Kazis, Lee, Zhang, & Miller, 2002).

Based on these findings, the overall aim of the present study was to compare veterans with HTN to veterans with HTN and PTSD, with regards to variables thought to be associated with antihypertensive medication adherence. These two groups were

chosen to compare differences between them with medication adherence to improve health among hypertensive veterans. Variables were selected using Connelly's (1987) Model of Self-Care in Chronic Illness and previous research. The overall purpose was to examine direct and indirect effects of predisposing factors (veterans' health motivation and perception of the seriousness of their illness), enabling factors (veterans' well-being and social support), and number of comorbid diagnoses, alcohol intake, and perceived involvement in hypertensive treatment on antihypertensive medication adherence. Additional data examined included antihypertensive medication pharmacy refills, and blood pressure data.

## Methods

### Sample

After approval by the Institutional Review Boards of VA CT Healthcare System and University of Utah, the Veterans Health Information Systems and Technology Architecture (VISTA) was used to obtain diagnosis codes at VA CT Healthcare System. The International Classification of Diseases (ICD) identified 2,400 patients receiving care in primary-care clinics for HTN only and HTN and PTSD. The 2,400 eligible patients were divided into two groups of 1,200 for mailed surveys. The first 1,200 were divided into two groups of 600, with one group diagnosed with HTN only and the other group with a combination of HTN and PTSD.



### Inclusion and Exclusion Criteria

Inclusion criteria included the patient's ability to speak English, 21 or more years of age, assignment to a primary-care provider, and a diagnosis of HTN and/or HTN and PTSD in the past 12 or more months. Participants were not considered eligible if they had a history of traumatic brain injury, drug addiction, or major psychiatric diagnoses of psychosis or schizophrenia disorders, since all of these factors may disable cognitive functioning (Bowie, Reichenberg, Patterson, Heaton, & Harvey, 2006; Jorge, 2005).

### Design

A cross-sectional design was used to examine factors influencing antihypertensive medication adherence. The veterans were selected from all veterans with HTN only or HTN and PTSD who were receiving care at the primary-care clinic. In the first group of 1,200 veterans, a total of 1,199 (one name and address was a duplicate) potential participants were mailed questionnaires (599 for veterans with HTN only and 600 for veterans with HTN and PTSD). An initial sample applicant pool of 1,199 veterans was based on an anticipated conservative response rate of 20% returned surveys, and financial considerations, as opposed to the greater response rate of 40% suggested by Dillman, Smyth, and Christian (2009). A letter was mailed with the survey booklet explaining the study and seeking voluntary participation. Return of the survey booklet indicated consent to participate in the study and consent to review their medical charts for designated information. There were 448 respondents who returned the surveys, 96 (22.3%) surveys were missing data, after medical records were reviewed, a total of 428 (95.5%) met the inclusion criteria (Figure 4.2).

A mailed survey was selected because of its convenience for the participants, thus helping participants to feel more relaxed in the privacy of their own homes (Dillman et al., 2009). To enhance the response rate an incentive of a \$20 gift card was offered after the participants returned the surveys. Personal identifiers were removed to maintain protection of the respondents throughout the study. Surveys were marked with a unique identifier indicating either HTN only or HTN and PTSD.

#### Approach to Data Analysis

The required sample size for path analysis has been estimated to be 10-20 times the number of parameters (Kline, 2011). The proposed path model had 24 parameters (paths and variables), requiring a minimum sample size of 120 per path model, to achieve a power of 0.80 as a two-tailed test with  $\alpha = 0.05$ , and a moderate effect size. Figure 4.3 shows the proposed theoretical path model with four variables from Connelly's Model of Self-Care in Chronic Illness and three from the literature. The four theoretical variables were selected based on their relevance to general self-care and medication self-care behaviors: 1) health motivation, 2) the veterans' perceptions of the seriousness of hypertension, 3) well-being, and 4) social support. Three additional variables selected from previous research and thought to be influential on medication adherence were: 1) degree of comorbidity, 2) amount of alcohol intake, and 3) the patient's perceived involvement in care. The outcome variable is medication adherence.

## Instruments

Instruments with previous demonstration of adequate internal consistency were selected to measure the constructs from Connelly's Chronic Illness Model (1987) and from the literature. The seven measures for this study included: the alcohol use disorder identification test, the multidimensional scale of perceived social support, the health distress scale, the health motivation scale, the short form (SF) -12, the perceived involvement of care scale, and the Morisky medication adherence scale. In addition, the Charlson comorbidity index was used for medical diagnoses from the computerized patient record system. Table 4.1 describes the instruments, screening tools, and internal consistency (Cronbach's alpha).

The Charlson comorbidity index is a measurement tool for mortality rates but was used in this study to assess the number of diagnoses between the veteran groups. The index measured 19 diseases with weighted scores from 1 to 6 points. In this study, the total scores ranged from 0 to 33. In a review of 13 various methods to evaluate comorbidity, the Charlson comorbidity index was used with the International Classification of Diseases (ICD)-9 records, and demonstrated predictive validity (de Groot, Beckerman, Lankhort & Bouter 2003).

The alcohol use disorder identification test-consumption is a screening tool used to identify patients at risk for alcohol misuse. There are three questions with potential responses from 0 to 4, (0=never; 4=4 or more times a week; 0=1 or 2, 4=10 or more; 0=never; 4=daily or almost daily) resulting in a possible summed range of 0 to 12. Higher scores indicate higher risk of alcohol misuse (Bryson et al., 2008; Bush, Kivlahan, McDonell, & Fihn, 1998). Bradley et al. (1998) reported correlations with these questions

which were asked once and again 3 months later in 264 patients with a test-retest reliability of 0.65 to 0.85.

The multidimensional scale of perceived social support scale evaluates the respondent's perceived support from family, friends, and significant others. The scale has 12 items, each with a 7-point Likert-type scale (1=very strongly disagree, 7=very strongly agree) with possible scores of 12 to 84. Internal consistencies were 0.90, 0.94, and 0.95 for family, friends, and significant other subscales, respectively (Dahlem, Zimet & Walker, 1991). Higher scores indicate stronger social support from family, friends, and significant others (Zimet, Powell, Farley, Wekman, & Berkoff, 1990).

The health distress scale evaluates a patient's perception of the seriousness of having an illness (in this study, the illnesses are HTN and PTSD). The scale consists of four items scored using a 5-point Likert-type (0=none of the time, 5=all of the time) response format for a possible range of 0 to 20. Higher scores indicated more health distress. Internal consistency was 0.87 (Lorig et al., 1996; Stanford School of Medicine, 2013). Higher scores indicated the veterans with HTN and PTSD had increased distress about one's health (Stanford School of Medicine, 2013).

The health motivation scale evaluates patients' level of motivation and the association with healthy behaviors (Moorman & Matulich, 1993). The health motivation scale consists of eight items measuring subscales of active and passive health motivation, with the scoring of 8 to 56. Internal consistencies were 0.75 and 0.85 for passive and active subscales, respectively (Shoham, Saker, & Gavish, 2012). For this study, one item was deleted due to an error in the survey booklet. An example of active health motivation is a person who tries to prevent health problems before he or she feels ill. An example of

passive health motivation is a person who worries about a health issue but does not try to make changes. Each item was scored using a 7-point Likert type response scale (1= very strongly agree, 7=very strongly agree) resulting in a possible scoring range of 7 to 49. Internal consistency was 0.82 for the truncated scale with the missing item. Higher means indicate an increase in health motivation (Labig, Zantow, & Peterson, 2005; Moorman & Matulich, 1993; Shoham et al., 2012).

The SF-12 (Version 2) is the shorter version of the SF-36 designed from the Medical Outcomes Study (Quality Metric, 2012; Ware, Kosinski, & Keller, 1996). Certain items are reversed coded with higher summation scores indicating better physical and mental health (Quality Metric, 2012). The SF-12 has 12 items from which two summary scales can be generated: the physical component summary (PCS) and mental component summary (MCS) subscales (Ware, et al., 1996). Internal consistencies were 0.80 and 0.78 for the physical and mental summary scales, respectively (Larson, Schlundt, Patel, Beard, & Hargreaves, 2008). The PCS was not a significant contributor to the path model.

The perceived involvement of care scale is a 13-item scale with dichotomous responses (0=disagree, 1=agree) measuring the patient's perception of his or her healthcare (Lerman et al., 1990). The summation scores can range from 0 to 13. Internal consistency was 0.73 for the total scale (Lerman et al., 1990). Higher scores indicate greater perceived involvement in care (Lerman et al., 1990; Rodriguez, Appelt, Switzer, Sonel, & Arnold, 2008).

The Morisky medication adherence scale is an 8-item scale. Seven questions used a dichotomous response (yes=0, no=1); the eighth item was transformed into a

dichotomous response format in this study as suggested by Gatti, Jacobson, Gazmararian, Schmotzer, and Kripalani (2009). In this study, item eight was collapsed as yes or no, with never/rarely as 0 and the other four items as 1 to match the rubric of the seven other items. In addition, item eight showed a lack of response variability because most veterans answered that they never/rarely/once in a while had difficulty remembering to take their medications, 94.9% and 91.2%, respectively, for veterans with HTN and PTSD. Scores for all eight items (yes=1, no=0) were summated as a continuous variable and reversed coded for ease of interpretation. In this study, higher summated scores reflected higher medication adherence.

### Data Analysis

Research Electronic Data Capture (REDCap; Harris, et al., 2009) was used for data entry. Data were double entered and checked for errors. Medical record data were also checked for errors three separate times using a random sample of 10% of extracted data. Missing data from 96 (22.3%) surveys were recovered by telephoning participants and by re-mailing pages with missing data to participants. In the final data set there were 12 (2.8%) randomly missing data points that were unable to be recovered.

Chi-square tests were conducted to compare characteristics of veterans with HTN only to veterans with HTN and PTSD. Evaluation of differences between groups was assessed using independent *t*-tests for the continuous variables. Descriptive statistics were used for years diagnosed to assess years diagnosed with HTN and PTSD. A medication possession ratio was calculated using pharmacy refill data for antihypertensive medications and correlated with self-reported medication adherence (Krousel-Wood et al.,

2009; Shah, Steiner, Vermeulen, Fleming, & Cory, 2007). Pearson product moment correlations were used to evaluate positive and negative relationships of the variables within the proposed path model. A path analysis was conducted to examine direct and indirect effects on the medication adherence.

Using Analysis of Moment Software (AMOS; version 22; IBM Corporation, 2013), a path model was drawn and tested to assess the direct and indirect effects of theoretically selected variables on antihypertensive medication adherence. There are 8 observed variables and the calculation of data points (sample moments) is  $[8 * (8+1)/2] = 36$  (Byrne, 2010). Figure 4.3 shows the proposed path model with 6 correlations (curved paths), 10 regression coefficients (paths), 8 factor variances (exogenous and endogenous variables), and 4 error variances, for a total of 28 parameters (24 free parameters) with 12 degrees of freedom. The path model was reduced sequentially by eliminating insignificant paths until a final solution with acceptable fit to the data were achieved (Clayton & Pett, 2010).

## Results

A total of 428 participants were recruited for the study—241 in the HTN only group and 187 in the HTN and PTSD group. A summary of the differences in characteristics between groups for race, marital status, education level, and age are presented in Table 4.2. Participants in both groups were mostly male, but participants with HTN and without PTSD were more likely to be older, widowed, and Caucasian ( $p < .01$ ). Participants with HTN and PTSD were more likely to be divorced or separated ( $p < .01$ ).

Differences in the survey instruments between veterans with HTN only and veterans with HTN and PTSD are shown in Table 4.3. Veterans with HTN and PTSD had greater concern about their HTN and felt more discouraged about consequences from HTN ( $p<.01$ ). They also had a decreased sense of psychological well-being, less perceived support from family, friends, and significant others ( $p<.01$ ).

Results for length of time with diagnoses, blood pressure, medications, and pharmacy refills with self-report of medication adherence are presented in Table 4.4. The  $t$ -test showed veterans with HTN and the additional diagnosis of PTSD had higher blood pressures ( $p=.01$ ). The blood pressure data were collected from the electronic medical record that was documented at their primary care visit. The medication possession ratio is a calculation of medication refills. The medication possession ratio (MPR) had a positive relationship ( $r=.323$ ;  $p<.01$ ) with adherence, presented in Table 4.5. As the MPR increased, adherence also increased.

### Model Fit

Initially all variables were evaluated for their direct and indirect effects on antihypertensive medication adherence among the entire sample of 428 veterans (Figure 4.3). Because initial results showed that the data did not fit the proposed model, modification indices were examined and where appropriate, were used to improve the model fit. Paths were deleted sequentially until all retained paths were statistically significant for their direct and indirect effects on antihypertensive medication adherence.



### Final Path Models

In the path analysis, each group was tested for significant paths among the variables. The number of comorbid diagnoses, social support, and health distress were significant and remained in the final path model for the veterans with HTN only (Figure 4.4). The number of comorbid diagnoses and health distress had an inverse relationship with well-being. As the degree of comorbidity and health distress decreased, the veterans' well-being increased. Social support had a positive relationship, and as it increased, the veterans' well-being increased. Table 4.6 shows the degree of comorbidity, social support, and health distress, moderated by psychological well-being, had small indirect effects on the veterans' medication adherence. The path model only explained small variances ( $R^2$ ) of 16% of psychological well-being, and 9% of medication adherence (Figure 4.4).

Alcohol intake, social support, and health distress were significant and remained in the final path model for veterans with HTN and PTSD (Figure 4.5). Alcohol intake and health distress had an inverse relationship with well-being. As alcohol intake and health distress decreased, the veterans' well-being increased. Social support had a positive relationship with well-being. As the social support system increased, the veterans' well-being increased. Table 4.7 shows health distress, alcohol intake, and social support, moderated by psychological well-being, had small indirect effects on medication adherence. This path model explained a small variance ( $R^2$ ) of 23 % of psychological well-being, and only 3% of medication adherence (Figure 4.5).

### Discussion

One of the four theoretical factors from Connelly's (1993) model, the veterans' perceptions of the seriousness of hypertension (measured by health distress), had significant direct and indirect paths to medication adherence. The enabling factor of social support and the predisposing factor of health distress had positive and negative paths, respectively, to psychological well-being (measured by SF-12 MCS subscale). When veterans had more social support and less health distress, their psychological well-being increased. Fewer medical diagnoses in veterans with HTN only, and less alcohol consumption in veterans with HTN and PTSD, also increased psychological well-being. An increase in the number of comorbid diagnoses and less health distress had a direct association with medication adherence in veterans with HTN only.

Nurses evaluating antihypertensive medication adherence in both groups should assess patients' social support system and health distress level in planning care for the veterans. For example, veterans lacking a social support system because they are widowed or divorced may benefit from assistance from support groups. Veterans who had PTSD were reported to benefit from support with other veterans (Laffaye, Cavella, Drescher, & Rosen, 2008). Health distress in veterans may be alleviated with education about how to control their HTN. In addition, programs for exercise, relaxation, and sleep management may assist these veterans (Lorig, Ritter, & Gonzalez, 2003).

Among veterans with HTN and PTSD, a screening tool is used by clinicians, in Veterans Administration primary-care clinics, to assess alcohol consumption. Alcohol consumption may provide one way to assess those at risk for suboptimal antihypertensive medication adherence. Veterans may not realize the impact of alcohol on their blood

pressure and nurses can teach about the effects of high alcohol intake on blood pressure. In a recent study, participants did not realize that alcohol consumption increased blood pressure (Warren-Findlow, Seymour, & Huber, 2012).

A major limitation was the low variance ( $R^2$ ) found with medication adherence in both groups, which may be related to the complexity of this health issue. Findings showed psychological well-being does not influence medication adherence. Despite significant pathways, the indirect/direct effects and variances for the degree of comorbidity, alcohol intake, social support, and health distress did not explain the moderator of psychological well-being or the outcome variable of medication adherence. Even though the mailed surveys had a good response ( $n=428$ , 35.7%), 413 (68.8%) of veterans with HTN and PTSD did not respond, and 358 (59.7%) with HTN also did not respond to the survey. Veterans who did not respond may be due to their lack of adherence to antihypertensive medications and did not want to answer a survey about it. If data were available from the large percentage of veterans who did not respond, the variance for medication adherence may have increased. The finding for medication adherence was no significant difference in medication adherence between the two groups of veterans because they were adherent (mean 6.85, SD 1.65). Measuring the medication adherence on a Likert-type scale may have shown a difference.

The ICD-9 codes were a limitation because the diagnoses may not be current and did not provide the level of PTSD but were chosen because only medical diagnoses were requested in the mailed consent for the chart review. PTSD is a very complicated diagnosis, and mental health specialists diagnose PTSD from criteria in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). PTSD symptoms can change over

time, depending on treatment. Further research on comparing the treatments veterans receive for PTSD is another area to consider in relation to medication adherence.

Other limitations of this study include an exceptionally low number of female veterans and a lack of ethnic diversity. There has been a change in the number of women serving in the military which has increased after 1973 to 14% for those who enlisted into the armed forces and 24% for those who were deployed to a combat theater. Further, female veterans were recently found to be more at risk for PTSD than male veterans (Frayne et al., 2004; Patten & Parker, 2011). Future studies may want to make an extra effort to recruit female veterans who served after 1973.

In summary, nurses identifying veterans at risk for suboptimal antihypertensive medication adherence of less than 80% may consider assessing these factors of health distress and social support in both groups of veterans. Additional assessment of veterans with HTN and PTSD would include alcohol consumption, and veterans with HTN should include multiple medical diagnoses. In addition, the small variance in both path models show further research is needed on other variables, such as the variability of adherence levels, and self-care behaviors. Also, to investigate what adherence means to veterans with hypertension may lead to a better understanding of antihypertensive medication adherence. Providing veterans with the assistance they may need with medication self-care behaviors can help those veterans avoid complications, disabilities, and a loss of independence—something that is important for both the veteran and for optimal use of future healthcare resources.

Table 4.1

Instrument and Screening Tool Descriptions, Scoring, Interpretation, and Internal  
Consistency Reliability (Cronbach's alpha)

Variable	Instruments	<i>N</i>	Subscales	Items	Range	Internal Reliability
Health Motivation	Motivation Scale	426		8	8-56	0.82
		428	Active	4	3-21	0.91
		428	Passive	4	4-28	0.81
Perception of the seriousness of HTN	Health Distress Scale	428		4	0-20	0.93
Well-Being	SF-12 Scale	426		12	12-56	0.95
		427	Physical Component Summary	6	6-26	0.89
		427	Mental Component Summary	6	6-30	0.90
Social Support	MPSS	427		12	0-84	0.95
		427	Family	4	4-28	0.93
		427	Friends	4	4-28	0.94
		427	Significant Other	4	4-28	0.94
Perceived involvement in treatment	Perceived Involvement in Care Scale	424		13	0-13	0.84
		424	Doctor Facilitation	5	0-5	0.84
		424	Patient Involvement	4	0-4	0.81
		424	Patient Decision-Making	4	0-4	0.70
Antihypertensive medication adherence	Morisky Medication Adherence Scale	419		8	0-8	0.75
Alcohol Intake	Screening Tool AUDIT-C	426		3	0-12	

Note: MSPSS = Multidimensional Scale of Perceived Social Support; AUDIT-C = Alcohol Use Disorder Identification Test-Consumption.

Table 4.2  
 Characteristics of the Participating Veterans ( $n = 428$ )

	HTN		HTN+PTSD		Total		$\chi^2$	$p$	Cramer's $V$
	$n$	%	$N$	%	$n$	%			
Gender							1.24	.266	
Female	8	3.3	3	1.6	11	2.6			
Male	233	96.7	184	98.4	417	97.4			
Total	173	100.0	133	100.0	428	100.0			
Ethnicity							1.64	.200	
Hispanic or Latino	1	0.6	3	2.3	4	1.3			
Not Hispanic or Latino	172	99.4	130	97.7	302	98.7			
Total	173	100.0	133	100.0	306	100.0			
Race							7.93 <sup>1</sup>	.005	.14
American Indian	2	0.8	3	1.6	5	1.2			
Caucasian	232	97.5	169	91.4	401	94.8			
African American or Black	2	0.8	10	5.4	12	2.8			
More than one race	2	0.9	3	1.6	5	1.2			
Total	238	100.0	185	100.0	423	100.0			
Marital Status							29.66	.001	.27
Divorced, Separated	29	12.2	53	28.8	82	19.4			
Married, Significant	160	67.2	114	62.0	274	64.9			
Other									
Never Married	9	3.8	9	4.9	18	4.3			
Widowed	40	16.8	8	4.3	48	11.4			
Total	238	100.0	184.0	100.0	422	100.0			
Education Level							19.30	.001	.21
Less than high school	55	22.8	20	10.7	75	17.5			
Graduated from high School	104	43.2	68	36.4	172	40.2			
Attended/graduated college	66	27.4	83	44.4	149	34.8			
Received post grad degree or equivalent degree	16	6.6	16	8.5	32	7.5			
Total	241	100.0	187	100.0	428	100.0			
Occupation							76.39	.001	.42
Full-time employment	12	5.0	21	11.3	33	7.7			
Part-time employment	13	5.4	3	1.6	16	3.8			
Not employed due to disability	11.0	4.6	63	33.9	74	17.3			
Retired	205	85.0	99	53.2	304	71.2			
Total	241	100.0	186	100.0	427	100.0			
Age	Mean	SD	Mean	SD			$t$	$P$	
	76	9.1	66.7	8.7			11.89	.001	
					428	100.0			

Note. Note. HTN=hypertension; HTN+PTSD=hypertension and post-traumatic stress disorder; <sup>1</sup>data collapsed to Caucasians and persons of other races.

Table 4.3

Comparison of Veterans with Hypertension Only ( $n=241$ ) and Veterans with Hypertension and PTSD ( $n=187$ ) regarding Survey Instruments and Screening Tool

	HTN		HTN+PTSD		95% CI	<i>t</i>	<i>p</i>
	M	SD	M	SD			
Health Motivation Scale	4.74	1.11	4.87	1.18	-0.34, -0.10	-1.11	.274
Active	5.45	1.24	5.54	1.22	-0.33, 0.14	-0.78	.435
Passive	4.21	1.47	4.35	1.52	-0.43, 0.14	-0.98	.328
Health Distress	1.14	1.14	1.95	1.52	-1.07, -0.55	-6.09 <sup>1</sup>	.001
SF-12 Scale	38.27	4.20	35.87	4.32	1.58, 3.21	5.77	.001
Physical Component Summary	40.76	10.52	38.91	11.39	-0.25, 3.94	1.73	.084
Mental Component Summary	51.87	9.49	39.03	11.80	10.75, 14.93	12.10	.001
Multidimensional Scale of Perceived Social Support	5.55	1.22	4.83	1.46	0.47, 0.99	5.52	.001
Family Subscale	5.70	1.35	4.78	1.72	0.62, 1.22	6.00 <sup>1</sup>	.001
Friends Subscale	5.14	1.39	4.40	1.65	0.44, 1.03	4.84 <sup>1</sup>	.001
Significant Other Subscale	5.84	1.40	5.29	1.72	0.25, 0.86	3.54 <sup>1</sup>	.001
Alcohol Intake Summary	1.69	1.99	2.05	2.46	-0.80, 0.08	-1.62 <sup>1</sup>	.107
Perceived Involvement Care Scale	7.25	3.57	7.87	3.17	-0.43, 0.22	-1.87	.062
Doctor Facilitation Subscale	3.62	1.71	3.73	1.68	-0.43, 0.22	-0.62	.538
Patient Information Subscale	2.55	1.51	2.83	1.44	-0.57, -0.00	-1.97	.048
Patient Decision Making Subscale	1.06	1.23	1.30	1.27	-0.48, 0.01	-1.91	.058
Morisky Medication Adherence Scale	7.14	1.30	6.48	1.97	0.33, 0.99	-2.25 <sup>1</sup>	.025

Note. <sup>1</sup>*t*-test for unequal variances. Note. HTN=hypertension; HTN+PTSD=hypertension and post-traumatic stress disorder. Not all *n*'s=241 and 187 due to missing data.

Table 4.4

## Years of Diagnoses, Blood Pressure Data, and Medications

	HTN			HTN+PTSD			<i>t</i>	<i>p</i>
	<i>n</i>	M	SD	<i>n</i>	M	SD		
Years diagnosed with HTN	241	9.16	5.81	186	8.08	5.0	2.01	.045
Years diagnosed with PTSD				<i>n</i>	M	SD		
				186	3.02	4.57		
Mean BP	<i>n</i>	M	SD	<i>n</i>	M	SD	-2.60	.010
	241	91.42	10.59	184	94.04	9.85		
	HTN		HTN+PTSD		Total			
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
Medications								
Less than 8	94	68.6	43	31.4	137	100		
8 or more	147	50.9	142	49.1	289	100		

Note. HTN = hypertension; PTSD = post-traumatic stress disorder, range 1-18 years; BP = mean blood pressure; MBP= mean blood pressure.

Table 4.5

## Medication Possession Ratio and Self-Reported Adherence

		Adherence
Mean of MPR	Pearson Correlation	.323*
VA Pharmacy	Sig. (2-tailed)	.000
	N	299

Note. MPR = medication possession ratio; VA pharmacy.

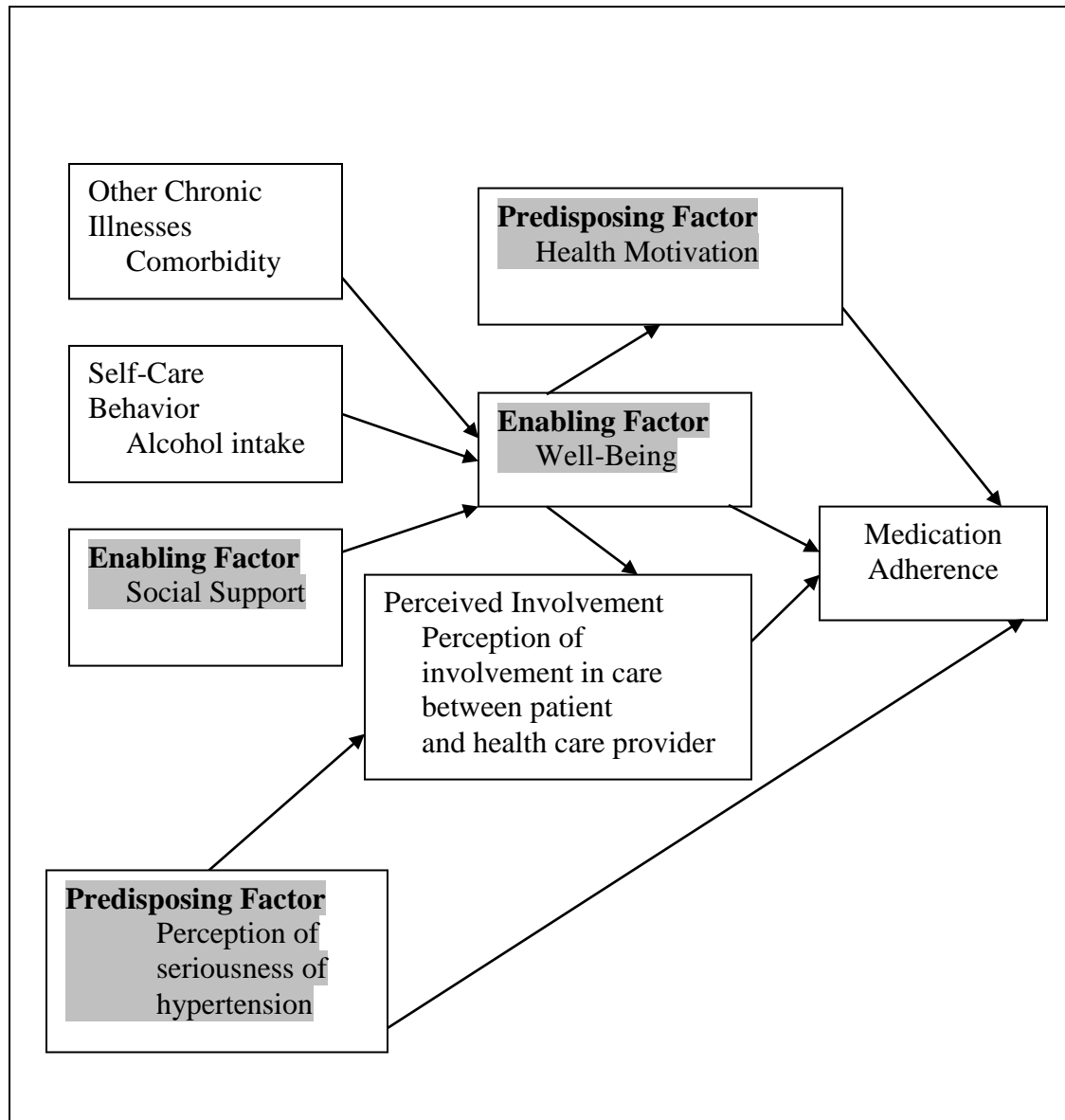


Table 4.6  
 Path Coefficients  
 Summary of Reduced Model for the Veterans with HTN ( $n = 241$ )

Variable	Medication Adherence		
	Direct	Indirect	Total
Comorbidity	0.14	-0.03	0.11
Social Support	-	0.05	0.05
Health Distress	-0.19	-0.04	-0.23
Mental Health	0.18	-	0.18

Table 4.7  
 Path Coefficients  
 Summary of Reduced Model for the Veterans with HTN and PTSD ( $n = 187$ )

Variable	Medication Adherence		
	Direct	Indirect	Total
Alcohol Intake	-	-0.03	-0.03
Social Support	-	0.05	0.05
Health Distress	-	-0.07	-0.07
Mental Health	0.18	-	0.18



*Figure 4.1.* Theoretical Model from Connelly (1987) Model of Self-Care in Chronic Illness and Variables from the Literature. Boxes with Gray Highlights are Variables. Adapted from “Self-Care and the Chronically Ill Patient,” by C.E. Connelly, 1987, *Nursing Clinics of North America*, 22, p. 623.

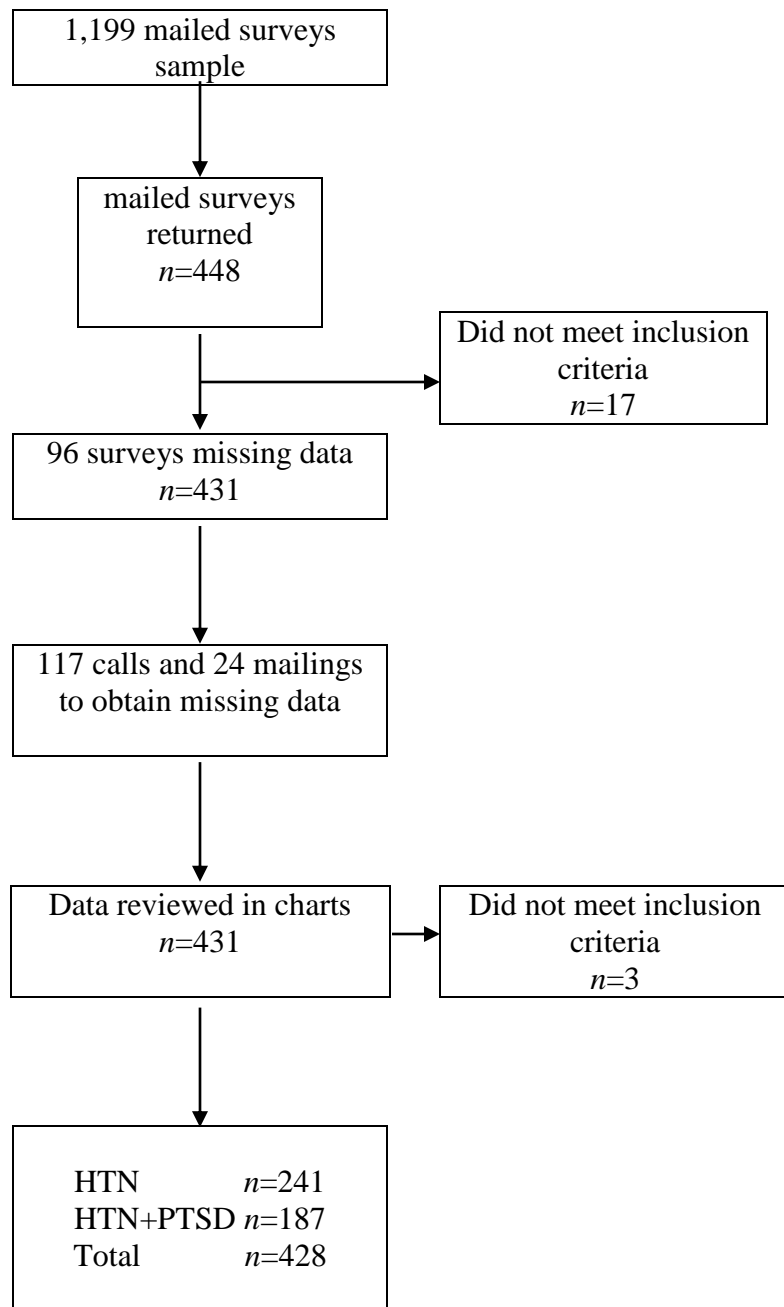
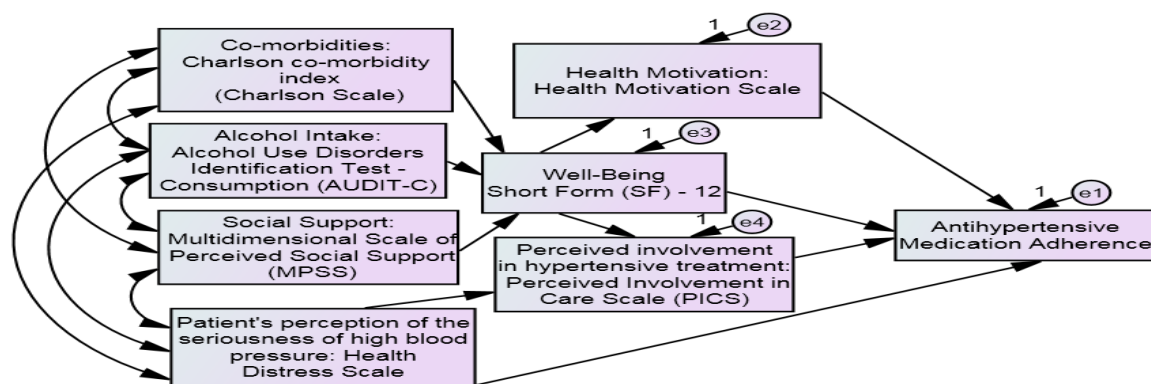
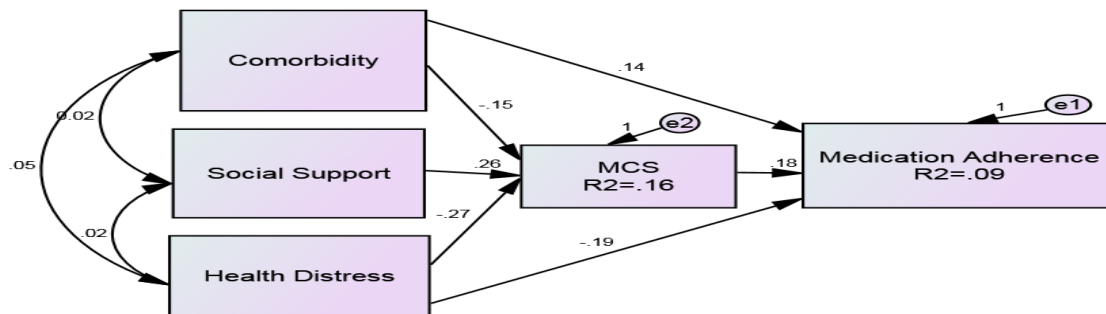


Figure 4.2. Recruitment Diagram.

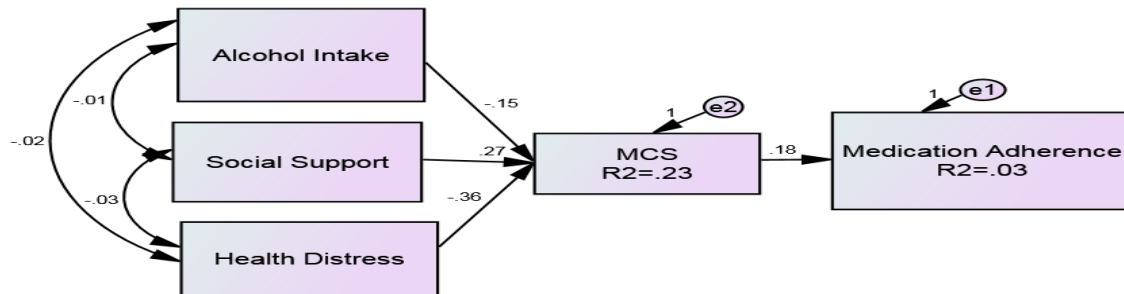


*Figure 4.3.* Proposed Path Model Incorporating Connelly's (1987) Model of Self-Care in Chronic Illness and Variables from the Literature. Variables Selected from Connelly's Model were: the Predisposing Factors of Health Motivation and the Patient's Perceptions of the Seriousness of High Blood Pressure; and the Enabling Factors of Well-being and Social Support.



Path Model	$\chi^2$	df	<i>p</i>	CFI	RMSEA	RMSEA 90% CI	AIC	ECVI
	3.65	1.1	.06	.96	.105	.00 to .23	31.66	.132

*Figure 4.4.* Path Model for Medication Adherence using the Mental Component Summary Subscale of the SF-12 for Veterans with Hypertension ( $n=241$ ). CMIN/DF=3.04.



Path Model	$\chi^2$	df	$p$	CFI	RMSEA	RMSEA 90% CI	AIC	ECVI
	9.12	3.0	.03	.89	.105	.03 to .19	33.12	.178

*Figure 4.5.* Path Model for Medication Adherence using the Mental Component Summary Subscale of the SF-12 Veterans with Hypertension and PTSD ( $n=187$ ). CMIN/DF=3.66.

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## Addendum to Chapter 4

### Results

A cross-sectional design was used to evaluate variables for direct and indirect effects on antihypertensive medication adherence among veterans diagnosed with hypertension (HTN) and those veterans diagnosed with both HTN and post-traumatic stress disorder (PTSD). Data collection from mailed surveys occurred from August 2013 to January 2014, and data were entered into the Research Electronic Data Capture (REDCap) through the University of Utah. Analyses of data were conducted with descriptive statistics, Chi-square test, independent *t*-test, Pearson product moment correlations, analysis of variance, and path analysis.

### Theoretical Framework

The Model of Self-Care in Chronic Illness is dependent upon patients' outcomes with self-care behaviors (Connelly, 1987). Predisposing factors which contribute to self-care (health motivation and veterans' perceptions of the seriousness of the illness), and enabling factors which facilitate self-care behaviors (well-being and social support) were examined with three additional variables from literature (number of comorbid diagnoses, alcohol intake, and veteran's perceived involvement in care; Bryson et al., 2008; Connelly, 1993; Fix, et al., 2014; Ren, Kazis, Lee, Zhang, & Miller, 2002). The direct and indirect relationships of these variables on medication adherence were examined.

## Methods

### Sample

After approval by two Institutional Boards, a convenience sample of veterans with HTN and HTN and PTSD was recruited from the primary clinics at VA CT Healthcare System (inclusion and exclusion criteria is described in Chapter 4). There were 2,400 veterans eligible for the study. The first 1,200 were selected and an initial sample pool of 1,199 (1 patient duplicated was deleted) were mailed the survey packet. Financial consideration was taken into account when considering the number of initial surveys to be mailed. An excellent response of 35.7% was obtained thus we did not send reminder postcards to the remaining veteran pool of potential participants. The final sample was  $n=428$  (431 HTN only, and 187 HTN and PTSD). A detailed description of how groups were identified is explained in Chapter 3 and descriptive and inferential statistics are described in Chapter 4.

The sample was comprised of 417 (97.4%) males and 11 (2.6%) females, with 401 (94.8%) of the sample self-identifying as Caucasian ( $p<.01$ ). Mean age was 76 years for participants with HTN and 66.7 years for participants with both HTN and PTSD ( $p<.01$ ). The vast majority of veterans in both groups had an educational level of high school or higher.

### Missing Data and Data Cleaning

Survey data were double-entered into Research Electronic Data Capture (REDCap; Harris, et al., 2009) and each entry was compared for errors. Errors were rechecked using original surveys and corrected in REDCap until all data were entered

correctly. Surveys were remailed to participants who were missing one or more full pages of the survey, requesting that they complete the survey. Those participants who missed random questions were telephoned for the information. These participants were telephoned one to four times, during weekdays and weekends, and at different times of the day and early evening in an effort to capture all possible data. Missing data from 96 (22.3%) surveys were recovered by telephoning participants. In the final data set there were 12 (2.8%) missing data points that were unable to be recovered.

A data extraction form (Appendix C) was designed for the computerized medical records to validate blood pressures, medications, prescription refills, and medical diagnoses. The medication possession ratio (MPR), a method used for assessing antihypertensive medication adherence with prescription refills, was calculated for each antihypertensive medication refill listed in the computerized medical record. If a participant used more than one antihypertensive medication, an average was documented. The MPR was calculated as follows: the numerator was the sum of the total days of supply minus the last refill supply, and the denominator was the difference between the last refill date and first refill date (Shah, Steiner, Vermeulen, Fleming, & Cory 2007). The range for medication adherence was from 0.8 to 1.0 (80 to 100%) for antihypertensive medication adherence. For example, a veteran had five, 90 day refills, for 450 pills for the days supply; the last refill of 90 days was subtracted for the numerator. The patient had the first refill on 9/26/2012 and last refill on 9/26/2013 for the denominator which provided the number of days. The result was 0.986 for 99% adherence. Example of calculation:

$$\text{MPR} = \frac{\text{All days' supply (450)} - \text{last day's supply (90)}}{\text{Last refill date (09/26/2013)} - \text{first refill day (09/26/2012)}} = 0.986$$

Accuracy of the data extraction form in REDCap was checked. First, 10% of the MPRs were calculated by hand to confirm the data were correct in comparison to the computerized calculations in REDCap. Second, the computerized data extraction form was checked for data entry errors by reviewing 10% of charts for the original sample of 431, which was 43.1 (rounded to 43), and divided into 23 and 20 charts for review of each diagnostic group. This procedure was for accuracy of data through a computerized randomization. A coin was flipped each time to decide which group had 23 or 20 charts reviewed. This procedure was completed three times until the percentage of errors was less than 5%, and the last review was 3.68%.

Areas containing the most data entry errors were: first, the Charlson Comorbidity Index, because not all the ICD-9 codes were listed under patient problems; second, appointment and blood pressure data, because of various documentation methods; and third, refill dates for the MPR were did not equal an exact number of 12 months (for example, refills for 90 days changed to only a 30-day supply).

Missing data from the mailed surveys which were unable to be retrieved did not show any systematic pattern and is a missing at random (MAR) pattern (Byrne, 2010). Missing answers from the questionnaires were in the areas of social support, alcohol intake, involvement in care, and medication adherence. Expectation maximization (EM) was the method used for data MAR to estimate missing values from the observed parameters (Tabachnick & Fidell, 2007).

### Data Analysis

Chapter 4 describes the approach to data analysis and the results of descriptive statistics, Chi-square for veterans' demographics, *t*-tests for age and blood pressure data, and Pearson product moment correlations for pharmacy refill data with self-reported medication adherence. Regression analysis and analysis of variance (ANOVA) were conducted to determine predictor variables on the dependent variable. Pearson product moment correlations were conducted between the variables and diagnoses, in addition to correlations between age and medication adherence.

On the mailed survey, the veterans were allowed to choose more than one answer for reasons not taking their medications. Frequencies of the responses from the 428 veterans were: "I always take my medications ( $f = 398$ )"; "I may not take it due to cost ( $f = 8$ )"; "I may not take medication due to a change in my schedule ( $f = 23$ )"; "I may not take my medication because I feel fine ( $f = 30$ ).” The findings showed veterans reported that they were adherent.

### Regression Analysis and Correlations

Prior to testing the path model, a regression model was conducted with the independent variables which demonstrated only a portion of the variance (11.9%) explained the dependent variable of medication adherence (Table 4.8). The analysis of variance in Table 4.9 shows the predictor variables which were significant except for the perceived involvement in care variable. Table 4.10 presents the regression analysis coefficients with significant independent variables of degree of comorbidity, alcohol intake, social support, and health distress on the dependent variable of medication



adherence.

### Psychometrics and Comparisons of Instruments

Seven measures were employed in the mailed surveys, and the Charlson Comorbidity Index was used with the electronic chart review. All instruments in this study had adequate psychometric properties as described in Chapter 4. The significant findings between groups were: health distress ( $<.01$ ), the SF-12 and Mental Component Summary scale (MCS;  $<.01$ ), the full and subscales of the Multidimensional Scale of Perceived Social Support ( $<.01$ ).

### Model Fit

The proposed theoretical path model for both diagnostic groups was evaluated for fit of the data, sequentially deleting least significant paths until all retained paths demonstrated a relationship with medication adherence (higher scores reflected better level of medication adherence). Chi-square was high at 103.48 and nonsignificant, but did not show adequate fit. Comparative fit index (CFI) was .51 ( $>.90$  considered as good fit), and root mean square error of approximation (RMSEA) was .195 ( $<.05$  considered good fit). In assessing the proposed theoretical model with the independence model, which is the statistical model (Kline, 2011), the Akaike information criterion (AIC), and the expected cross validation index (ECVI) were both lower, which is desirable. However, the data did not fit the proposed theoretical model, so model modifications were evaluated to improve the fit of the model to the data.

Examination of modification indices suggested deletion of paths from alcohol

intake and perceived involvement to improve the parameters. These paths were not significant as indicated by critical ratios less than 1.96, and were deleted from the model one at a time. Final path model with SF-12 (Figure 4.6) for all participants showed exogenous and endogenous variables had decreased from a total of eight to six within the model. Social support showed a positive association, and degree of comorbidity showed a negative association with the SF-12. Health distress showed a negative relationship, whereas health motivation showed a positive relationship with medication adherence. The SF-12 had a positive association with health motivation and medication adherence. However, only a small portion of the variances explained the SF-12, health motivation, and medication adherence.

All of the variables were added back into the model with the SF-12 separated into physical and mental component summaries. The results showed the physical component was not a contributor to the model. Modification indices suggested a path from PTSD to medication adherence which resulted in an improvement in AIC, the comparative-fit index improved which increased to .99, and RMSEA decreased to .09. However, the ECVI showed the default model close to saturation, which was a just-identified model with no degrees of freedom, and rejection of the null hypothesis would not be possible (Byrne, 2005; Kline, 2011).

Final path model with MCS from the SF-12 was conducted for all participants (Figure 4.7). Further examination of modification indices suggested relationships (added paths) from health distress alcohol intake, PTSD, social support and health distress to mental health. In addition, paths from alcohol intake and health distress were added to medication adherence. The variables explained 41% of the variance on mental health.

However, only 10% of the variance explained medication adherence.

In summary, the model derived from theory did not fit the data. Modification indices which utilize mathematical relationships were employed to improve fit of the model to the data as opposed to theoretically derived relationships among variables. Two variables deleted were perceived involvement in care and health motivation which were not significant. Significant direct and indirect paths were alcohol intake, degree of comorbidity, social support, health distress, and the mental component summary on medication adherence. The discussion of the final models for veterans with HTN only and veterans with HTN and PTSD were analyzed separately by groups is described in Chapter 4.

Table 4.8  
Regression Model Summary

Medication Adherence Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
	.366	.134	.119	1.546

Note: Analysis accounted for 11.9% of the variance on the dependent variable.

Table 4.9  
Analysis of Variance (ANOVA)

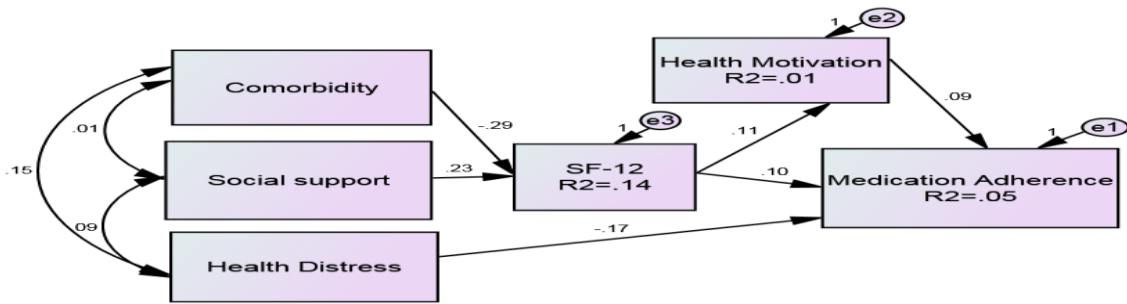
Medication Adherence Model	Sum of Squares	Df	Mean Square	F	Sig
Regression	155.23	7	22.18	9.27	.000
Residual	1004.35	420	2.39		
Total	1159.58	427			

Note. Predictors in model = degree of comorbidity, alcohol intake, social support, patient's perception of the seriousness of high blood pressure, health motivation, well-being. Dependent variable = medication adherence.

Table 4.10  
Regression Analysis  
Coefficients<sup>a</sup>

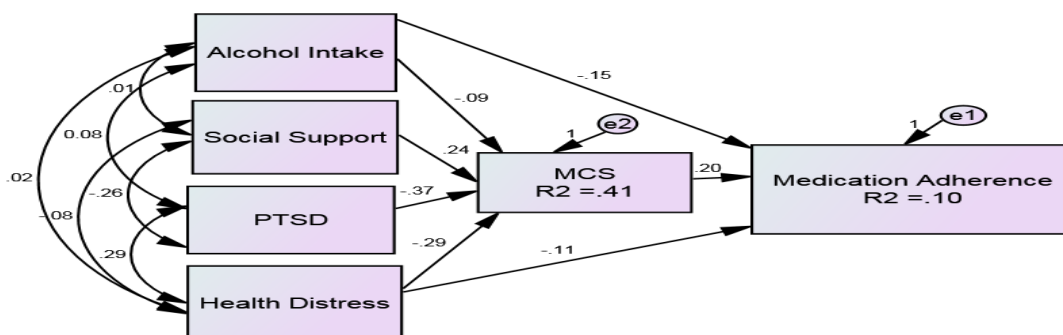
Variables	B	<i>t</i>	<i>P</i>
HTN; HTN +PTSD	.10	1.91	.056
Health motivation	-.08	-1.77	.078
Well-Being	-.10	-1.87	.062
Comorbidity	-.12	-2.54	.011
Alcohol Intake	.15	3.24	.001
Social Support	-.12	-2.47	.014
Health Distress	.15	2.88	.004

<sup>a</sup>Dependent Variable: medication adherence.



Path Model with SF-12	$\chi^2$	Df	CFI	RMSEA	RMSEA 90% CI	AIC	ECVI
	103.48	6.0	.51	.195	.163 to .229	133.49	.313

Figure 4.6 Path Model with SF-12 for Medication Adherence for all Veterans (n=428).



Path Model with MCS	$\chi^2$	Df	CFI	RMSEA	RMSEA 90 % CI	AIC	ECVI
	8.50	2.0	.98	.087	.033 to .151	46.50	.109

Figure 4.7 Path Model with Mental Component Summary Scale (MCS) for Medication Adherences for all Veterans ( $n=428$ ).

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## CHAPTER 5

### SUMMARY

Hypertension (HTN) is a national health problem, with uncontrolled HTN leading to increased risk for stroke, the leading cause of long-term disability and the fourth leading cause of death nationally (Go et al., 2013). HTN is also a common diagnosis in the United States military, affecting more than 5 million veterans, (Furmaga et al., 2008). Suboptimal antihypertensive medication adherence leads to uncontrolled blood pressure and chronic disabling complications. Unfortunately, patients may not be cognizant of the complications from suboptimal antihypertensive medication adherence because HTN is an asymptomatic disease known as the “silent killer” (World Health Organization, 2013).

Recent findings show individuals with post-traumatic stress disorder (PTSD) have increased risk for HTN (Kibler, Joshi, & Ma, 2008). Under stressful situations, the sympathetic nervous system is activated by biological changes in the body that increase heart rate and blood pressure. Veterans exposed to combat are at risk for PTSD, a condition that may not be immediately apparent when they return home but may occur months later (Boscarino, 2008; McFarlane, 2010). This study was designed to ultimately lead to improved strategies nurses can use when assessing veterans with HTN only and veterans with both HTN and PTSD, who are at risk for suboptimal antihypertensive medication adherence.



### Theoretical Framework

The theoretical model of Self-Care Behaviors in Chronic Illness (Connelly, 1987) describes predisposing factors that engage patients in their self-care behaviors and enabling factors that assist or hinder self-care behaviors. This study tested the predisposing factors of patient health motivation and veterans' perceptions of the seriousness of HTN, and the enabling factors of patient well-being and social support using a path analysis for their direct and indirect effects on antihypertensive medication adherence (Connelly, 1993). Three other variables shown in previous research for their association with medication adherence were included in this study: degree of comorbidity, alcohol intake, and perceived involvement in care.

Empirical evidence from Connelly (1993) showed how medication self-care behaviors were associated with the patient's well being and perception of the seriousness of his/her illness. In addition, the patient's well-being and health motivation were associated with general health self-care behaviors. Social support was negatively correlated with medication adherence in Connelly's study (1993), but other researchers have found social support to be positively associated with antihypertensive medication adherence (Trivedi, Ayotte, Edelman, & Bosworth, 2008).

### Initial Results

The sample for this study was comprised of 428 veterans receiving care in the VA Connecticut Healthcare System. Veterans with HTN only and veterans with HTN and PTSD were compared for differences in variables thought to be associated with medication adherence. The survey measures were the health motivation scale, health

distress scale, SF-12 Scale, multidimensional scale of perceived social support, perceived involvement in care scale, alcohol use disorder identification test-consumption (AUDIT-C), and Morisky self-report medication adherence scale. In addition, the Charlson comorbidity index was employed for medical diagnoses documented in the patients' electronic medical record.

All veterans in the study had HTN, and half had the additional diagnosis of PTSD. Differences were found between the two groups of veterans. Veterans without PTSD were older, married, prescribed more medications, and diagnosed with multiple comorbid conditions. Veterans with both HTN and PTSD were younger, more likely to be separated or divorced, and higher alcohol intake. Even though most veterans in the study responded that they took their medications, the reasons for omitting doses of their medications included a change in their schedule and the fact that they were feeling fine.

The medication possession ratio is a calculation of pharmacy refills and was used in this study to validate self-reported on antihypertensive medication adherence (Shah, Steiner, Vermeulen, Fleming, & Cory, 2007). The medication possession ratio mean showed a negative relationship with poor adherence; an increase in the medication possession ratio is related to better antihypertensive medication adherence. The self-report was validated by the pharmacy data and showed that veterans ( $n=302$ ) were adherent in obtaining their antihypertensive medication refills. Mean blood pressure values were higher in veterans with both HTN and PTSD of 94.0 mmHg in comparison to veterans with HTN, who had a mean of 91.4 mmHg.

### Summary of the Path Model

The proposed path model was theoretically based on Connelly's (1987) model of Self-Care Behaviors in Chronic Illness. Predisposing factors of health motivation and veterans' perceptions of the seriousness of HTN (measured by health distress) and enabling factors of well-being and social support were tested for their association with medication adherence. Additional variables from previous research were degree of comorbidity, alcohol intake, and perceived involvement in care.

Results of the initial testing of the path model encompassed the entire sample of 428 veterans. The Chi-square was nonsignificant but not adequate to suggest that the data fit well with the model. In addition, the comparative fit index (CFI) was low ( $>.90$  is acceptable), and the root mean square error of approximation (RMSEA) was high ( $<.05$  is acceptable). To achieve better fit of the model to the data, modification indices were examined and suggested deletion of alcohol intake and perceived involvement in care due to the lack of a relationship with medication adherence. Subsequently, paths from health distress to perceived involvement in care and antihypertensive medication adherence were also deleted due to the lack of association with medication adherence.

To make the model more meaningful, the SF-12 was divided into the subscales of physical and mental health (well-being), and all of the variables re-entered into the path analysis for the final models of both groups. Adding a path from alcohol intake to well-being improved the fit of the model to the data. Variables deleted were health motivation and patient's perceived involvement in hypertensive treatment.

Further evaluations of modification indices were conducted and final path models were evaluated by veteran group. For veterans with HTN only the retained variables were

the predisposing factor of health distress, and the enabling factors of psychological well-being and social support. A retained variable selected from previous research was the number of comorbid diagnoses. The final model was determined to demonstrate adequate fit to the data. Findings showed indirect effects on medication adherence were fewer medical diagnoses ( $\beta = -.15$ ), less health distress ( $\beta = -.27$ ), and more social support ( $\beta = .26$ ), increased well-being ( $\beta = .18$ ). In addition, direct effects of increased number of medical diagnosis and less health distress increased medication adherence. However, only a small portion of the variance explained medication adherence.

The final model for veterans with HTN and PTSD retained the theoretical variables of the predisposing factor of health distress and enabling factors of social support, and well-being. A retained variable selected from previous research was alcohol intake. Findings showed indirect effects on medication adherence were less alcohol intake ( $\beta = -.15$ ), more social support ( $\beta = .27$ ) and less health distress ( $\beta = -.36$ ), increased well-being ( $\beta = .18$ ). This model also showed a small portion of the variance explained medication adherence. More details of the models are described in Chapter 4 and in the Addendum to Chapter 4.

### Limitations

The unexplained variances in both final models show further research is required in medication adherence with other variables and self-care behaviors. Despite a good response with the mailed surveys ( $n=428$ , 35.7%), many veterans with HTN and PTSD did not respond ( $n=413$ , 68.8%) as well as veterans with HTN only ( $n=358$ , 59.7%). If all of the veterans responded, the variances may have been different for medication

adherence. Veterans who were not participants in the survey may not be adherent with their antihypertensive medications and did not want to share that information. In addition, the veterans did participate in the survey reported adherence with their medications and no significant differences were found between the veteran groups with medication adherence. The measurement scale for medication adherence was dichotomous which limited finding differences between groups. Further, veterans in this study were highly adherent to their antihypertensive medication, indicating a substantial response bias.

Another limitation is that PTSD is a very complicated medical diagnosis. The ICD-9 codes were used because the consent was for reviewing medical diagnoses in the veterans' charts. However, if the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria were used, it would have included veterans who were more symptomatic of their disease.

The number of female veterans was exceptionally low because there were fewer females in the armed forces until 2010 (Patten & Parker, 2011). The participants were also not diverse in race or ethnicity because the sample was from one VA facility in the Northeast, so cannot be generalized to the national population of veterans. The use of modification indices as opposed to a purely theoretically driven model suggest that there are other variables that may be associated with antihypertensive medication adherence.

### Recommendations for the Future

To further explore other variables and self-care behaviors for their association with antihypertensive medication adherence among veterans with and without PTSD. These findings showed the variables which had significance but did not explain

medication adherence. For future research, the goal should be to recruit veterans who are less adherent, and include larger numbers of female veterans. Previous demographics of women veterans in the military showed that after 1973, there has been an increase of 14% of women enlisted in the armed forces and 24% who have been in combat theater.

Subsequently, females were reported to be at higher risk for PTSD (Frayne et al., 2004; Patten & Parker, 2011). Future studies of female veterans with HTN and PTSD is an area for further investigation, including stratification of women serving within military subdivisions.

Another area of future study is to address health literacy and HTN. McNaughton et al. (2014) found an association between low health literacy (23%) in patients ( $n=46,263$ ) who were hospitalized for their HTN. Low literacy was found in patients who did not have a formal diagnosis of HTN, and were frequently evaluated in the emergency department versus in a primary care setting (McNaughton et al., 2014).

### Clinical Implications

As younger veterans increase in age, their risk of HTN will increase; there is also the possibility of a delayed form of PTSD being diagnosed. Long-term strategies may incorporate improving isolation of veterans who do not have social support and providing them an opportunity to consider meeting with peer groups to provide support, especially for those who are widowed (Trevidi et al., 2008). Laffaye, Cavella, Drescher, and Rosen (2008) found that veterans with PTSD valued the emotional support from other veterans.

Teaching about how HTN can be better controlled may decrease health distress and prevent complications. Lorig, Ritter, and Gonzalez (2003) found that when combined

with traditional health care, interventions of exercise programs, sleep management, relaxation exercises, and teaching about communication improved management of overall health. Additionally, offering programs to help veterans to decrease health distress is one strategy that could be used to enhance self-care behaviors to maintain medication adherence.

Further, offering veterans assistance from counselors to address alcohol issues would provide structure and increase better emotional health. Brief counseling has been associated with decreased alcohol consumption (Bryson et al, 2008). Moreover, Warren-Findlow, Seymour, and Huber (2012) found patients with HTN did not realize that alcohol consumption was related to HTN, something that counselors could help veterans understand, and perhaps use as a motivating factor to improve adherence. Nurses should be especially alert for low levels of social support and more health distress in veterans with both HTN and PTSD.

Assessing the number of medical diagnoses is a part of preventing suboptimal medication adherence in veterans with HTN. Ellis, Zhao, and Egede (2009) reported that veterans with HTN who had experienced a stroke had a higher comorbidity index, which was associated with higher mortality rates. Also, better antihypertensive medication adherence was directly associated with veterans who had higher degree of comorbidity and less health distress. A higher degree of comorbidity may be due to more frequent clinic visits and follow-up with their healthcare provider.

### Summary

Assessing suboptimal antihypertensive medication is crucial for the prevention of uncontrolled blood pressure and the prevention of disabling complications. Despite the small portion of the variances on medication adherence, there are clinical implications for nurses in the primary care setting. As the number of veterans is increasing and aging, this study has suggested ways nurses can impact the future health of our nation's veterans. Providing veterans with the assistance they may need with medication self-care behaviors can help those veterans avoid complications, disabilities, and a loss of independence—something that is important for both the veteran and for optimal use of future healthcare resources and prevention of strokes.



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APPENDIX A

IRB FORMS/CONSENT LETTER



VA CONNECTICUT HEALTHCARE SYSTEM  
Human Research Protection Program

Initial Approval of a Human Research Project

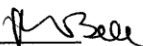
Date: 3/21/13

To Principal Investigator: Christopher Ruser, M.D.	MIRB Number: 01713
Project Title: Factors Influencing Antihypertensive Medication Adherence in Veterans with Hypertension and Veterans with Hypertension and PTSD	

The following decisions have been made by the Human Studies Subcommittee regarding your project:

<b>Risks to subjects are minimized. Risks are reasonable in relation to benefits. Selection of subjects is equitable. Provisions for safety monitoring are adequate. Provisions to protect privacy and confidentiality are adequate.</b>
<b>Consent Form was Reviewed and Approved:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Requested <i>Approval indicates that the HSS found that the information provided in the Consent Form is complete, accurate, and understandable to a research subject who possesses standard reading and comprehension skills. The HSS has been assured that the informed consent will be obtained by the principal investigator or a trained and supervised designee under suitable circumstances.</i>
<b>Witness Signature is required on consent form:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Consent for Use of Picture and/or Voice is required:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not Requested
<b>Waiver of Informed Consent (WIC) granted:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not Requested If yes, <input type="checkbox"/> full study or <input checked="" type="checkbox"/> screening (identifying potential subjects) only <input type="checkbox"/> All subjects or <input type="checkbox"/> one particular group (what group?)
<b>Waiver of HIPAA Authorization (WoA) granted:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not Requested If yes, <input checked="" type="checkbox"/> full study or <input type="checkbox"/> screening (identifying potential subjects) only <input type="checkbox"/> All subjects or <input type="checkbox"/> one particular group (what group?)
<b>Waiver of Written Informed Consent (WWIC) granted:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not Requested If yes, <input checked="" type="checkbox"/> all subjects or <input type="checkbox"/> one particular group (what group?)
If yes, Consent Form approved <input checked="" type="checkbox"/> Yes or Information Sheet approved <input type="checkbox"/> Yes
<b>Subjects are considered to be vulnerable to coercion:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If yes, there are additional adequate safeguards <input type="checkbox"/> Yes
<b>Enrollment of non-Veterans is Justified and Approved:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not Requested
<b>The project is a Clinical Trial:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Drug Information Record is on file:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> N/A
<b>Surrogate Consent Approved:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not Requested <i>Approval indicates that all of the following conditions have been met: a) the research cannot be done with only competent subjects; b) risk to the subjects is outweighed by benefit; c) an incompetent subject who resists will not have to participate; d) the basis for the decision regarding a subject's competency will be fully described.</i>
<b>Payment of subjects Approved:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Requested <i>Approval indicates that the HSS found that the payment is reasonable and commensurate with the subject's contribution.</i>
Documentation Requirements: <b>Research Alert in Medical Record</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>Creation or updating of Medical Record</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Risk Level:</b> <input checked="" type="checkbox"/> Not greater than minimal <input type="checkbox"/> Moderate <input type="checkbox"/> High

<b>Principal Investigator:</b> Christopher Ruser, M.D.	<b>MIRB #:</b> 01713
<b>This project was Approved by HSS at its meeting on</b> <u>3/21/13</u>	

  
 HSS Chair, or Designee

4/1/2013  
 Date

The Research was approved by the <b>Subcommittee on Research Safety</b> on:
The <b>Research &amp; Development Committee</b> was notified on: <u>4/3/13</u>
Other Applicable subcommittees:

Neither you nor any of the identified co-investigators participated in the review and decision-making. **All applicable approvals have been obtained and you may now proceed with the research.**

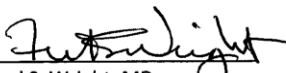
**Approval for this project expires on 3/20/14** and will be subject to continuing review before the expiration date. This review will require that you submit a Continuing Review Application to the HSS before the end of the current approval period.

If you are a member of the Yale faculty, this protocol requires approval by the Yale HIC before the study can begin. No study interventions may take place until Yale HIC approval has been granted. For timely approval, if appropriate, submit a copy of this protocol, approved Consent Form(s) and HIPAA Authorization with this memo to the Yale HIC without delay.

The HSS reminds you of several important requirements:

1. The Consent Form(s) and HIPAA Authorization used must be the ones most recently approved by the HSS. Be sure that both are filled in completely.
2. The procedures and interventions must be those proposed in the protocol and approved by the HSS.
3. Any changes to the protocol or the Consent Form(s) must be proposed to the HSS in writing as a modification to an approved project, and must be approved before they are initiated.  
The HIPAA Authorization may be amended as necessary and, a copy forwarded to the Research Office.
4. All Consent Form(s) must be reviewed, and signed by the Principal Investigator.  
(Co-investigators may sign, if the PI is unavailable, however, the PI must co-sign as soon as possible).
5. Any Adverse Event that is both Serious and Unanticipated must be reported to the HSS within 5 business days of your becoming aware of it.
6. Any Unanticipated Problem Involving Risk to Subjects or Others must be reported to the HSS within 5 business days of your becoming aware of it.
7. Any Deviation from the approved protocol or Consent Form(s) must be promptly reported to the HSS.
8. For each signed HIPAA Authorization and Consent Form(s), there must be:
  - The original in your file
  - A copy given to the subject (or representative)
  - A copy retained for submission to the HSS with your request for Continued Approval

If you have any questions, please contact Cora Milewski or Brendan Sullivan at (203) 932-5711, ext.3350.

  
 Fred S. Wright, MD  
 Associate Chief of Staff for Research

4/3/13  
 Date



**INSTITUTIONAL REVIEW BOARD**  
**THE UNIVERSITY OF UTAH**

75 South 2000 East Salt Lake City, UT 84112 | 801.581.3655 | IRB@utah.edu

**IRB:** [IRB\\_00065259](#)

**PI:** Suzanne Chaplik

**Title:** Factors Influencing Medication Adherence in Veterans with Hypertension and Veterans with Hypertension and Post-Traumatic Stress Disorder

This New Study Application qualifies for an expedited review by a designated University of Utah IRB member as described in 45 CFR 46.110 and 21 CFR 56.110. The research involves one or more activities in Categories 5 and 7 (published in 63 FR 60364-60367). The designated IRB member has reviewed and approved your study as a Minimal risk study on 7/1/2013. The approval is effective as of 7/1/2013. Federal regulations and University of Utah IRB policy require this research protocol to be re-reviewed and re-approved prior to the expiration date, as determined by the designated IRB member.

Your study will expire on 6/30/2014.

Any changes to this study must be submitted to the IRB prior to initiation via an amendment form. The University of Utah Institutional Review Board acknowledges that all research procedures will be conducted at the VA Connecticut Healthcare System, and that the VA Connecticut Healthcare System Human Research Protection Program has issued approval for this study.

#### **DETERMINATIONS**

**Waiver/Alteration Determination:** The IRB has determined that the request for **waiver of documentation of informed consent** is approved for this research under 45 CFR 46.117(c).

**Waiver/Alteration Determination:** The IRB has determined that the request for the **waiver of authorization** is approved for this research under 45 CFR 164.512(i).

- **APPROVED DOCUMENTS**

- **Surveys, etc.**

- Survey

- **Literature Cited/References**

- References

- **Other Documents**

- VA Research Protocol Safety Survey.pdf

- Introduction Letter; For Reference Only

- VA Initial Approval.pdf Click [IRB\\_00065259](#) to view the application and access the approved documents.



**VA CONNECTICUT Healthcare System  
West Haven, CT 06516**

July 22, 2013

Dear Veteran,

We are asking for your assistance with a research study being conducted at the VA Healthcare System in West Haven. This voluntary study involves completing a survey about living with hypertension and taking medications, and evaluating additional information from your medical records. The researcher will need to obtain the: 1) length of time for hypertension treatment; 2) number of medical diagnoses; 3) blood pressures at office visits; 4) medications for your hypertension; and 5) medication refills at VA CT Healthcare System. You are receiving this letter because you are currently being treated for a diagnosis of high blood pressure.

The time to complete the survey is approximately 20 minutes. For your time in completing this survey, you will receive a \$20.00 gift card as a gesture of our appreciation. The Health Insurance Portability and Accountability Act (HIPPA) will be followed to protect your information. All information will be secured and de-identified for your confidentiality.

If you decide to participate in the study, please return the survey in the prepaid mailing envelope. Participation in this study will not provide any direct medical benefits. If you are not interested in participating, disregard the reminder card which will arrive in approximately two weeks, and you will not be contacted again.

We appreciate your time and consideration for completing the survey. The results of this study will help other veterans in the future.

Many thanks in advance,

A handwritten signature in black ink, consisting of a stylized, cursive name.

Chief of Primary Care Clinics

APPENDIX B

INSTRUMENTS



## DEMOGRAPHIC FORM

**Please complete questions one through ten on this page and the next page about yourself. The information is only for this research study.**

1. Age \_\_\_\_\_

2. Number of years diagnosed with hypertension \_\_\_\_\_

3. Gender: Male  Female

4. Race (“x” ONLY one with which you MOST CLOSELY identify):

- African-American or Black
- Asian
- American Indian
- White
- More than one race
- Decline to Answer
- Other

5. Ethnicity: (“x” ONLY one with which you MOST CLOSELY identify):

- Hispanic or Latino
- Not Hispanic or Latino
- Unknown or not reported

6. Marital Status:

- Divorced
- Married
- Significant other
- Separated
- Never Married

## DEMOGRAPHIC FORM

## 7. Years of education:

- Less than high school
- Graduated from high school
- Attended or graduated from college
- Received a postgraduate degree or have an equivalent degree

## 8. Occupational Status:

- Full-time employment
- Part-time employment
- Disabled/Not employed
- Retired

Please answer these questions are about your blood pressure medication.

## 9. Where do you obtain your blood pressure medications?

- VA
- Another Pharmacy

10. Have you ever omitted blood pressure medications due any of the reasons listed below? Circle as many answers you would like about your blood pressure medication.

- a. I never omit the medication
- b. I may omit the medication due to cost.
- c. I may omit the medication due to a change in my schedule.
- d. I may omit the medication because I feel fine.

## HEALTH MOTIVATION SCALE

**Instructions.** Many people may or may not have personal goals in health prevention of hypertension. Please read the eight statements, on the next two pages, and answer to the best of your knowledge with an answer from: strongly disagree (1) to very strongly agree (7). This will help us to better understand how important health prevention is in the daily lives of people. Please circle the number which best describes how you feel.

Circle the “1” if you Very Strongly Disagree      Circle the “5” if you Mildly Agree  
 Circle the “2” if you Strongly Disagree              Circle the “6” if you Strongly Agree  
 Circle the “3” if you Mildly Disagree                Circle the “7” if you Very Strongly Agree  
 Circle the “4” if you are Neutral

	Very Strongly Disagree	Very Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1) I try to prevent common health problems before I feel any symptoms.	1	2	3	4	5	6	7
2) I am concerned about common health issues and try to take action to prevent them.	1	2	3	4	5	6	7
3) I try to protect myself against health issues I hear about.	1	2	3	4	5	6	7
4) I don't worry about common health issues until they become a problem for me or someone else close to me.	1	2	3	4	5	6	7

## HEALTH MOTIVATION SCALE

	Very Strongly Disagree	Very Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
5) There are so many things that can hurt you these days. I'm not going worry about them.	1	2	3	4	5	6	7
6) I often worry about the health issues I hear about, but don't do anything about them.	1	2	3	4	5	6	7
7) I don't take any action against common health issues, I hear about until I know I have a problem.	1	2	3	4	5	6	7
8) I would rather enjoy my life than try to make sure I am not exposing myself to a health hazard.	1	2	3	4	5	6	7

## HEALTH DISTRESS SCALE

**Instructions: Many people may or may not feel distressed about their diagnosis of hypertension. These questions will help us to better understand the concerns with hypertension. Please answer the four questions in relation to dealing with hypertension this past month.**

How much time during the past month...	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All the time
1. were you discouraged by your health problems related to your high blood pressure?	0	1	2	3	4	5
2. were you fearful about your future health because of your hypertension?	0	1	2	3	4	5
3. was your high blood pressure a worry in your life?	0	1	2	3	4	5
4. were you frustrated by your health problems because of hypertension?	0	1	2	3	4	5

## SF-12 SCALE

**Instructions: Feeling of well-being changes with one's health. Please answer the 12 questions, on the next three pages, by marking one box. If you are unsure about how to answer, please give the best answer you can.**

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. Moderate activities, such as moving a table, pushing vacuum cleaner, bowling, or playing golf.

Yes, limited a lot	Yes, limited a little	No, Not limited at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Climbing several flights of stairs.

Yes, limited a lot	Yes, limited a little	No, Not limited at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Accomplished less than you would like.

<input type="checkbox"/> All of the time	<input type="checkbox"/> Most of the time	<input type="checkbox"/> Some of the time
<input type="checkbox"/> A little of the time	<input type="checkbox"/> None of the time	

## SF-12 SCALE

b. Were limited in the kind of work or other activities.

- All of the time       Most of the time     Some of the time  
 A little of the time       None of the time

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Accomplished less than you would like.

- All of the time       Most of the time     Some of the time  
 A little of the time       None of the time

b. Did work or other activities less carefully as usual.

- All of the time       Most of the time     Some of the time  
 A little of the time       None of the time

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all     A little bit       Moderately       Quite a bit       Extremely

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks –

a. Have you felt calm and peaceful?

- All of the time       Most of the time     Some of the time  
 A little of the time       None of the time

## SF-12 SCALE

b. Did you have a lot of energy?

- All of the time       Most of the time       Some of the time  
 A little of the time       None of the time

c. Have you felt downhearted and blue?

- All of the time       Most of the time       Some of the time  
 A little of the time       None of the time

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time       Most of the time       Some of the time  
 A little of the time       None of the time



## MULTIDIMENSIONAL SCALE OF PERCEIVED SOCIAL SUPPORT

**Instructions: Family, friends, or a significant other (wife, husband, boyfriend, girlfriend) may provide assistance with your health needs of hypertension. Please answer the 12 questions, on the next two pages, to help us understand if family, friends, or a significant other may make a difference with your hypertension.**

**Circle "1" if you Very Strongly Disagree**  
**Circle "2" if you Strongly Disagree**  
**Circle "3" if you Mildly Disagree**  
**Circle "4" if you are Neutral**

**Circle "5" if you Mildly Agree**  
**Circle "6" if you Strongly Agree**  
**Circle "7" if you Very Strongly Agree**

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1) There is a special person who is around when I am in need.	1	2	3	4	5	6	7
2) There is a special person with whom I can share joys and sorrows.	1	2	3	4	5	6	7
3) My family really tries to help me.	1	2	3	4	5	6	7
4) I get the emotional help support I need from my family.	1	2	3	4	5	6	7
5) I have a special person who is a real source of comfort to me	1	2	3	4	5	6	7
6) My friends really try to help me.	1	2	3	4	5	6	7

## MULTIDIMENSIONAL SCALE OF PERCEIVED SOCIAL SUPPORT

Circle "1" if you Very Strongly Disagree  
 Circle "2" if you Strongly Disagree  
 Circle "3" if you Mildly Disagree  
 Circle "4" if you are Neutral

Circle "5" if you Mildly Agree  
 Circle "6" if you Strongly Agree  
 Circle "7" if you Very Strongly Agree

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
7) I can count on my friends when things go wrong.	1	2	3	4	5	6	7
8) I can talk about my problems with my family.	1	2	3	4	5	6	7
9) I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
10) There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7
11) My family is willing to help me make decisions.	1	2	3	4	5	6	7
12) I can talk about my problems with my friends.	1	2	3	4	5	6	7

## CHARLSON CO-MORBIDITY INDEX

Age of the patient \_\_\_\_\_

Comorbidity Component:

Myocardial Infarction	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Congestive heart failure	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Peripheral vascular disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Cerebrovascular disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Dementia	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Chronic pulmonary disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Connective tissue disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Peptic Ulcer disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Diabetes mellitus	Uncomplicated <input type="checkbox"/>	with End Organ Damage <input type="checkbox"/>
Renal Disease	Moderate to <input type="checkbox"/>	Severe <input type="checkbox"/>
Hemiplegia	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Leukemia	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Malignant solid tumor	Non-metastatic <input type="checkbox"/>	Metastatic <input type="checkbox"/>
Malignant lymphoma	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Liver Disease	Mild <input type="checkbox"/>	Moderate to Severe <input type="checkbox"/>

Co-morbidity Index Calculated \_\_\_\_\_

## ALCOHOL USE DISORDER IDENTIFICATION TEST CONSUMPTION

**Instructions: Please circle the answer the three questions which best describes your alcohol consumption. This will help us understand better about alcohol consumption and taking medications for hypertension.**

1. How often do you have a drink containing alcohol?
  - a. Never
  - b. Monthly or less
  - c. 2-4 times a month
  - d. 2-3 times a week
  - e. 4 or more times a week
  
2. How many drinks containing alcohol do you have on a typical day when you are drinking?
  - a. 0
  - b. 1 or 2
  - c. 3 or 4
  - d. 5 or 6
  - e. 7 to 9
  - f. 10 or more
  
3. How often do you have six or more drinks on one occasion?
  - a. Never
  - b. Less than monthly
  - c. Monthly
  - d. Weekly
  - e. Daily or almost daily

## PERCEIVED INVOLVEMENT IN CARE SCALE

**Instructions: Please read each statement and think about your primary VA healthcare provider and answer the 12 questions by circling the answer that best describes the last clinic visit for evaluation of your hypertension.**

- |     |  |                |
|-----|--|----------------|
| 1.  | My doctor asked me whether I agree with his/her decisions.   | Disagree Agree |
| 2.  | My doctor gave me a complete explanation for my medical symptoms or treatment.                             | Disagree Agree |
| 3.  | My doctor asked me what I believe is causing my medical problems.  | Disagree Agree |
| 4.  | My doctor encouraged me to talk about personal concerns related to my medical symptoms.                    | Disagree Agree |
| 5.  | My doctor encouraged me to give my opinion about my medical treatment.                                     | Disagree Agree |
| 6.  | I asked my doctor to explain the treatment or procedure to me in greater detail.                           | Disagree Agree |
| 7.  | I asked my doctor for recommendations about my medical symptoms.   | Disagree Agree |
| 8.  | I went into great detail about my medical symptoms.  | Disagree Agree |
| 9.  | I asked my doctor a lot of questions about my medical symptoms.  | Disagree Agree |
| 10. | I suggested a certain kind of medical treatment to my doctor.  | Disagree Agree |
| 11. | I insisted on a particular kind of test or treatment for my symptoms.                                      | Disagree Agree |
| 12. | I expressed doubts about the test or treatment that my doctor recommended.                                 | Disagree Agree |
| 13. | I gave my opinion (agreement or disagreement) about the types of test or treatment that my doctor ordered. | Disagree Agree |

## MORISKY SELF-REPORT MEDICATION ADHERENCE SCALE

**Instructions: Please think about your medication treatment for hypertension and circle yes or no to each of the seven questions and choose the best answer for question eight.**

- |  |     |    |
|--|-----|----|
| 1. Do you sometimes forget to take your high blood pressure pills?   | Yes | No |
| 2. Over the past 2 weeks, were there any days when you did not take your hypertension medicine?                                    | Yes | No |
| 3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?   | Yes | No |
| 4. When you travel or leave home, do you sometimes forget to bring along your medications?   | Yes | No |
| 5. Did you take your hypertension medicine yesterday?  | Yes | No |
| 6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?                            | Yes | No |
| 7. Do you ever feel hassled about sticking to your blood pressure treatment plan?  | Yes | No |
| 8. How often do you have difficulty remembering to take all of your blood pressure medication? (Please circle the correct number). |     |    |

Never/Rarely.....0

Once in a while.....1

Sometimes.....2

Usually.....3

All the time.....4

APPENDIX C

COMPUTERIZED PATIENT RECORD SYSTEM (CPRS)

DATA EXTRACTION FORM

COMPUTERIZED PATIENT RECORD SYSTEM (CPRS) DATA EXTRACTION  
FORM

Patient's Name:
Code:
Hypertension (HTN) Diagnosis: yes no
Number of years diagnosed with HTN:
PTSD Diagnosis: yes no
Number of Years diagnosed with PTSD:
Date of Clinic Appointment for HTN:
Date of Follow-up Visit for HTN:
Attended Rescheduled Cancelled
Most recent BP readings at clinic visit and follow-up visit:
Days of prescription: 30 days 60 days 90 days
Number of refills ordered:
Medication Possession Ratio:
<u>Numerator (All day's supply – last day's supply)</u>
Denominator (Last refill date – first refill date)
MPR Average
Total number of medications