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The Impact of the Veterans Health Administration's Home Based Primary Care on Health Services Use, Expenditures, and Mortality

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The Impact of the Veterans Health Administration's Home Based Primary Care

on Health Services Use, Expenditures, and Mortality

by

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A dissertation submitted in partial fulfillment
of the requirement for the degree of
Doctor of Philosophy
School of Aging Studies
College of Behavioral and Community Sciences
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Dedication

This project is dedicated to all service men and women who have served our country, to those who have fought to defend our country, to those who have sacrificed for the citizens of our county, and especially to those who have fallen ill, disabled, or homebound. It is with great honor and gratitude that I dedicate this work to you.

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Abstract

Background: Among patients with multiple chronic conditions, care coordination and integration remains one of the major challenges facing the U.S. health care system. A home-based, patient-centered primary care program has been offered through the Veterans Health Administration (VHA) since the 1970s for frail veterans who have difficulty accessing VHA clinics. The VHA Home Based Primary Care (VHA HBPC) aims to integrate primary care, rehabilitation, disease management, palliative care, and coordination of care for frail individuals with complex, chronic diseases within their homes. Early research suggested that VHA HBPC was associated with positive outcomes (e.g., reduced resource use and patient satisfaction). However, evidence regarding the effect of the VHA HBPC program on health services use (especially hospital and nursing home use), expenditures, and other patient outcomes remains limited. The present study is designed to fill this gap as the rise in the number of veterans with complex health care needs will likely increase in the coming decades.

Objectives: The current study aimed to examine the impact of VHA HBPC on health services use, expenditures, and mortality among a cohort of new VHA HBPC enrollees identified in the national VHA data system. The specific aims of this study were: 1) to examine the effect of VHA HBPC on major health service use (hospital, nursing home, and outpatient care) paid for by the Veterans Administration; 2) to examine the effect of VHA HBPC on total health services expenditures; and 3) to examine whether VHA

HBPC enrollees experienced similar mortality and survival as compared to a matched concurrent cohort.

Methods: This study used a retrospective cohort design. A new VHA HBPC enrollee cohort (the treatment group) and a propensity matched comparison cohort (the comparison group) were identified from VHA claims in fiscal years (FY) 2009 and 2010 and were followed through FY 2012. Data on health service use, expenditures, and mortality/survival data were obtained via the VHA administrative datasets (i.e., Decision Support System, Purchased Care, and Vital Status Files). Propensity scores of being enrolled in the VHA HBPC were generated by a logistic regression model controlling for potential confounders. After 41,244 matched pairs were determined adequate through several diagnostic methods, means tests, relative risk analyses, and generalized linear models were used to estimate the effect of VHA HBPC on outcomes. Additionally, a Cox proportional hazards regression model was used to estimate the effect of VHA HBPC on survival. Subgroup analyses were conducted stratifying by age (85 and older), comorbidities (2 or more), and the receipt of palliative care. Based on the results of the original analyses, a series of sensitivity analyses were conducted that modified the described sample selection criteria and matching algorithm.

Results: Analyses of the original cohort revealed that VHA HBPC patients had significantly higher risks of being admitted into a hospital (RR 1.53, 95% CI 1.51-1.56) or nursing home (RR 1.65, CI 1.50 - 1.81). The average total expenditures during the study period were significantly higher for the VHA HBPC group as compared to the control group ($85,808 vs. $44,833, respectively; $p < .001$). In terms of mortality and survival, VHA HBPC enrollees had higher mortality (RR 1.45, CI 1.43 – 1.47), and

shorter survival (HR 1.89, CI 1.86 – 1.93) as compared to those in the comparison group. Subgroup analyses found that these relationships generally remained when stratified by age 85 or older or having two or more comorbidities. However, for those who received palliative care, VHA HBPC participants had significantly lower risk of VHA hospitalization overall (RR 0.84, CI 0.81 – 0.87) and immediately prior to death. Finally, exploratory post-hoc analysis suggested that VHA HBPC recipients were at higher risk of VHA hospitalization at 30 (RR 1.11, CI 1.06 – 1.16), 60 (RR 1.16, CI 1.11 – 1.20), and 90 days (RR 1.16, 1.12 – 1.21) prior to death relative to the comparison group. After selecting only those that had a baseline hospitalization and refining the matching algorithm to account for time to death and additional comorbidities, VHA HBPC participants who had been enrolled in the program for at least six months had lower risks for hospital (RR 0.89, CI 0.88 – 0.90) and nursing home admissions (RR 0.74, CI 0.67 – 0.81). However, total expenditures remained significantly higher among those in VHA HBPC relative to the comparison group ($89,761 vs. $85,371, respectively; *p* < .001).

Discussion: This study found that without accounting for important covariates such as initial hospitalization, time to death, and a range of comorbidities, VHA HBPC was associated with higher health service use, higher expenditures, higher mortality, and shorter survival as compared to a similar group of patients not receiving VHA HBPC. After accounting for these factors, VHA HBPC was associated with a lower risk of nursing home use, and after six months, VHA HBPC was associated with lower risk of both nursing home and hospital use. These findings suggest that while VHA HBPC may improve quality of life and patient satisfaction through patient-centered integrated

primary care, it may not generate cost savings for the healthcare system. Future

research is needed to understand variation in program implementation and how this

affects the impact of VHA HBPC on service use and cost.

Chapter 1: Background

Introduction

The importance of primary care is underscored by the Agency for Healthcare Research and Quality's notion of primary care being "foundational" to achieving a better healthcare system (Agency for Healthcare Research and Quality, 2013b). Primary care physicians are the most common type of physician utilized for a single condition or for multiple conditions among patients with all degrees of comorbidity (Centers for Disease Control and Prevention, 2010; Starfiled et al., 2003). Even when patients have a high degree of comorbidity, patients are still more likely to see their primary care physician compared to a specialist (Centers for Disease Control and Prevention, 2010; Starfiled et al., 2003).

Patients with comorbidities are prevalent among primary care practices. Among a sample of 226 primary care practices across 43 states, it was determined that 45.2% of patients had more than one comorbidity and that comorbidity increases with age (Ornstein, Nietert, Jenkins, & Litvin, 2013). Focusing on the nature of primary care practice and the prevalence of comorbidity, Starfield et al. (2003) posited that primary care should retain its stronghold as the basis for patient care but should also consider evolving to adequately address patient needs. One of these evolutions in healthcare has been the rise of the medical home.

Though not a new term, the concept of the medical home has gained in popularity, as part of a growing effort to provide complex patients with more

comprehensive care. The patient-centered medical home is characterized as care that

is continuous, comprehensive, accessible, and coordinated across providers

(Rittenhouse & Shortell, 2009). Additionally, the medical home is one that is team-

based according to the patients' needs and can include an array of providers (e.g.,

specialists, nurses, social workers, pharmacists, therapists). Medical homes, in

particular, have been associated with lower total costs and outpatient costs among the

most costly and complex patients (Flottemesch et al., 2012) and are conceptualized

based on the components of evidence-based medicine and an ongoing partnership

between patients and physicians (American College of Physicians, 2005).

To continue efforts to improve healthcare in general, and in primary care

specifically, the American College of Physicians promotes the delivery of care through

the medical home based on the Chronic Care Model recognizing the complexity and

chronicity of patients and their conditions and posit that this model of care can be

applicable to those with or without chronic conditions (American College of Physicians,

2005). This model of care delivery emphasizes the relationship between the patient and

the physician and care self-management guided by decision support tools that includes

a range of options supporting the patient's health goals (American College of Physicians,

2005).

Chronic disease management is important to controlling healthcare costs,

especially considering that those with multiple chronic conditions cost up to seven times

as much as those with only one condition (Agency for Healthcare Research and Quality,

2006) and a substantial portion of the rise in costs among Medicare beneficiaries over

the last two decades has been attributed to the management and treatment of chronic

conditions such as diabetes and hypertension (Thorpe, Ogden, & Galactionova, 2010).

Chronic disease management and treatment was associated with 75% of the $2 trillion

spent on healthcare in the U.S. (Centers for Disease Control and Prevention, 2009,

2013). In 2010, Medicare spent over $300 billion on beneficiaries, and among those

with six or more chronic conditions, the cost was three times as much as the average

Medicare beneficiary (Centers for Medicare & Medicaid Services, 2012). Furthermore,

the Veterans Administration's (VA) expenditures for chronic diseases were $14.3 billion

over ten years ago (Yu et al., 2003) and such expenses are likely considerably higher

today.

Not surprisingly then, many models of care aim to both enhance patient quality of

care and safety, as well as reduce unnecessary expenses, hospitalizations, adverse

events, and disease exacerbation by providing enhanced care continuity. This is

important because each time there is a change in care, there is an opportunity for

miscommunication where information about patient preferences and goals can be

jeopardized (Coleman, 2003; Hauser, 2009).

Moreover, those individuals that are among the frailest of patients likely have

difficulty accessing healthcare. Access issues span a range of challenges including

social, societal, and behavioral, but fundamentally, decreased access to primary care is

associated with adverse outcomes, for example, higher mortality (Jerant, Fenton, &

Franks, 2012).

Home-based primary care can be a solution for those who cannot receive care in

a traditional clinical setting and has been characterized as an "emerging model of

primary care" (Landers et al., 2005). Given the importance of chronic disease

management, those who cannot access healthcare due to being homebound are a group of highly vulnerable patients. There are an estimated 3.6 million older adults who are considered homebound (Qiu et al., 2010).

Specifically, the homebound have higher rates of metabolic, cardiovascular, musculoskeletal conditions, and higher rates of cognitive impairment, dementia, and depression (Qiu et al., 2010).   In a study of chronically ill homebound individuals, it was found that 49% had dementia, 33% had diabetes mellitus, 26% had depression, 18% had coronary heart disease, and 13% had cancer (Wajnberg, Ornstein, Zhang, Smith, & Soriano, 2013). Moreover, the same study found that the most common symptoms among the homebound were loss of appetite, lack of well-being, tiredness, and pain (Wajnberg et al., 2013).

In the broader healthcare context, primary care provided in patients' homes has the potential to effectively fill a gap in services for homebound individuals (Desai, Smith, & Boal, 2008). Primary care delivered in patients' homes is delivered mostly by geriatricians and family or internal medical doctors in order to improve patient care and autonomy (Landers, Gunn, & Stange, 2009). However, the effectiveness of this model to improve patient outcomes is mixed, and overall, there seems to be limited evidence on home-based primary care provided in the U.S. Others have suggested that in order to expand home-based primary care as a delivery model, more rigorous research on home-based primary care is needed (Olsan, Shore, & Coleman, 2009).

Therefore, the current study examines the VHA's Home Based Primary Care (VHA HBPC)[1] by determining the effectiveness of the program on service use, cost, and survival. First, a review of the literature on home-based primary care (in general, not limited to the VHA HBPC program) in the United States is presented. It should be noted that the literature focused specifically on primary care delivered in the home is limited. Therefore, this review includes literature on house calls made by physicians specifically for primary care and includes literature referring to physician house calls that did not specify primary care, but identified physician's specialties as geriatricians, family physicians, general practitioners, or internal medical doctors delivering *routine care* in patient's homes. Following the review, an overview of VHA HBPC is provided including a review of the evidence. Then, the present study is described, followed by a discussion of the implications of the results.

Physician Services Provided In Patients' Homes

Prevalence of Home-Based Primary Care & Physician House Calls. Overall, very few (<1%) older adults receive a house call from a physician (Landers et al., 2005; Meyer & Gibbons, 1997). However, there seems to be a re-emergence of such care. From 1998 to 2004, the annual number of Medicare beneficiaries who received house calls increased by 43% (Landers et al., 2005). While this is a relatively large increase, the overall rate of house call utilization remains low, increasing from 0.78% in 1998 to 0.90% of all out-patient evaluation and management services among fee-for-service Medicare beneficiaries (Landers et al., 2005). Similarly, Peterson, Landers, &

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[1] The acronym for the Home Based Primary Care, VHA HBPC, is used only when referring to the program provided through the Veteran's Health Administration (VHA). When home-based primary care is spelled out, it is referencing this type of care in general terms, i.e., not specific to the VHA.

Bazemore (2012) found that the number of physician house calls more than doubled from 478,000 in 2000 to 995,294 in 2006 among Medicare beneficiaries, coinciding with an increase in the number of beneficiaries who received house calls (up from 164,825 in 2000 to 282,526 in 2006). However, the number of physicians making house calls declined, indicating that a smaller number of physicians were seeing a higher volume of patients in their homes (Peterson et al., 2012). Of note, visits by nurse practitioners and physicians assistants to patients in the home increased between 1998 to 2004 (Landers et al., 2005).

Using the 2004 National Long Term Care Survey, Liang & Landers (2008) found that 4% of the sample, or 168 out of 4,953 respondents, reported receiving a house call from a physician. This rate of receiving a physician house call is high in comparison to other evidence. Part of the discrepancy in the rate of physician house calls could be due to the definition of a physician house call and due to the differences between self-reported and claims data.

Recipients of Home-Based Primary Care & Physician House Calls. Those who receive house calls are often more frail with more functional limitations compared to those that do not receive this service (Liang & Landers, 2008). Specifically, those who utilized a physician in the home compared to those that did not utilize a physician in the home were more often: older (84 years of age versus 81), non-white (17% compared to 10%), a recipient of Medicaid (23% versus 16%), living in an urban area (29% compared to 18%), residing in housing that had support for older adults or adults with disabilities (24% versus 16%), had 2 deficits in activities of daily living (ADLs;

compared to 1), had 3 deficits in instrumental ADLs (IADLs; compared to 1), and were more often hospitalized in the last year (37% compared to 28%; Liang & Landers, 2008).

Similarly, in a review of the literature from 1990 to 2006, home-based primary care models were described as serving those that: are frail, are in need of assistance with 3 or more ADLs, have IADL dependencies, and, often serve those with a range of mobility including those that can leave their homes for short durations to those that are strictly homebound (Olsan et al., 2009). Additionally, these programs typically serve those that are white, widowed females, age 65 years and older who often have low, fixed incomes (Olsan et al., 2009). The chronic conditions of those served by these programs are typical of older adults in general and include: hypertension, heart disease, congestive heart failure, chronic obstructive pulmonary disease, stroke, diabetes, depression, dementia, osteoarthritis, cancer, infections, impaired vision and hearing, falls, pressure ulcers, and malnutrition (Olsan et al., 2009).

A well-established home-based primary care program, St. Vincent's Hospital's Chelsea-Village Program (Kellogg & Brickner, 2000), has served older, frail residents of New York City since the 1970's by providing longitudinal, multidisciplinary care in patients' homes. The care team is comprised of physicians, resident physicians, nurses, and social workers. The average patient is 84 years old and is characterized by common ailments of old age such as, pulmonary and cardiac issues, orthopedic needs, neurologic disorders, and generalized weakness and frailty (Kellogg & Brickner, 2000). The program is now known as the Mount Sinai Chelsea-Village House Call Program or the Mount Sinai Visiting Doctors Program and provides care to the underserved homebound population (Mount Sinai Hospital, 2013).

An analysis of 27-years of data from St. Vincent's Hospital's Chelsea-Village Program described it as serving those that mostly lived alone (57.9%), considered themselves single (22.3%) or widowed (46.8%), and were referred to the program through the hospital (44.1%) or through someone in the community (49.2%; Kellogg & Brickner, 2000). A more recent analysis of the program between 2008 and 2010 found that 75% of new enrollees were female, 36% were White, 43% had Medicaid, 38% lived with a caregiver, 91% needed assistance with one or more ADLs, and 99% needed assistance with one or more IADLs (Wajnberg et al., 2013).

Another housecalls program was established in 1980 as part of a larger ambulatory practice with three geriatricians and two nurse practitioners in Providence, Rhode Island (Reuben, Fried, Wachtel, & Tinetti, 1998). Between 1993 and 1995 an analysis of 71 outpatient medical records were reviewed and described the program as serving mostly females (81% of patients) aged 85 or older (52% of patients) who were dependent in bathing and dressing (65% and 42% of patients, respectively) and were treated for acute illnesses (59% of patients) including upper respiratory tract infections, pneumonia, and congestive heart failure (Reuben et al., 1998). All patients lived within 15 minutes of the medical center but none were able to leave their homes for routine care due to ambulatory issues, or in a few cases, psychological barriers (Reuben et al., 1998). Patients were seen, on average, five times a year for either routine or urgent care (Reuben et al., 1998).

The Effects of Home-Based Primary Care & Physician House Calls. Several authors have concluded that this mode of the delivering physician's services is consistently associated with patient and caregiver satisfaction (Anetzberger, Stricklin,

Gauntner, Banozic, & Laurie, 2006; Laditka, Jenkins, Trevisani, & Mathews, 2001; Muramatsu, Mensah, & Cornwell, 2004; Olsan et al., 2009). In particular, patients and caregivers reported a positive psychological impact from knowing they had access to in-home medical care, and caregivers reported feeling empowered, informed, and relieved from the burden of transporting patients to and from medical appointments (Muramatsu et al., 2004). Patients also noted that physician's house calls provided access to care they otherwise would not have received (Laditka et al., 2001).

Intended to fill a gap among the homebound, home-based primary care should decrease the use of other types of unnecessary or inappropriate care by providing enhanced access to care and care management. To understand the effect of enrollment into a house calls program, Wajnberg et al. (2010) used a pre-post design to determine the effect of a house call program on hospitalizations and skilled nursing facility utilization among a sample of patients in a capitated insurance program, the Montefiore Medical Center Care Management Company (Wajnberg et al., 2010). It was found that there was a significant decrease in the rate of hospitalization after enrollment (61% prior to and 38% after, $p < .001$) and a significant decline in the use of skilled nursing facilities (38% before enrollment and 18% after, $p < .001$; Wajnberg et al., 2010). The authors suggested that increased access to healthcare could explain the reason for the change in hospital and skilled nursing facility utilization.

However, the evidence of the effectiveness of these services is not invariable. A two-year randomized controlled trial of a collaborative model of primary care included primary care physicians, registered nurses, and case assistants who conducted patient and family assessments in the patients' homes or clinic offices, provided home visits or

clinic visits, and provided coordination and supportive longitudinal care (Schraeder, Shelton, & Sager, 2001). Compared to a group not receiving treatment, evaluation of the program did not find a reduction in the rates of hospital use among participants in the treatment group after the first year (26.4% of treatment group versus 21.7% of comparison group) or after the second year (25.0% versus 22.6%; Schraeder et al., 2001). There was also not a significant difference in length of hospital stay (6.0 days after year 1 and 5.3 after year 2 among the treatment group compared to 5.0 after year 1 and 6.1 in year 2 among the comparison group), or Medicare payments (Schraeder et al., 2001). Not surprisingly then, the cost of the program was not offset by a reduction in hospital use. The authors, however, concluded that the intervention enhanced patient outcomes since those in the treatment group had a significantly lower risk of death during the second year (odds ratio = 0.51, 95% confidence interval [CI] = 0.29 - 0.91; Schraeder et al., 2001).

The Business Case for Home-Based Primary Care & Physician House Calls.
In 1993, it was estimated that physician house calls cost Medicare $63.2 million, or 0.2% of all Medicare physician expenditures (Meyer & Gibbons, 1997). An analysis of the St. Vincent's Hospital's Chelsea-Village Program estimated that the average cost per person per year of patient care was $3,936 (Kellogg & Brickner, 2000).

The adoption of home-based primary care models has been relatively slow, likely due to the fact that direct billing of such services does not generate enough revenue to meet operating costs (Desai et al., 2008). However, Desai et al. argued that such programs can generate substantial revenue at the systems level despite the inability of a program to generate enough revenue to operate independently (Desai et al., 2008).

For example, in fiscal year 2001 a local Midwestern physician's house call program generated $623,987 despite the $119,879 deficit incurred to the health system in which the program operated (Muramatsu et al., 2004). The author described the benefit of the program to the health system as being the largest referral source for the system's home health agency and hospice programs (Muramatsu et al., 2004). Another program, operated through Johns Hopkins Hospital System, also produced an overall shortfall of $84,165 in fiscal year 1992 (Finucane, Fox-Whalen, & Burton, 1994). The authors noted similarly that the benefit of the program from referrals to the hospital was justification for the program and resources (Finucane et al., 1994).

More recent evidence suggests that home-based primary care can be cost-effective. In a well-designed observational analysis of Medicare's Independence at Home program, De Jonge et al. (2014) found that recipients had significantly lower Medicare costs compared to a matched control group. Moreover, the effect of the program seemed most promising among the most frail, which tend to be generally the most costly group of patients.

VHA HBPC

A home-based primary care program that serves a demographically different population (compared to those served in the programs described above) is offered through the VHA to eligible patients. VHA HBPC offers primary care, rehabilitation, disease management, palliative care, and coordination of care to frail individuals with complex, chronic diseases within their homes (Department of Veterans Affairs, 2007). Although primary care is a focus of the program, VHA HBPC is described as providing comprehensive in-home long-term care services (Department of Veterans Affairs, 2007)

and is operationally similar to that of the patient-centered medical home model. Early research suggested that VHA HBPC (then referred to Hospital Based Home Care) provides a comparatively wide array of services to enrollees (Weaver et al., 1995).

VHA HBPC began being offered through the VHA in 1970 as a demonstration project and was modeled after the program at the Montefiore Hospital in New York (Cooper, Granadillo, & Stacey, 2007). The VHA's program was designed to provide long-term in-home care for older adults that could be cared for at home but were unable to receive care at outpatient clinics (Cooper et al., 2007). The program was not designed to be a substitute for long-term institutional care (Cooper et al., 2007).

VHA HBPC is considered unique in that patient-centered services are provided through an interdisciplinary team in a longitudinal fashion usually through death rather than care provided only during disease exacerbation (Department of Veterans Affairs, 2007). This is noteworthy because the average VHA HBPC enrollee has more than eight chronic conditions, limitations in two or more activities of daily living, spends an average of 315 days in the program (Beales & Edes, 2009), and is often discharged due to death. Therefore, the VHA HBPC population is a vulnerable population in which high medical expenses could easily be incurred.

Like other physician house call programs, VHA HBPC aims to reduce the use of unnecessary services by providing access to care and chronic disease management. This is important since recently the Congressional Budget Office suggested that the future costs of VHA healthcare will be "substantially higher" than the amount appropriated (Congressional Budget Office, 2010). This is due, in part, to the increased use of medical care provided through the VHA (Marlis, 2012). For example, the

average daily number of Veterans receiving non-institutional extended care (which includes VHA HBPC and other programs such as adult day care, skilled nursing and rehabilitation, and home health) increased from 95,092 Veterans in 2011 to 113,254 Veterans in 2012 to an estimated 120,118 Veterans in 2013 (Department of Veterans Affairs, 2013).

A Program Description of VHA HBPC. VHA HBPC provides "all-inclusive" home care to individuals with complex, chronic diseases whose condition is likely to worsen over time (Department of Veterans Affairs, 2007). This program was originally established in 1972 as the Hospital Based Home Care program and has since been renamed the Home Based Primary Care Program to better reflect the setting in which care is most often provided (Department of Veterans Affairs, 2007).

Continuous patient-centered care led by a physician-supervised interdisciplinary team is provided in the homes of Veterans. Specifically, VHA HBPC enrollees are monitored on an ongoing basis, have routine comprehensive assessments to prevent or detect the worsening of a condition, and receive timely interventions throughout the course of their disease (Department of Veterans Affairs, 2007). VHA HBPC provides care that is characterized as continuous and comprehensive rather than time-limited and specific such as home care services provided through other means (Department of Veterans Affairs, 2007).

The services provided through VHA HBPC are meant to be accessible, comprehensive, coordinated, longitudinal, accountable, and acceptable (Department of Veterans Affairs, 2007). Specifically, patient access to providers is available for emergencies during nights, weekends, and holidays. Comprehensive services are

holistic in order to treat the majority of the enrollee's health problems. Coordinated care provided by VHA HBPC is defined as providing patient referrals to appropriate services, collaboration and communication to the primary care providers and specialists, and education about disease treatment and self-care for the patient and caregiver. Accountable care is described as attention to resource management and providing cost efficient care. Acceptable care refers to the consent of the patient and caregiver of VHA HBPC and the willingness to participate in the goals of the individualized care plan (Department of Veterans Affairs, 2007).

The goals of the program are to promote the Veteran's health and independence, reduce the need for hospitalization or other institutional care, assist in transitioning the Veteran from a health care facility to home, provide support to the caregiver, enhance the Veteran's quality of life through symptom management, provide assistance with chronic disease management, meet the changing healthcare needs of the Veteran, and provide the option of dying at home (Beales & Edes, 2009). With an interdisciplinary team monitoring care, greater coordination of services designed to result in an enhanced level of care continuity. In fact, VHA HBPC incorporates specific features that have been associated with improved care and reduction in need for hospitalization among high-risk patients such as frequent in-person contact, acting as a communications hub, delivering evidence-based education to patients, and providing timely and comprehensive transitional care after hospitalizations (Brown, Peikes, Peterson, Schore, & Razafindrakoto, 2012).

The target population of VHA HBPC is Veterans who do not benefit from clinic-based services due to their inability to access services, usually due to their illness or

disability. Specifically, VHA HBPC targets: those with impaired mobility or functional limitations which make leaving the home difficult without assistance of another individual; those who are unable to cope with the clinical environment due cognitive, physical or psychiatric impairment; those who need frequent, coordinated interventions from multiple episodes; those who require hospice care for an advanced disease; and those who experience recurrent hospitalizations or urgent care episodes or are at risk of nursing home placement and have either congestive heart failure, chronic obstructive pulmonary disease, a neurological disease, diabetes mellitus, coronary artery disease, cancer, acquired immunodeficiency syndrome, and/or end-stage liver disease (Department of Veterans Affairs, 2007).

A description of VHA HBPC enrollees suggests that the average age of enrollees is 76.7 years, with an average of 19.36 diagnoses that require continuous management, and take an average of 15 medications per enrollee (Cooper et al., 2007). Furthermore, many VHA HBPC enrollees are being treated for depression and most have some form of cognitive impairment (Cooper et al., 2007).

In addition to the targeting criteria, admission requirements for the program include: living within the VHA HBPC service area; the Veteran and/or caregiver accepting VHA HBPC as the primary care provider; the determination that the Veteran's needs can be met by VHA HBPC; the Veteran has an identified caregiver if determined necessary by the VHA HBPC team; the home has been determined the most appropriate place for care as determined by the VHA HBPC team; and the home environment has been deemed safe for the well-being of the Veteran, caregiver, and VHA HBPC team (Department of Veterans Affairs, 2007).

Once enrolled, many Veterans are served by VHA HBPC for the remainder of their lives. Discharge from VHA HBPC can be for the following reasons: death, inpatient stay for 16 or more days, a determination that the Veteran can be effectively treated through routine clinic-based care, the needs of the Veteran exceed the capabilities of the VHA HBPC team, the Veteran or caregiver request discharge from the program, the Veteran and/or caregiver do not participate adequately in the treatment plan, the home environment is considered unsafe for either the Veteran and/or the VHA HBPC team members, continuation of home care is determined to be unsafe for the Veteran or caregiver relative to other care options, or the Veteran relocates out of the service area. If a VHA HBPC enrollee is discharged from the program due to an inpatient stay of 16 or more days but later is readmitted to VHA HBPC, the complete interdisciplinary assessment (described below) must be repeated and the Veteran is treated as new patient.

Services provided in VHA HBPC include primary care, rehabilitation, disease management, palliative care, and coordination of care. An interdisciplinary team is in place to provide the necessary services and includes a physician medical director, a program director, and staff from nursing, social work, rehabilitation, dietetics, and pharmacy. Other services often needed include pastoral and mental health services. Every VHA HBPC program has a minimum of 3 full time, direct care nursing staff members, but the specific staffing mix is specified such that the VHA HBPC team must be able to meet the needs of the patient population (Department of Veterans Affairs, 2007).

Case loads are determined at the local level and usually range between 20 to 30 patients to each registered nurse or licensed practical nurse, 80 to 105 per social worker, 85 to 155 per rehabilitation therapist, and 95 to 125 per dietician (Department of Veterans Affairs, 2007). Teams meet weekly to discuss patients and determine care plans. The frequency of home visits are based on the Veteran's needs and clinical judgment (Department of Veterans Affairs, 2007).

Veterans can be referred to VHA HBPC from any care setting as long as the primary care provider concurs with VHA HBPC being an appropriate mode of care for the Veteran. Once referred, the Veteran must be evaluated by at least one member of the VHA HBPC program to determine if the home environment is appropriate for VHA HBPC. Once this determination is made, the Veteran is assessed in their home by at least three team members specializing in different disciplines. Assessment includes health history, physical, psychosocial, financial, cultural, spiritual, nutritional, functional, home environment, and pain symptomology. The members of VHA HBPC formulate individualized treatment plans based on the Veteran's and caregiver's needs. If services are received outside of the VHA HBPC team, VHA HBPC adopts a medical management and care coordination role. The treatment plan is modified as needed and reviewed at least every 90 days (Department of Veterans Affairs, 2007).

VHA HBPC collaborates with services that cannot be provided through the direct care staff of the VHA HBPC team. These services can include mental health services, short-term respite, personal care, skilled home care that is beyond the scope or frequency of VHA HBPC, palliative care, care coordination, home telehealth to expand the geographical reach of the program, volunteer services, and other VHA services that

enable appropriate management of VHA HBPC patients (Department of Veterans Affairs, 2007). These ancillary services can be provided through VHA or through Medicare if the Veteran is enrolled in Medicare. The Veteran has the ultimate right to choose where to receive services but the VHA must offer to pay for contracted care or provide the necessary services (Department of Veterans Affairs, 2005, 2007, 2008).

Evidence on VHA HBPC. Several studies have examined the VHA HBPC program including both descriptive and quantitative analyses. Below is an overview of these studies, followed by a discussion of the limitations and remaining questions regarding VHA HBPC.

Patient outcomes associated with VHA HBPC. An early randomized study of VHA HBPC among those with severe disabilities or who were terminally ill was conducted utilizing data from 1984 through 1987 from the Hines, Illinois VHA hospital. Survival was similar in both VHA HBPC patients (124.6 days) and the control group (128.2 days) (Cummings et al., 1990). To determine differences in patient outcomes, multivariate analysis of covariance indicated that there were no differences between the groups in terms of ADL functioning, cognition, or patient morale at one or six months following baseline (Cummings et al., 1990). However, differences were found at one but not six months after baseline for patient satisfaction with VHA HBPC recipients reporting significantly higher levels of satisfaction with care compared to controls (Cummings et al., 1990).

Another early analysis of the Hines, Illinois VHA hospital's HBPC program indicated that there were no differences between the terminally ill enrolled in VHA HBPC compared to a randomized comparison group in terms of ADL limitations,

cognitive status, or morale at one month from baseline but found that VHA HBPC enrollees had higher patient satisfaction at one month (p = .02), although this difference was not maintained through the six month evaluation (Hughes et al., 1992). This study also examined survival days and found that VHA HBPC recipients were not different than the control group (76.2 days vs. 83.1 days) (Hughes et al., 1992). However, survival time revealed a marked difference (i.e., shorter duration) from the earlier examination of survival time among terminally ill patients at the same VHA medical center (Cummings et al., 1990).

A later and larger study of 16 VHA HBPC programs found that patients with a terminal diagnosis who were enrolled in VHA HBPC had significant improvement in health-related quality of life compared to those in the control group (Hughes et al., 2000). However, there was no difference in health-related quality of life between groups among the non-terminally ill (Hughes et al., 2000). Among terminal patients, there was no difference found in patient satisfaction among those enrolled in VHA HBPC compared to terminal patients not in VHA HBPC (Hughes et al., 2000). There was, however, a significant increase in patient satisfaction among nonterminal patients in VHA HBPC (Hughes et al., 2000). Similar to these earlier studies, a recent study interviewed 31 newly enrolled VHA HBPC recipients who reported high levels of satisfaction with VHA HBPC team access, education, and continuity of care (Edes et al., 2014).

Service use associated with VHA HBPC. Cummings et al. (1990) found that those receiving VHA HBPC were more likely to receive visits from a physician, physical therapist, social worker, and home health aide and/or dietician compared to a randomized control group receiving usual care even despite both groups receiving

similar number of service visits on average (22.8 for VHA HBPC enrollees compared to 21.7 for controls). The number of days receiving of home care was significantly greater for those in VHA HBPC compared to the control group (98 vs. 79 days, respectively) (Cummings et al., 1990). Number of days spent in a VHA hospital did not differ significantly by group although there was a difference in time in specific hospital wards. VHA HBPC recipients spent a higher proportion of their time on the intermediate care ward and less time on the general care wards compared to the control group (Cummings et al., 1990). Outpatient service utilization differed significantly with VHA HBPC recipients receiving fewer outpatient clinic visits (1.33 visits compared to controls 3.39 visits) (Cummings et al., 1990). The authors concluded that the program was not associated with adverse outcomes and resulted in marginal reductions in hospital length of stay.

In another analysis, the Hines VHA study of the terminally ill in VHA HBPC, found that there was a significant decline in number of hospital days, from an average of 15.9 days prior to enrollment to an average of 10 days and VHA HBPC enrollees spent an average of 3.5 fewer days in the hospital immediately prior to death compared to the randomized control group receiving usual care (Hughes et al., 1992). There were also differences in the number of outpatient clinic visits by group with VHA HBPC patients having significantly fewer outpatient visits although VHA HBPC recipients had significantly more home visits from a nurse compared to controls (Hughes et al., 1992).

A larger study of 16 VHA HBPC programs by Hughes et al. (2000) found a relative reduction in the proportion of VHA HBPC enrollees who were admitted to the hospital in the first six months, but the reduction was not retained at 12 months.

Additionally, a relative reduction in hospital readmissions was found only at six months among those enrolled in VHA HBPC (Hughes et al., 2000). There was also not a significant difference in the number of hospital days among re-hospitalizations between the VHA HBPC and control groups (Hughes et al., 2000).

Chang, Jackson, Bullman, and Cobbs (2009) assessed 183 VHA HBPC enrollees from the Washington, DC program who were in the program for at least six months during 2001 to 2002 and found that there was a significant decrease in the total number of hospitalizations (-43.7% change) and the total number of days in the hospital (-49.9% change) after enrolling into the program compared to prior to enrollment. However, they did not find a significant difference in the total number of emergency department visits (-18.5% change, non-significant) after enrollment into VHA HBPC (Chang et al., 2009).

In an analysis of a Missouri VHA HBPC program that specifically targeted those in advanced stages of chronic heart failure and chronic obstructive pulmonary disease, it was determined through linear regression that actual hospitalization days were 7.5 days per patient per six months less than expected ($p < .001$) (Edes, Lindbloom, Deal, & Madsen, 2006).

Cost associated with VHA HBPC. A cost analysis was conducted on the Missouri VHA HBPC program that targeted those in advanced stages of chronic heart failure and chronic obstructive pulmonary disease. It was found that those enrolled in VHA HBPC produced a cost savings of $1,873 per patient per month based on reduced services use including a reduction in hospital days after enrollment in the program compared to pre-enrollment (Edes et al., 2006). This was based on the difference of

the cost of services prior to enrollment versus during enrollment by calculating the sum

of the median number of hospital days (decrease from 7.5 to 1), median ancillary

outpatient visits (decrease from 10 to 7), median allied health outpatient visits (3, no

change), primary and specialty care visits (decrease from 9 to 6), and the VHA HBPC

visits (increase from 0 to 6). Similarly, another more recent analysis was conducted

comparing expected costs to actual costs for 9,425 newly enrolled VHA HBPC

recipients which found that Medicare costs were 10.8% lower than projected, VA plus

Medicare costs were 11.7% lower than expected, and combined hospitalizations were

25.5% lower than prior to VHA HBPC enrollment (Edes et al., 2014).

These findings supported the early randomized cost effectiveness study that

determined that VHA HBPC produced a net savings of 13% compared to those in usual

care (Cummings et al., 1990) and another study that suggested that VHA HBPC

produced a net savings of 18% (albeit non-significant difference) among those

diagnosed with a terminal condition with a 6-month prognosis (Hughes et al., 1992).

Although those in VHA HBPC had significantly more home health care than the

comparison group which more than doubled the cost of home care ($658 more in 1985

dollars), the savings were attributed to lower VHA (48% lower) and private sector

hospital costs over a six month period and to lower institutional care costs for those

enrolled in VHA HBPC (Hughes et al., 1992). Based on the differences in rates of

utilization, these findings on cost differences were expected.

Another cost analysis finds different results than the four aforementioned studies.

The analysis of 16 VHA HBPC programs found that total costs among those enrolled in

VHA HBPC were 6.8% higher compared to the randomized control group. Even though

the costs among the VHA HBPC group were lower for hospital readmissions and private sector costs, home-based care and nursing home costs were significantly higher compared to the control group (Hughes et al., 2000). The only sector identified as significantly reducing cost among the VHA HBPC group was outpatient services (Hughes et al., 2000).

These disparate findings could be a result of the differences between VHA HBPC programs and differences in study designs. The majority of studies that found cost savings were single-site studies, whereas, the higher cost findings were found among the study of 16 VHA HBPC programs. These differences support the need for further research that includes multiple VHA HBPC sites.

Other research on VHA HBPC. Other research suggested that VHA HBPC enrollees could benefit from in-home pharmacy evaluations to increase adherence to medication compliance (Hsia Der, Rubenstein, & Chov, 1997). Recently, VHA HBPC patient records were used to determine the applicability of using the Medication Appropriateness Index to monitor medication adherence, efficacy, and adverse events (Davis, Hepfinger, Sauer, & Wilhardt, 2007).

Another study examined the characteristics associated with VHA HBPC enrollment among those with mental health diagnoses. It was determined that VHA HBPC enrollees with mental health diagnoses are more likely to be older, male, divorced, separated, or widowed, suffer greater service-related disability, have a VA pension, and have higher incomes compared to those that did not utilize VHA HBPC (Miller & Rosenbeck, 2007). It was also found that VHA HBPC enrollees with mental health diagnoses were less likely to be diagnosed with drug abuse or dependence but

were more often diagnosed with all other mental health diagnoses, most commonly Alzheimer's disease or dementia (Miller & Rosenbeck, 2007). VHA HBPC enrollees with mental health diagnoses had greater morbidity and were more likely diagnosed with chronic conditions like hemiplegia/paraplegia, diabetes, mild liver disease, rheumatologic disease, chronic pulmonary disease, cerebrovascular disease, and congestive heart failure (Miller & Rosenbeck, 2007).

   Limitations of the evidence on VHA HBPC. Based on these data, VHA HBPC seems like a promising model of care, but worthy of further investigation. A number of limitations are evident within the existing literature. Specifically addressing the evidence on cost effectiveness, two of the studies (Cummings et al., 1990; Hughes et al., 1992) were conducted prior to the availability of cost data in VHA administrative patient records (1984-1987), had relatively small samples (N=171 and 419, respectively), and utilized only local data. Hospital costs were based on 1985 average accounting costs per day. Moreover, in the Edes, et al. (2006) study, cost savings from intensive care units and emergency departments were *assumed* to be zero and the sample size was 34 patients.

   The evidence that suggested VHA HBPC is associated with fewer hospital days and number of hospitalizations should also be considered limited. First, the Hughes et al. (1992) study uses local data from the 1980's with a small sample size. Second, the Edes et al. (2006) study reported a reduction of ICU and ED use based on a regression using data from only 34 patients. Additionally, the confidence intervals raise doubt regarding the conclusions that can be drawn from this evidence. Moreover, the time examined was based on 120 days after enrollment compared to two years prior to

enrollment. Chang et al. (2009) based their findings on local data which only measured six months pre- and post-enrollment, used only *t*-tests, and did not have a comparison group. Finally, patient outcomes in terms of survival time were determined based on simple means tests without covariate accountability.

There are several reasons why the above limits the evidence on the effectiveness of VHA HBPC. First, when studies use only a pre-post design and do not have a control or comparison group, there could be selection bias in the sample. Selection bias can undermine the findings due to prior group differences that existed in the selected sample rather than differences based on participation in VHA HBPC. This is why a comparison group, at a minimum, is vital to understanding a program's effects.

Using simple averages to determine patient outcomes in terms of survival does not take into account the multitude of factors that affect survival. Several techniques, like regression-based survival analysis, take into account not only the time until event, but also accounts for covariates that can potentially confound the relationship between the entry into the observation period and the event. Likewise, more robust statistical estimations are needed to confirm the earlier findings using national data. Therefore, the current literature regarding VHA HBPC's impact on service use, cost, and survival remain unclear. Thus, the current study aims to expand the evidence associated with VHA HBPC by using national data with a comparison group to examine service utilization, average total expenditures, and survival.

Chapter 2: The Present Study

The overall goal of the proposed study is to determine the impact of VHA HBPC on service utilization, expenditures, and survival. This section describes the study objectives, the logic model used to develop the hypotheses, and the theoretical framework used to conceptualize the relationship between the factors of interest. Finally, the aims and corresponding hypotheses are conveyed.

Objectives

Although evidence exists regarding the effectiveness of VHA HBPC, more research is needed. The current study aims to accomplish three objectives. First, this study will examine the effect of VHA HBPC on major healthcare service use (i.e., hospital, nursing home, and outpatient care) paid for by the U.S. Department of Veterans Affairs (VA).[2] Next, this study will examine the effect of VHA HBPC on total expenditures paid for by the VA. Third, this study will examine whether VHA HBPC enrollees experience similar mortality and survival as compared to a matched concurrent cohort.

This study is critical due to the rise in the number of Veterans that are homebound from traumatic brain injury, mental health issues, and spinal cord injuries, which is likely to increase the demand for VHA HBPC. Although current evidence describes the VHA HBPC population as generally older with chronic comorbid

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[2] The VA is comprised of three sectors: the Veterans Health Administration (VHA), the Veterans Benefits Administration, and the National Cemetery Administration. Reference to the VA refers to the Department as a whole whereas reference to the VHA refers specifically to the Veterans Health Administration.

conditions, the proposed study is significant to improving the care received by young and old Veterans alike who need medical care in the home.

In addition to the overall effect of VHA HBPC on service use, cost, and survival, this study will look at specific strata including those age 85 and older, those with two or more comorbidities, and those who were diagnosed as recipients of palliative care. The following describes the rationale for these specific examinations.

Older Adults and VHA HBPC. It is well-understood that healthcare costs increase dramatically for older adults who are approaching the end of life, often due to substantial disease burden and aggressive attempts to treat complex medical conditions (Chastek et al., 2012; Frederix et al., 2013; Hogan, Lunney, Gabel, & Lynn, 2001; Yu, Smith, Kim, Chow, & Weaver, 2008). Conversely, other research suggests that older age is associated with less aggressive end-of-life care (Miesfeldt et al., 2012), including lower rates of hospitalizations (Menec, Lix, Nowicki, & Ekuma, 2007). The average age of VHA HBPC enrollees is 76.7 years (Cooper et al., 2007), and therefore, it is important to examine the effect of VHA HBPC by those who are the oldest old.

Comorbidity and VHA HBPC. Comorbid conditions are common in the general population and resource use has been associated with the degree of comorbidity rather than the specific diagnosis (Starfiled et al., 2003). Moreover, research suggested that comorbidity mediates the role between age and survival (Jung et al., 2012). Given the average age of VHA HBPC enrollees and considering that the average VHA HBPC enrollee has 19.36 diagnoses that require continuous management (Cooper et al., 2007), degree of comorbid conditions should be considered in this investigation.

Hospice and VHA HBPC. Throughout the last decade, the VHA has focused on increasing access to hospice care through a variety of initiatives which resulted in an increase in the number of inpatient deaths in hospice bed sections and an increase in referrals to community hospice providers (Department of Veterans Affairs, 2011). The implications of the increased use of hospice care among VHA HBPC enrollees are important given that hospice care has been associated with decreased health care costs near the end of life in some studies (Brumley et al., 2007; Kelley, Deb, Du, Carlson, & Morrison, 2013; Penrod et al., 2010) and an increase in others (Emanuel et al., 2002; Pyenson, Connor, Fitch, & Kinzbrunner, 2004).

Considering that those who are receiving hospice would have different health service patterns as a result of this service and that many of the previous studies on VHA HBPC selected a sample that included only those with terminal illnesses, it is necessary to examine the effect of VHA HBPC by identifying those that received such services. Additionally, this type of examination is needed given that many die while enrolled in VHA HBPC.

Logic Model

The logic model presented here proposes that a vulnerable population who needs healthcare services due to a variety of comorbidities and disability, experience disease exacerbation, a lack of disease management, and a lack of coordination of care without VHA HBPC (Figure 1). This population is in need of services but cannot leave the home to access those services. Therefore without VHA HBPC, service use, such as avoidable hospitalizations and nursing home use, increases along with expenditures.

This logic model assumes that the intervention of VHA HBPC will help patients manage their diseases and symptoms and receive the necessary coordination of care that is associated with a decrease in avoidable services, e.g., hospitalizations, which should decrease expenditures. This logical model stems from Andersen's behavioral model, described below.

Without VHA HBPC

Vulnerable population unable to access care*	Disease exacerbation, lack of disease management & coordination of care	Higher resource use and expenditures

With VHA HBPC

Vulnerable population unable to access care*	Symptom and disease management, coordination of care	Decrease avoidable hospitalizations and nursing home use which should decrease expenditures

The point at which VHA HBPC intervenes on health behavior.

Figure 1. Logic Model to Understand Why One Should Expect VHA HBPC to Decrease Service Utilization and Cost.

This model is influenced by Andersen's behavioral model, discussed below.

Theoretical Framework: Andersen's Behavioral Model

Andersen's (1973) behavioral model is a model frequently applied to health service research and can be applied as a framework for the current investigation. This model is comprised of three determinants that explain health services utilization. The first of these determinants is predisposing characteristics which include demographic characteristics (e.g., age, sex, and race). The basic notion related to predisposing characteristics is that some individuals with certain characteristics will be more likely than others to use health services regardless of the fact that these predisposing characteristics are not directly related to health services.

The second determinant is referred to as enabling resources. Enabling resources include family (e.g., income, health insurance) and community characteristics (e.g., price of health services, ratio of health personnel to the population). Specifically, individuals must have the means to receive services. Additionally, access to health facilities and the appropriate personnel have to be available in order for persons to receive services. As such, these factors can either enable or prohibit an individual's receipt of health care services. For example, a study found an association between disparities in physician utilization and enabling factors (i.e., level of income and health insurance status) after adjusting for predisposing factors and need for care (Blackwell, Martinez, Gentleman, Sanmartin, & Berthelot, 2009).

The final determinant to explain health services utilization is need and the perceived need for healthcare. How individuals view their health, how they experience health symptoms, and the ideas they attach to this experience is of importance when considering health services utilization. For example, research underscores the

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importance of the need of services when determining service use for bereavement

services (Bergman, Haley, & Small, 2011). Additionally, awareness of unmet needs has

been linked to the use of home- and community-based service utilization (Chen &

Thompson, 2010). Finally, Elhai et al. (2008) found that predisposing and enabling

factors were associated with outpatient utilization among Veterans, but need factors

provided an additive effect over predisposing and enabling variables accounting for the

strongest effects.
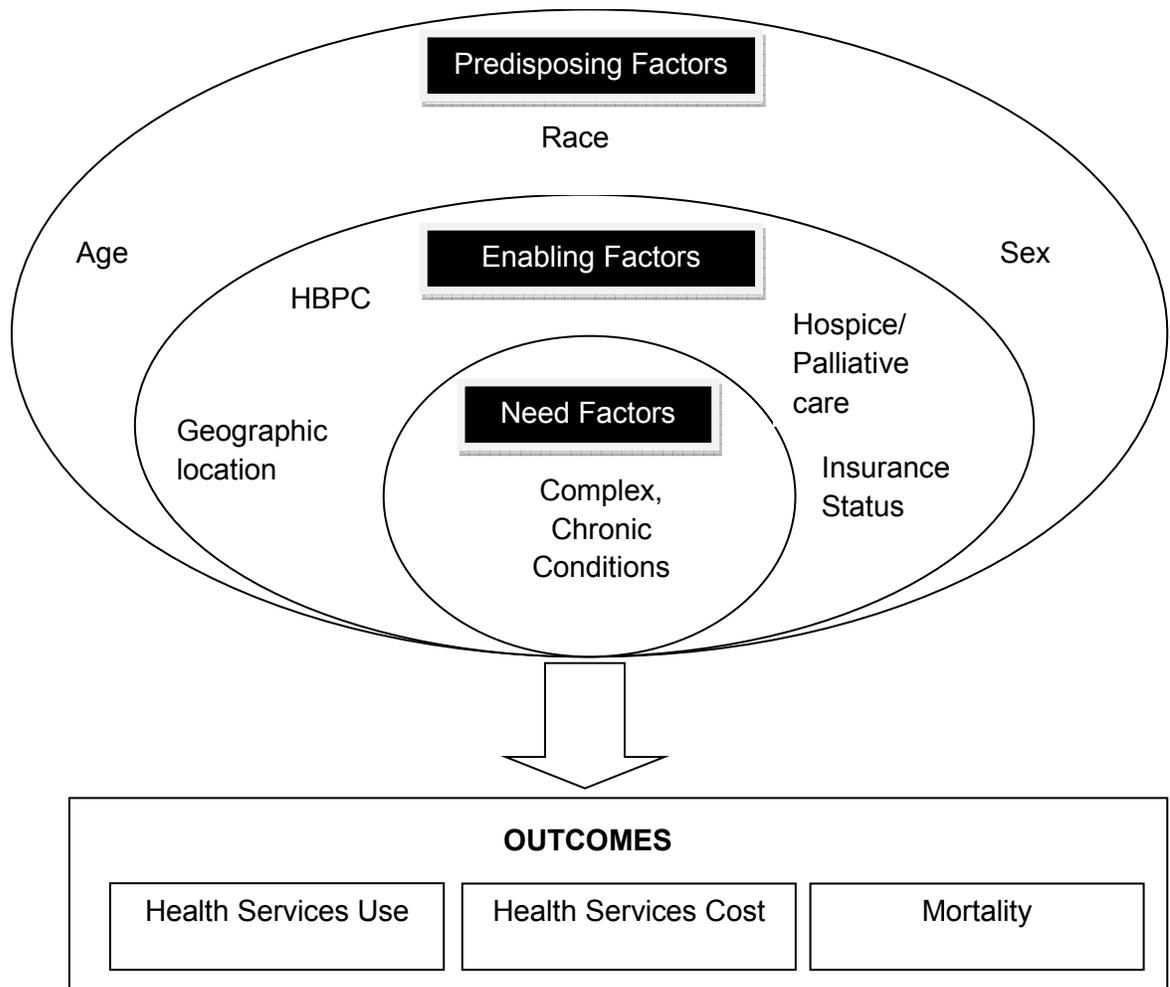
Figure 2. Health Behavior Model for VHA HBPC

Predisposing Factors. The typical enrollee of VHA HBPC has characteristics

that are commonly associated with those that have complicated post-hospital transitions

of care (Kind, Smith, Frytak, & Finch, 2007) which can lead to higher service use such

as being older, male, and African American (Chang et al., 2009; Hughes et al., 2000).

Therefore, age, race, and sex will be accounted for in this study.

Enabling Factors. VHA HBPC enrollment in itself could be an enabling factor

associated with healthcare use. Related to VHA HBPC enrollment is geographic

location. While almost all VA medical centers offer VHA HBPC, living within a specified

distance of these services could affect access to services. Research on Veterans

suggests that rurality status is associated with service use and medical costs (Bailey,

Manning, & Peiris, 2012). Additionally, insurance status has been linked to physician

utilization (Blackwell et al., 2009). In this case, VHA service connectedness serves a

proxy for insurance status. Service connectedness influences the amount of cost-share

the Veteran can expect when utilizing services and is based on service history and

disability status.

Furthermore, hospice, by philosophical and regulatory definition, is associated

with less aggressive care at the end of life. For example, in a study examining

emergency department use among those age 65 and older from 1992 to 2006, it was

found that those that utilized hospice at least one month prior to death were rarely

admitted to the emergency department (Smith et al., 2012). Therefore, hospice care

could be considered an enabling, or more appropriately in this case, a prohibiting factor

associated with certain types of care. For these reasons, palliative care (in place of

hospice[3]), geographic location, service connectedness or eligibility (in place of insurance status), and likelihood of VHA HBPC enrollment will be accounted for in this analysis.

Need Factors. Need is particularly important in an older Veteran population which has experienced an increased clinical complexity and dependency compared to age-matched non-Veterans (Shay & Burris, 2008). Additionally, those enrolled in VHA HBPC are by enrollment criteria, those who are in need of healthcare services. Therefore, comorbidities will be used as a proxy for need of services in this study.

Aim 1

This study will examine the effect of VHA HBPC on health service utilization.

Hypothesis 1. It is expected that VHA HBPC will have an effect on health service utilization by decreasing nursing home use and acute hospitalizations and by increasing outpatient service utilization.

Aim 2

This study will examine the effect of VHA HBPC on total healthcare expenditures paid by the VA.

Hypothesis 2. It is expected that VHA HBPC is associated with lower total healthcare expenditures due to expected decreased nursing home use and acute hospitalizations.

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[3] Hospice care is compassionate care for those facing a life-limiting illness or injury provided through a team approach to medical care, pain management, and emotional and spiritual support specific to the patient's preferences (National Hospice and Palliative Care Organization, n.d.-a). Palliative care is patient and family-centered care that anticipates, prevents, and treats suffering throughout the continuum of the illness addressing physical, intellectual, emotional, social, and spiritual needs (National Hospice and Palliative Care Organization, n.d.-b). A distinguishing characteristic between these two related types of care is that palliative care can be provided concurrently with curative or life-prolonging care.

Aim 3

This study will examine if there is a survival differential associated with VHA HBPC enrollment.

Hypothesis 3. It is expected that VHA HBPC is associated with differential survival.

Method

Data Sources. The VHA system is ideal for examining service utilization and expenditures because of the fact that all VHA healthcare providers are part of a centralized reporting system which makes the VHA the single largest integrated healthcare system in the U.S. Specifically, the Veterans Integrated Health Systems and Technology Architecture, or VISTA, is the health information system that captures information on daily operations at all VHA facilities for both inpatient and outpatient services at the patient level through the use of electronic health records. VISTA is decentralized but data is extracted from VISTA to create national datasets (Barnett, 2003).

Decision support system (DSS). The extracted VISTA data is the main source for the database referred to as DSS. DSS is an activity-based allocation system which uses DSS Identifiers, also referred to as "stop codes" to collect workload information, support patient care continuity, resource allocation, performance measurement, quality management, and third-party collections (Veterans Health Administration, 2008). This coding system has been nationally implemented since 1999 and indicates who provides specific clinic products.

DSS Identifiers are six digits comprised of a primary and secondary coding scheme. The first three digits (i.e. the primary code) indicate the type of services provided followed by the second three digits (i.e. the secondary code) which indicate the secondary modifier. These codes were used to identify VHA service utilization and expenditure information at the patient level from inpatient and outpatient files.

Purchased care files. The VA makes payments to non-VHA providers when care is needed for a Veteran that the VHA cannot provide. This information is accessible from the Purchased Care files, formerly known as the Fee Basis files. This study utilized inpatient purchased care files to determine non-VHA acute hospitalizations that were paid for by the VA. Patient identifiers enable merging across data files.

Vital status file. The VHA Vital Status Files contains mortality data from multiple VHA and non-VHA sources (i.e., Medicare Vital Status File and the Social Security Administration) (Veterans Health Administration, 2014). The file contains information including social security number, date of birth, gender, and date of death.

Measures. The following are operationalizations of the variables in this study.

VHA HBPC. VHA HBPC enrollees were identified through DSS by the utilization codes of 156 (psychologist), 157 (psychiatrist), and 170-177 (physician; registered nurse, registered nurse practitioner, physician assistant, or licensed practical nurse; nurse extender or physician extender; social worker; therapist [recreation, physical, or occupational]; dietician; clinical pharmacist; telephone; other). VHA HBPC status was dichotomized (1=VHA HBPC enrollee, 0=not enrolled in VHA HBPC) and used as a

treatment indicator to determine associations with health services utilization, expenditures, and survival.

Initial treatment date. To determine when to start analyzing the use and cost of services, the initial treatment date was used as day one. For the treatment group, the initial treatment date was the first date of VHA HBPC utilization. For the comparison group, the initial treatment date was the first date of an outpatient utilization after the beginning of the study period (the first day of FY 2009, i.e., October 1, 2008).

Healthcare utilization. Health services were categorized into nursing home care, acute hospitalizations (VHA and non-VHA), and outpatient utilizations. These variables were constructed separately as dichotomous variables (yes/no). Additionally, counts of service utilization were constructed for hospitalizations and for outpatient utilizations.

Hospitalization was determined by a claim for inpatient utilization. Hospitalizations were included in the analysis if they occurred after the initial treatment date and before the end of the study period (i.e., September 30, 2012).

The number of past hospital utilizations was identified by inpatient hospitalization codes in FY 2008 and was used in the case/control matching technique (values were binary indicators of 1, 2, or 3 or more with zero past hospitalizations being the reference category). The number of hospitalizations after the initial treatment date were calculated as an outcome variable.

Nursing home utilization was identified through the outpatient files (values 650, 651, 653, and 654). Nursing home utilization was included in the analysis if utilization occurred after the initial treatment date and before the end of the study period (September 30, 2012).

Palliative and bereavement care. Considering that many VHA HBPC users are in the program at the end of life, ICD-9-CM procedure codes were used to determine use of palliative care (V66.7) or bereavement services (V62.82). The utilization of hospice care was considered but the data were not ideal to examine hospice use. Therefore, the use of the ICD-9-CM code V66.7 was used as a proxy for recipients of hospice care since hospice-specific codes weren't implemented throughout the VHA until FY 2012. Also, because such codes could be associated with the likelihood of death, they were identified as separate binary indicators and used to predict VHA HBPC treatment in the case/control matching technique. Up to 20 ICD-9-CM primary diagnosis codes, sourced from the outpatient file, were used to determine the receipt of palliative care or bereavement services.

Expenditures. Cost information for care provided by the VHA is available through DSS. These costs are considered total costs of care (i.e., direct and indirect). The Purchased Care files also contain cost information for the amount the VA paid for non-VHA inpatient utilization, which were also included in this study. Cost information was constructed separately for VHA-provided services including hospital, nursing home, and outpatient services, and for non-VHA provided inpatient hospital services. These services were summed to determine total cost of care.

Demographics. All demographic variables were identified by DSS, including age, race, and service eligibility. Age was defined in years and represents baseline age. Sex was identified based on the dichotomous variable sex from the VHA Vital Status File and outpatient DSS files.

Race was derived from outpatient DSS files and was defined as: Black or African American, White, and other. Additional categories of race and ethnicity were available but these groupings had numbers too small to be informative in the analysis and were therefore categorized as other. Due to the high rate of missingness on the race variable, a 'missing race' category was created in order to retain all available information and cases in the analyses while maintaining the integrity of the race values that were available. Dummy indicators were constructed for Black, other, and missing, with white as the reference category.

Veteran eligibility is based on categories representing the degree of disability related to serving in the service and the degree of impairment. Not being service connected was compared to all other eligibility categories as a binary indicator.

Geographic location was considered for the model, but a recent study suggested that distance from a VHA medical center was an effective instrumental variable for determining the risk of hospitalization (Edwards, Prentice, Simon, & Pizer, 2014). Instrumental variables are not recommended for use in matching algorithms. Therefore, geographic location was not included, but was examined after the matches were selected and the determination was made that there was not a significant difference between the treatment and comparison groups in miles to the nearest VHA medical center offering VHA HBPC.

Comorbidity. The DSS variable 'Primary Diagnosis' uses ICD-9-CM codes to discern patient morbidity. Up to 20 ICD-9-CM codes, sourced from the outpatient file at baseline, were used to determine patient comorbidity. The ICD-9-CM codes used in this analysis were identified at baseline and were constructed into separate binary indicators

based on the Elixhauser method (Elixhauser, Steiner, Harris, & Coffey, 1998). While other methods of measuring morbidity exist, the Elixhauser method has shown superior performance compared to others, such as the Charlson index (Southern, Quan, & Ghali, 2004). The mutually exclusive morbidity categories used here were: congestive heart failure, cardiac arrhythmia, valvular disease, pulmonary circulation disorders, vascular disorders, hypertension uncomplicated, hypertension complicated, paralysis, neurological disorders, chronic pulmonary disease, diabetes, hyperthyroidism, chronic kidney disease/renal failure, liver disease, lymphoma, metastatic cancer, cancer without metastasis, rheumatoid arthritis/collagen, coagulopathy, weight loss, obesity, anemia, alcohol/drug abuse, psychoses, and depression. A separate variable was created to account for comorbidity by identifying if a patient had two of more of any of the Elixhauser categories.

Mortality. The date of death for subjects in this study was ascertained from the VHA Vital Status File. To examine survival, the difference between the initial treatment date and the date of death was calculated. If death did not occur, survival time represented the difference between the initial treatment date and the end of the study period (i.e., September 30, 2012).

Study Design. In order to examine the impact of VHA HBPC, a retrospective cohort design was utilized. The cohort under investigation was selected from FY 2009 and FY 2010 (i.e., the baseline period) and was followed through FY 2012.

Similar to another recent examination of VHA HBPC (Edwards et al., 2014), the treatment (VHA HBPC) cohort was selected by identifying patients who had more than one VHA HBPC utilization during the baseline period. If there was only one VHA HBPC

utilization, the patient was not considered a VHA HBPC participant, and thus, was a potential control. This is because having only one utilization likely indicates an assessment for VHA HBPC that did not result in program enrollment. Additionally, to be included in the treatment cohort, VHA HBPC enrollees had to be first-time participants in the program, determined by a two year look back which identified those who had VHA HBPC utilization during FYs 2007 or 2008. These cases were removed from the analyses.

All covariates (i.e., demographics, clinical characteristics, and frequency of past hospitalizations) were selected at baseline and compared by treatment status to determine if bias was present based on participation in VHA HBPC.   In this study, all covariates were used as binary indicators, and therefore, were compared using chi-square goodness-of-fit tests. As will be described in detail in the results, all but one of the covariates were significantly different based on participation in VHA HBPC. These baseline differences between groups necessitated the control for confounding by the use of propensity matched scores to identify an appropriate comparison group.

Propensity matching uses predicted probability of group membership obtained from a logistic regression model based on observed predictors. Propensity matching reduces the imbalance of the observed baseline characteristics between two groups by matching individuals based on the probability of exposure to the treatment, in this case, participation in VHA HBPC. Various methods of utilizing propensity scores exist (e.g., stratification based on the propensity score, regression adjustment, inverse probability weighting), but matching based on probability of treatment is believed to produce more precise estimates compared to other methods (Austin, 2007).

Since selecting a propensity method is somewhat subjective, a review of propensity score methods was conducted and it was concluded that matching is recommended when the data are appropriate for this method (Austin, 2007, 2009b, 2014). Other methods have limitations including extreme weights being common with inverse probability weighting which could be due to violations of the positivity assumption (Vittinghoff, Glidden, Shiboski, & McCulloch, 2012). Additionally, stratification of the propensity score can cause residual confounding (Vittinghoff et al., 2012), has been shown to produce the greatest bias, and is not recommended for use with time-to-event outcomes (Austin & Schuster, 2014). Type I errors tend to be higher in methods other than matching (Austin & Schuster, 2014). Therefore, although there is subjectivity in the selection of the method of propensity score modeling, matching is highly regarded and recommended if the data and study design are appropriate, as was the case in this study. Given this, and the robustness of the data, the matching technique was selected.

Statistical Analysis. All analyses were conducted in SAS 9.2 (SAS Institute Inc., 2009).

Sample. In this study, to generate patient-specific propensity scores to determine probability of participating in VHA HBPC, a multivariate logistic regression was used. All observed covariates that were predicted to be associated with the outcomes were included in the model, i.e., all covariates previously described. Specifically, these included: age (in years: 65-74, 75-84, 85-111; reference category: 0-64 years), sex (male=1), race (Black, other, missing; reference category: white), 25 comorbidities (dichotomous indicators), the number of comorbidities (two or more compared to less

than two), select ICD-9-CM procedures (i.e., palliative care and bereavement), and service eligibility (not service connected compared to all other eligibility, dichotomized). All variables were binary.

After the propensity scores were generated via multivariate logistic regression, the population was then randomly sequenced and matched one control to one treatment, which is the recommended number of case-controls (Austin, 2010), without replacement,[4] using nearest neighbor[5] matching with a caliper[6] distance of 0.20 of the standard deviation of the logit of the propensity score. The caliper distance of 0.20 of the standard deviation of the logit of the propensity score has been validated as yielding optimal performance when estimating treatment effects (Austin, 2009b; Y. Wang et al., 2013). By applying a caliper parameter to the match, the proportion of the standard deviation of the logit of the propensity score is defined. In other words, if the standard deviation of the control is more than 0.20 from the standard deviation of the logit of the propensity score of the treatment case, it is not selected as a match. The random generation will continue to the next randomly selected case and determine if the propensity score is within the selected 0.20 allowable range. This process continued until all cases were matched to controls.

Next, the distributional probabilities of cases and controls were compared to determine that the overlap assumption was met to allow for the analysis of outcomes

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[4] Without replacement indicates that matched controls cannot be placed into the pool of potential controls to be matched for another treatment case (Stuart, 2010). In other words, each matched control is a unique case.

[5] Nearest neighbor refers to selecting a case from the control group that is closest to, i.e. smallest distance from, the propensity score of a treatment case (Stuart, 2010).

[6] A caliper refers to the fixed allowable distance between the treatment case and the matched control case (Stuart, 2010).

between comparable groups. To do this, the distribution of the propensity scores were examined by VHA HBPC status. Then, the distributions of the observed covariates were checked by evaluating standardized differences by VHA HBPC status to confirm that the propensity scores created a balanced distribution between groups, of which, less than 10% is considered balanced (Austin, 2009a).   After ensuring the overlap assumption was met, analyses of the outcomes were conducted.

Aim 1. Healthcare services were analyzed by VHA HBPC status using descriptive statistics to indicate the rates of utilization. McNemar's test of significance was applied to determine if there was a statistically significant difference between VHA HBPC status and service utilization. McNemar's test was necessary to account for the matched study design.

In this analysis, multivariate statistics were not necessary to determine whether VHA HBPC enrollment significantly impacted healthcare service utilization since all covariates have been adjusted by the use of propensity score matching. Furthermore, previous research suggested that samples generated via propensity score methods can result in biased estimation of conditional odds ratios, like those produced by logistic regression models (Austin, 2007). Austin et al. (2007) posited that when using matched samples based on propensity scores, odds ratios produce sub-optimal performance whereas methods that measure differences in proportions or means have superior performance over odds ratios. Therefore, relative risks are recommended in propensity-matched studies since these methods outperform odds ratios in the decrease of the mean-squared errors.

Relative risks were calculated for each service category. By utilizing this type of study design and analysis, the results allowed conclusions to be drawn as to the association between VHA HBPC enrollment and specific types of service utilization relative to the comparison cohort.

Aim 2. Descriptive statistics were used to indicate how VA expenditures varied by VHA HBPC status by describing total average expenditures over the duration of the study period and by describing average expenditures specifically by nursing home care, hospitalization (VHA and non-VHA), and outpatient utilization.

Then, generalized linear models (GLM) with gamma link and log functions were used to examine whether there was a statistically significant difference in the average cost of care by VHA HBPC status. This modeling technique was appropriate for healthcare expenditures due to the nature of heteroscedasticity and skewness in the cost distributions while retaining the original dollar scale of the data (Blough & Ramsey, 2000). The models were weighted based on how many days each individual was observed in the study.

Aim 3. To determine if there was a significant difference in survival by VHA HBPC status, bivariate relative risk analysis was first conducted. Then, the examination of survival (i.e., dead or alive) time (in days) by VHA HBPC status was determined by utilizing a Cox proportional hazards model. In the current study, observations were right censored which was accounted for by the Cox proportional hazards model. Since this time-to-event analysis was conducted using the matched sample which adjusted confounding factors, the only additional adjustments made in the Cox regression model were exposure to treatment (i.e., participation in VHA HBPC) and quintile of the logit of

the propensity score. A robust estimator of variance is used to account for the lack of independence between groups due to clustering from matching. The event in this study is death (=1) or survival (=0). The origin of time was based on the initial treatment date. Time was scaled in days.

Sensitivity analyses. Five sensitivity analyses were conducted to validate the findings from the original sample. The first sensitivity analysis selected a new comparison cohort using exactly the same method as described above. The first validation comparison cohort was 100% unique from the original comparison cohort.

A second sensitivity analyses used the original sample but selected only those in VHA HBPC that were in the program for 6 or more months. This timeframe was selected because it is plausible that reducing service use is not possible immediately after an episode of disease or illness exacerbation, and because, this timeframe has been examined in other studies (e.g., Chang et al., 2009). A third sensitivity analysis selected another comparison cohort using all the same covariates used to generate the propensity scores in the original sample except the variable 'number of past hospitalizations' was replaced in the logistic regression model with the variable 'number of days since past hospitalization to initial treatment date'.

The fourth sensitivity analysis selected the comparison cohort based on the implications from the previous analyses conducted in this study. This included adding time to death and additional comorbidities to the matching algorithm and selecting the cohorts only after an occurrence of an inpatient hospitalization. Time to death was created in quartiles and added to the matching model. Also added to the model was the presence of the following comorbidities (based on ICD-9-CM primary diagnosis codes):

dementia, hip fracture or replacement, ulcer, pneumonia, respiratory failure, bone marrow failure, sepsis, and debility unspecified. These were selected based on recent research suggesting that claims data can be used to determine diminished functional status (Chrischilles et al., 2014). The comorbidities selected were based on those that were not already in the matching algorithm and those that were coded using ICD-9-CM codes. Due to the selection of the cohort to only those with a hospitalization, the initial treatment date represents the date of the baseline (FY 2009 or 2010) inpatient hospitalization.

Finally, the fifth sensitivity analyses used the same cohort as the fourth but only included those VHA HBPC enrollees that utilized VHA HBPC for six months or more. This was done for the same reasons as stated above, because it is plausible that reducing service use is not possible immediately after an episode of disease or illness exacerbation, and because, this timeframe has been examined in other studies (e.g., Chang et al., 2009). Therefore, the initial treatment date for the treatment cohort in this analysis is 180 days after the baseline (FY 2009 or 2010) inpatient hospitalization.

Chapter 3: Findings

Sample

The sample was selected by identifying utilization of outpatient services beginning in FY 2009 through FY 2010. During this timeframe, a total of 91,079 patients were identified as using VHA HBPC services and a total of 6,307,081 patients were identified as non-VHA HBPC users. Of the VHA HBPC users, a total of 25,190 had only one VHA HBPC utilization. These patients were not considered VHA HBPC enrollees but instead were used as potential controls. The look-back period (FY 2007-2008) identified 24,633 VHA HBPC users and these cases were discarded in order to select only new users of the program. The final cohort for generating propensity scores was comprised of 41,256 new VHA HBPC enrollees and 6,308,140 potential controls (this selection is illustrated in Figure 3).

To estimate the causal effects of participation in VHA HBPC using observational data from VHA administrative records, propensity scores were generated for matching to identify a comparison group with similar characteristics as those who participated in VHA HBPC. A logistic regression was used and included age, sex, race, Elixhauser morbidity groupings, number of comorbidities, select ICD-9-CM procedures (i.e., palliative care and bereavement), and service eligibility to predict VHA HBPC enrollment.

Propensity scores were generated for 6,349,396 patients and represented the predicted probability of participating in VHA HBPC. The average propensity score was
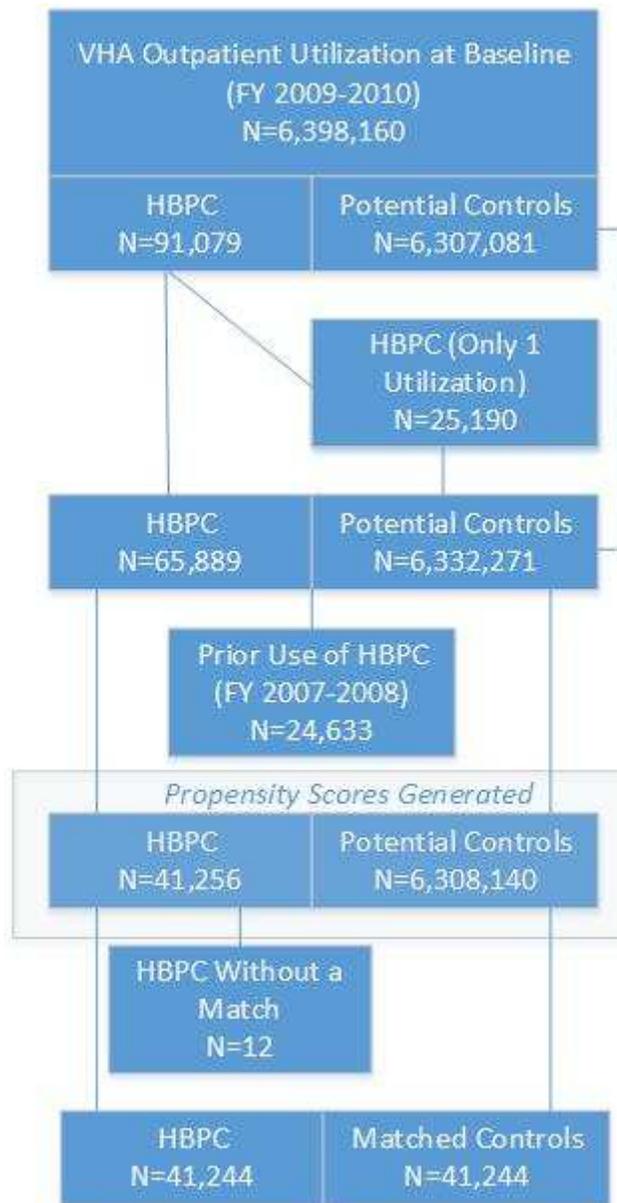
Figure 3. Sample Selection

0.01 (SD = 0.02) with a range from < 0.01 to 0.96 prior to matching. After these

propensity scores were generated via logistic regression, the population was randomly

sequenced and matched one control to one treatment, without replacement, using

nearest neighbor matching and a caliper distance of 0.20 of the standard deviation of

the logit of the propensity score to derive 41,244 matched pairs. Applying the caliper

method can result in unmatched treated cases if the propensity score of the control

cases was not within the distance specified of the treated case (Austin, 2014). In this

analysis, 12 treated cases were not matched and not included in the analyses of

outcomes. The post-match average propensity score was 0.04 (SD = 0.08) with a

range of < 0.01 to 0.90.
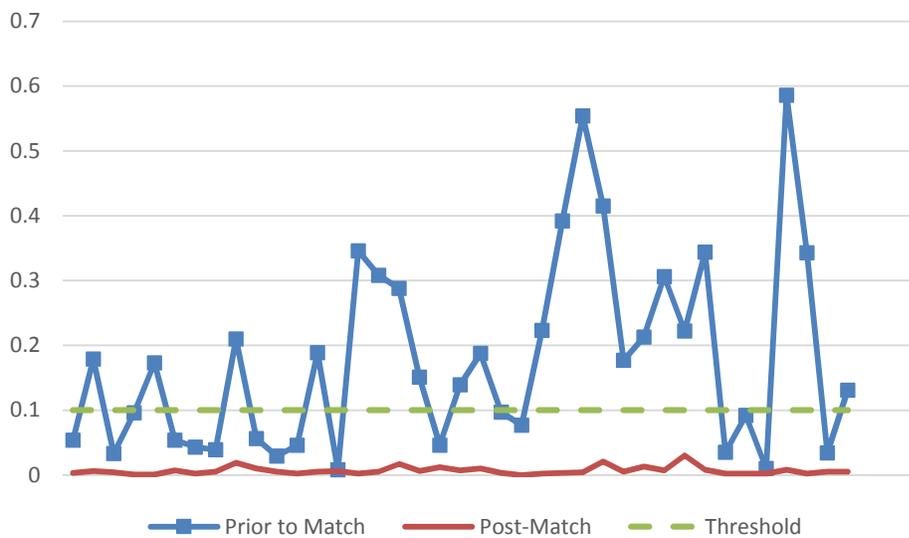
Figure 4. Standardized Differences Between Treatment and Control Groups

Given that the objective of this model was to balance observed covariates by

reducing residual variance rather than to predict exposure to VHA HBPC, the balance of

residual variance among covariates was examined in place of the usual examination of

model fit. In Figure 4, it is shown that the standardized differences (i.e., standardized

mean differences in units of the pooled standard deviation to compare balance in

observed variables) before propensity score matching varied greatly compared to the standardized differences after propensity score matching. Austin (2009a) recognized that there is no consensus on the acceptable level of balance between groups that is meaningful, but note that others have suggested standardized differences of 0.1 (represented by the dashed line in Figure 4) or below, which was achieved.

Moreover, Figures 5 and 6 show the change in the distribution of the logit of the propensity scores before and after matching. Prior to matching, the logit of the propensity scores had non-parametric density estimates of the distribution among the potential comparisons. This non-normal distribution of the propensity scores in the potential comparison group indicated that this group was not comparable to the treatment group prior to matching.

After matching based on a caliper of 0.20 of the standard deviation of the logit of the propensity score, density estimates of the distribution of the propensity scores between groups was normalized. From Figure 6, the display of the density of the logit of the propensity scores after matching, it can be concluded that the treatment and selected controls are comparable in terms of their likelihood to be treated by VHA HBPC given the observed covariates. The distributions of the logit of the propensity scores of both groups were nearly identical.

The overlap assumption was met, also illustrated in Figure 6. That is, there were controls throughout the entire range of the treatment group and vice versa. This is important because at every level of the treatment group, there needs to be a comparison case, and likewise, at every level of the control group there needs to be a
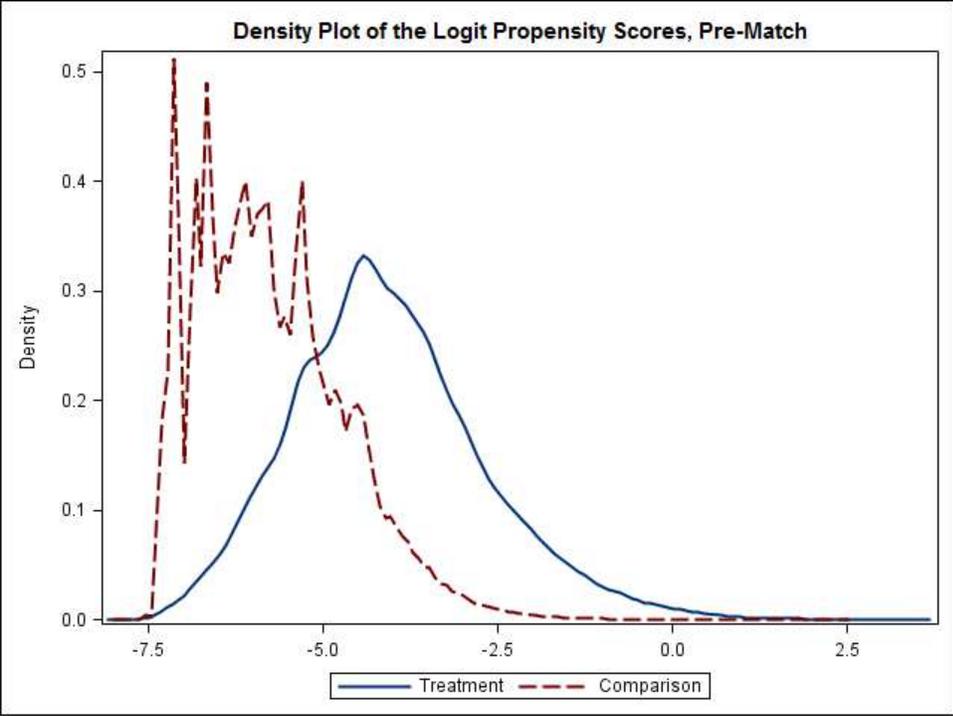
Figure 5. Density Plot of Propensity Scores Prior to Match
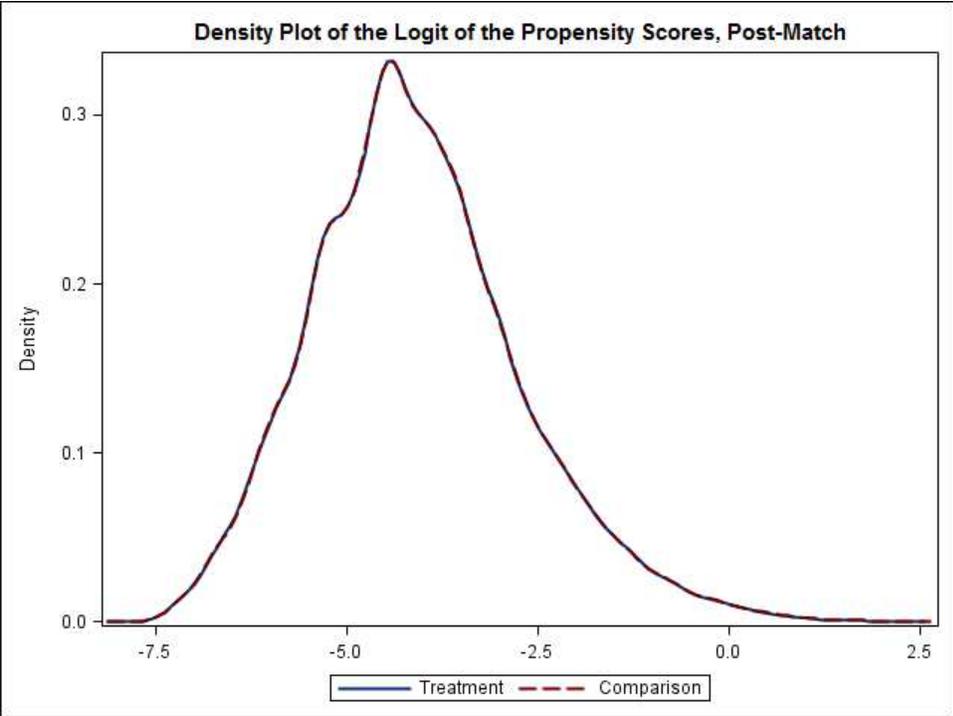
Figure 6. Density Plot of Propensity Scores Post-Match

treatment case in order to continue with inferential analyses. This is clearly depicted in Figure 6.

Descriptive statistics of the sample characteristics before and after matching are provided in Table 1. As noted above, all but one covariate had significant differences between the treatment and control groups prior to the match. After matching, nearly all covariates were not significantly different based on treatment status. The exceptions were age (0 to 64 years), number of past hospitalizations (3 or more), neurological disorders, cancer, and palliative care use. Furthermore, distance from each patient's residence (using zip code) to the nearest VA medical facility offering VHA HBPC was examined. It was concluded that there was not a significant difference between treatment groups in the distance between residence and VA medical facility with VHA HBPC.

Although the *c*-statistic typically indicates model fit, and in this case was 0.84, the presented diagnostic methods were appropriate and necessary to determine the adequacy of the matched sample generated by propensity scores via the logistic regression (Austin, 2009a; Vittinghoff et al., 2012; Westreich, Cole, Funk, Brookhart, & Sturmer, 2011). Nevertheless, the results from the model are presented in Table 2. These results will not be interpreted given the objective of the model. As described, the model was used to generate the propensity scores of which the diagnostics proved the selected sample was balanced and comparable with the only observed difference being the exposure to treatment (VHA HBPC).

Table 1. Sample Baseline (FY 2009 & 2010) Characteristics of VHA HBPC vs. Comparison, Before and After Matching Based on Propensity to Participate in VHA HBPC

Variables	Before Matching		After Matching	
	VHA HBPC	Comparison	VHA HBPC	Comparison
	n=41,256	n=6,308,140	n=41,244	n=41,244
	n (%)			
Male	40,553 (98.3)	6,284,114 (99.6)**	40,542 (98.3)	40,517 (98.2)
Age (in years)				
0-64	9,973 (24.2)	3,527,829 (55.9)**	9,973 (24.2)	9,716 (23.6)*
65-74	6,656 (16.1)	1,097,651 (17.4)**	6,656 (16.1)	6,732 (16.3)
75-84	12,856 (31.2)	1,056,689 (16.8)**	12,853 (31.2)	12,811 (31.1)
85-111	11,746 (28.5)	441,920 (7.0)**	11,737 (28.5)	11,880 (28.8)
Race				
Black	6,038 (14.6)	727,009 (11.5)**	6,037 (14.6)	6,072 (14.7)
Other	2,313 (5.6)	304,472 (4.8)**	2,312 (5.6)	2,335 (5.7)
White	26,839 (65.1)	3,468,822 (55.0)**	26,829 (65.1)	26,889 (65.2)
Missing	6,066 (14.7)	18,078,337 (28.7)**	6,066 (14.7)	5,948 (14.4)
Service Eligibility				
Not Connected	22,664 (54.9)	3,434,188 (54.4)*	22,660 (54.9)	22,692 (55.0)
Number of Past Hospitalizations				
1	4,715 (11.4)	219,093 (3.4)**	4,710 (11.4)	4,801 (11.6)
2	1,822 (4.4)	62,062 (1.0)**	1,819 (4.4)	1,713 (4.1)
3	1,649 (4.0)	41,962 (0.7)**	1,646 (4.0)	1,414 (3.4)**
Comorbidities				
CHF	4,740 (11.5)	118,776 (1.9)**	4,734 (11.5)	4,691 (11.4)
Cardiac Arrhythmia	4,521 (11.0)	312,524 (5.0)**	4,518 (11.0)	4,547 (11.0)
Valvular Disease	750 (1.8)	58,557 (0.9)**	749 (1.8)	747 (1.8)
Pulmonary Circulation Disorders	430 (1.0)	16,712 (0.3)**	430 (1.0)	418 (1.0)
Vascular Disorders	2,754 (6.7)	171,478 (2.7)**	2,752 (6.7)	2,855 (6.9)
Hypertension, Uncomplicated	17,478 (42.4)	2,245,724 (35.6)**	17,474 (42.4)	17,340 (42.0)
Hypertension, Complicated	716 (1.7)	74,570 (1.2)**	716 (1.7)	655 (1.6)
Paralysis	823 (2.0)	23,459 (0.4)**	820 (2.0)	854 (2.1)

Table 1. Sample Baseline (FY 2009 & 2010) Characteristics of VHA HBPC vs. Comparison, Before and After Matching Based on Propensity to Participate in VHA HBPC (Continued)

Variables (Continued)	Before Matching		After Matching	
	VHA HBPC n=41,256	Comparison n=6,308,140	VHA HBPC n=41,244	Comparison n=41,244
	n (%)			
Neurological Disorders	3320 (8.1)	117,357 (1.9)**	3,314 (8.0)	3,505 (8.5)*
Chronic Pulmonary Disease	7658 (18.6)	517,967 (8.2)**	7,654 (18.6)	7,733 (18.8)
Diabetes	14031 (34.0)	1,195,242 (19.0)**	14,024 (34.0)	14,062 (34.1)
Hyperthyroidism	922 (2.2)	148,119 (2.4)	922 (2.2)	888 (2.2)
Chronic Kidney Disease	2737 (6.6)	168,927 (2.7)**	2,733 (6.6)	2,686 (6.5)
Liver Disease	518 (1.3)	49,724 (1.0)**	518 (1.3)	527 (1.3)
Lymphoma	963 (2.3)	120,716 (1.9)**	963 (2.3)	930 (2.3)
Metastatic Cancer	239 (1.0)	14,246 (0.2)**	239 (1.0)	272 (1.0)
Cancer (without metastasis)	4648 (11.3)	346,228 (5.5)**	4,647 (11.3)	4,892 (11.9)*
Rheumatoid Arthritis	7054 (17.1)	1,171,772 (18.6)**	7,052 (17.1)	6,979 (16.9)
Coagulopathy	317 (1.0)	27,542 (0.4)**	317 (0.8)	323 (0.8)
Obesity	1139 (2.8)	234,935 (3.7)**	1,139 (2.8)	1,091 (2.7)
Weight Loss	1278 (3.1)	46,235 (1.0)**	1,277 (3.1)	1,281 (3.1)
Anemia	842 (2.0)	55,783 (1.0)**	840 (2.0)	837 (2.0)
Alcohol/Drug Abuse	3739 (9.1)	632,754 (10.0)**	3,739 (9.1)	3,791 (9.2)
Psychoses	2499 (6.1)	155,066 (2.5)**	2,496 (6.1)	2,556 (6.2)
Depression	8464 (20.5)	1,158,969 (18.4)**	8,463 (20.5)	8,518 (20.7)
2 or More Comorbidities	29,412 (71.3)	2,834,200 (44.9)**	29,400 (71.3)	29,482 (71.5)
Bereavement	1,150 (2.8)	33,495 (0.5)**	1,144 (2.8)	1,110 (2.7)
Palliative Care	3,750 (9.1)	27,488 (0.4)**	3,738 (9.1)	3,494 (8.5)*
	M SD			
Average Number of Comorbidities	2.25 (1.2)	1.46 (1.2)**	2.25 (1.2)	2.26 (1.3)

CHF Congestive Heart Failure
*p < .05; **p < .001; each 'no' group was compared to the 'yes' group.
Data Source: VHA DSS Outpatient and Inpatient Data Files, FY 2009-2010.

Table 2. Selected Multivariate Predictors of VHA HBPC Enrollment for Propensity Score Matching

	Odds Ratio	95% Confidence Interval
Male	**0.46**	**0.43-0.50**
Age (in years)		
65-74	**2.04**	**1.97-2.10**
75-84	**4.53**	**4.39-4.66**
85-112	**9.95**	**9.65-10.26**
Race		
Missing	**0.64**	**0.62-0.65**
Black	**1.47**	**1.43-1.51**
Other	1.04	0.99-1.08
Service Eligibility		
Not Connected	**0.83**	**0.81-0.84**
Number of Past Hospitalizations		
1	**2.35**	**2.27-2.43**
2	**2.83**	**2.68-2.98**
3	**3.57**	**3.36-3.79**
Comorbidities		
Congestive heart failure	**2.64**	**2.55-2.73**
Cardiac Arrhythmia	**1.26**	**1.21-1.30**
Valvular Disease	0.98	0.91-1.06
Pulmonary Circulation Disorders	**1.51**	**1.36-1.67**
Vascular Disorders	**1.47**	**1.41-1.53**
Hypertension, Uncomplicated	1.01	0.99-1.04
Hypertension, Complicated	**0.58**	**0.53-0.63**
Paralysis	**4.09**	**3.80-4.42**
Neurological Disorders	**3.41**	**3.28-3.55**
Chronic Pulmonary Disease	**1.79**	**1.74-1.84**
Diabetes	**1.80**	**1.75-1.84**
Hyperthyroidism	**0.79**	**0.73-0.84**
Chronic Kidney Disease	**1.36**	**1.29-1.42**
Liver Disease	**1.62**	**1.48-1.78**
Lymphoma	**0.89**	**0.83-0.95**
Metastatic Cancer	**1.18**	**1.03-1.36**
Cancer (without metastasis)	**1.20**	**1.16-1.24**

Table 2. Selected Multivariate Predictors of VHA HBPC Enrollment for Propensity Score Matching (Continued)

	Odds Ratio	95% Confidence Interval
Rheumatoid Arthritis	1.01	0.98-1.04
Coagulopathy	1.06	0.94-1.19
Obesity	1.05	0.99-1.12
Weight Loss	**2.11**	**1.99-2.24**
Anemia	**1.30**	**1.21-1.40**
Alcohol/Drug Abuse	**1.05**	**1.01-1.09**
Psychoses	**2.31**	**2.21-2.42**
Depression	**1.58**	**1.54-1.63**
2 or More Comorbidities	**1.36**	**1.31-1.40**
Bereavement	**2.99**	**2.80-3.19**
Palliative Care	**8.76**	**8.42-9.12**

Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Outpatient and Inpatient Data Files, FY 2009-2010.

Next, the propensity-score matched sample was used to determine the effect of the VHA HBPC on the outcomes of

interest. In this study, there are several outcomes of interest and each are described below using the described

propensity-matched sample.

Aim 1

The overall objective of Aim 1 was to examine if there were differences in healthcare utilization between those in VHA HBPC and those in the comparison group. Table 3 describes the utilization rates by group. Average differences between groups were tested with McNemar's test to determine differences between any utilization (yes/no) of a service type and *t*-tests were used to determine differences between groups in the average number of utilizations for each service type.

Table 3. Descriptive Statistics for VHA-Paid Healthcare Utilization Among Those in VHA HBPC and the Propensity-Matched Comparison Group, FY 2009-2012

	VHA HBPC	Comparison	VHA HBPC	Comparison
	% (n)		X (SD)	
Any Hospitalization				
(VHA and non-VHA)	54.55 (22,807)	35.57 (14,769)**	5.58 (7.08)	5.29 (7.72)**
VHA Hospitalization	47.65 (19,654)	31.82 (13,125)**	1.47 (2.53)	0.90 (2.03)**
Non-VHA Hospitalization	66.09 (7,938)	33.91 (4,073)**	3.18 (6.23)	3.08 (7.00)**
Nursing Home	2.67 (1,101)	1.62 (668)**		
Outpatient			205 (170)	143 (137)**

n =sample size; X = average; SD = standard deviation.
**p < .001.
Data Source: VHA DSS Outpatient and Inpatient Data Files, FY 2009-2012.

Beginning with any hospitalization (VHA and non-VHA), a higher proportion of VHA HBPC participants (54.55% versus 35.57%) utilized acute hospital care (*p* < .001). The average number of hospital utilizations were similar between groups (VHA HBPC: 5.58, comparison: 5.29), but this small difference was statistically significant (*p* < .001). Turning to inpatient VHA hospitalizations, there was a lower proportion of patients in the comparison group (31.82%) who had an inpatient VHA hospitalization compared to those in VHA HBPC (47.65%; *p* < .001). Additionally, the average number of inpatient VHA admissions was higher among those in VHA HBPC (X = 1.47, SD = 2.53)

compared to the comparison group (X = 0.90, SD = 2.03). This difference was

statistically significant, *p* < .001. For non-VHA hospitalizations, the proportion of VHA

HBPC participants who had an inpatient utilization was almost twice that of the

comparison group (66.09% versus 33.91%). Similarly, the average number of inpatient

utilizations was higher among VHA HBPC (3.18 versus 3.08, p < .001).

The relative risk of hospitalization was higher among those in VHA HBPC for any

hospitalization, VHA hospitalization, and non-VHA hospitalization (Table 4).

Table 4. Relative Risk of Hospitalization Among Those in VHA HBPC and the Propensity-Matched Comparison Group Including Subgroup Stratification, FY 2009-2012

	RR	95% CI
Any Hospitalization (VHA and non-VA)	**1.53**	**1.51 – 1.56**
VHA Hospitalization	**1.50**	**1.47 – 1.52**
Age 85 & Older	**1.47**	**1.42 – 1.52**
Two or More Comorbidities	**1.40**	**1.37 – 1.42**
Recipients of Palliative Care	**0.84**	**0.81 – 0.87**
Non-VHA Provided Inpatient Care	**1.94**	**1.87 – 2.00**
Age 85 & Older	**1.65**	**1.53 – 1.78**
Two or More Comorbidities	**1.82**	**1.75 – 1.89**
Recipients of Palliative Care	0.94	0.87 – 1.03

RR = Relative Risk; CI = 95% Confidence Interval.
Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Inpatient Data Files and Purchased Care Files, FY 2009-2012.

Post-hoc subgroup analyses were conducted to determine whether the effect of

VHA HBPC on hospitalization risks differs in certain subgroups (Table 4). These

analyses revealed that, relative to the comparison group, the risk of hospitalization for

those in VHA HBPC was significantly higher in nearly every subgroup for VHA and non-

VHA hospitalizations. However, among those who received palliative care, those in

VHA HBPC had a significantly lower risk of an inpatient VHA admission relative to the

comparison group (RR = 0.84, CI = 0.81 – 0.87). There was a non-significant difference

among recipients of palliative care for relative risk of non-VHA hospitalization.

Utilization of nursing home care was also examined. The findings, represented

in Table 3, indicate that a higher proportion of those in VHA HBPC (2.67%) utilized a

nursing home compared to the comparison group (1.62%; p < .001). Furthermore, the

relative risk of a nursing home admission was significantly higher among those in VHA

HBPC (RR = 1.65, CI 1.50 – 1.81). Post-hoc sensitivity analyses revealed that, among

the subgroups analyzed in this study, those with two or more comorbidities and those

age 85 and older in VHA HBPC had a higher risk of nursing home utilization relative to

the comparison group. There was not a significant difference in the relative risk of

nursing home utilization among who were recipients of palliative care.

Table 5. Relative Risk of Nursing Home Utilization Among Those in VHA HBPC and the Propensity-Matched Comparison Group Including Subgroup Stratification, FY 2009-2012

	RR	95% CI
Nursing Home Utilization	**1.65**	**1.50 – 1.81**
Age 85 & Older	**1.27**	**1.09 – 1.46**
Two or More Comorbidities	**1.73**	**1.54 – 1.94**
Recipients of Palliative Care	1.08	0.76 – 1.54

RR = Relative Risk; CI = 95% Confidence Interval.
Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Outpatient Data Files, FY 2009-2012.

Not surprisingly, a t-test revealed that those in VHA HBPC had a significantly

higher average number outpatient utilizations than those in the comparison group (203

vs. 143, respectively; F = 1.44, p < .001). Given that VHA HBPC is an outpatient

program, higher outpatient utilizations was expected. Risk analyses were not conducted

for outpatient services since the use of outpatient services is expected among all patients and represents a much wider array of care.

Due to a high number of expected deaths in this sample, a final post-hoc analysis was conducted to provide further description of end-of-life care among those in VHA HBPC (Figure 7). The overall rate of VHA hospitalization within 30 days of death was 15.93% for those in VHA HBPC versus 14.93% for those in the comparison. The rate of VHA hospitalization within 60 days of death was 21.78% for those in VHA HBPC versus 18.81% for those in the comparison group, and finally, the rate of VHA hospitalization within 90 days of death was 25.04% for those in VHA HBPC versus 21.52% for those in the comparison group.
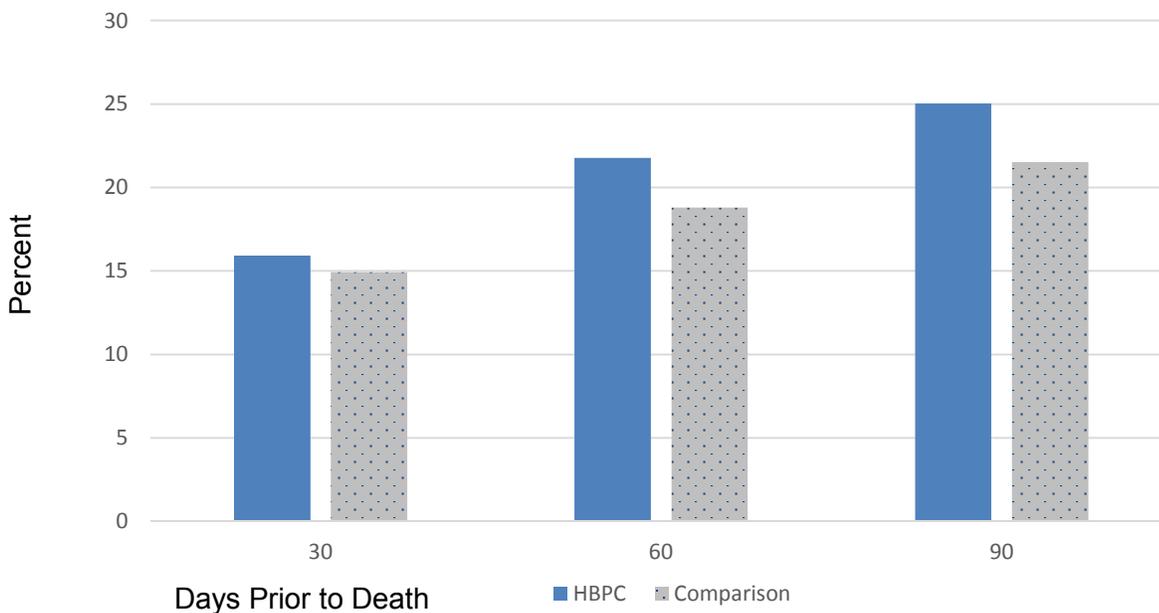
Figure 7. Rate of VHA Hospitalization at 30, 60, and 90 Days Prior to Death by VHA HBPC Status

Results revealed that at 30, 60, and 90 days prior to death, VHA HBPC participants

were at significantly higher risk of a VHA acute hospitalization relative to the control

group overall and by subgroup analyses except for recipients of palliative care (Table 6).

Among those who received palliative care, VHA HBPC recipients had a lower risk of

hospitalization across all intervals prior to death relative to the comparison group.

Table 6. Relative Risk of Hospitalization Before Death Among Those in VHA HBPC and the Propensity-Matched Comparison Group Including Subgroup Stratification, FY 2009-2012

Intervals Prior to Death	RR (95% CI)		
	30 Days	60 Days	90 Days
Hospitalization (VHA)	**1.11 (1.06 – 1.16)**	**1.16 (1.11 – 1.20)**	**1.16 (1.12 – 1.21)**
Age 85 & Older	**1.16 (1.08 – 1.26)**	**1.22 (1.14 – 1.30)**	**1.22 (1.15 – 1.29)**
Two or More Comorbidities	**1.08 (1.03 – 1.14)**	**1.12 (1.07 – 1.17)**	**1.11 (1.07 – 1.16)**
Recipients of Palliative Care	**0.69 (0.63 – 0.76)**	**0.73 (0.68 – 0.79)**	**0.75 (0.70 – 0.80)**

RR = Relative Risk; CI = 95% Confidence Interval.
Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Inpatient Data Files and Vital Status Files, FY 2009-2012.

Overall, the findings for Aim 1 did not support the hypothesis that VHA HBPC

would decrease risk of acute and nursing home care. Stratification analyses revealed

that these relationships did not vary by subgroup except among those who received

palliative care. There was generally no difference between groups among recipients of

palliative care in the risk of hospitalization or nursing home care except during the time

immediately prior to death for acute VHA hospitalization, which was the only findings

that supported the hypothesis.

Aim 2

The objective of Aim 2 was to examine total average expenditures of healthcare paid by the VA for those in VHA HBPC relative to a comparison group over the duration of the study period. GLM was utilized to account for the nature of cost data and was weighted by time in the study. The average time in the study was 1,104 (SD = 208) days for those in VHA HBPC and 1,351 (SD = 248) for those in the comparison group (p < .001). The SAS procedure GENMOD was utilized with the specifications of a gamma distribution and a log link.

Overall, findings revealed that recipients of VHA HBPC had a significantly higher average cost of care over the duration of the study period ($80,477 versus $42,325, p < .001). As displayed in Table 7, when examining specific types of services, all service costs were significantly higher among those in VHA HBPC relative to the comparison group.

The mean cost of VHA HBPC over the duration of the study period was $17,667 per patient. When this cost was subtracted from the mean cost of outpatient care, VHA HBPC recipients had a mean cost of $30,396 for outpatient care over the duration of the study which was still a significantly higher average cost among VHA HBPC relative to the comparison group (p < .001).

Table 7 displays the overall and post-hoc analyses by subgroups (i.e., the oldest old, those with two or more comorbidities, and those who received palliative care) which found that costs for VHA-provided services were significantly higher for VHA HBPC recipients for all service types examined among all subgroups over the duration of the study, with the exception for VHA hospital care among recipients of palliative care.

Table 7. Average VA Expenditures Over the Duration of the Study Among Those in VHA HBPC and the Propensity-Matched Comparison Group, FY 2009-2012

	VHA HBPC ($)	Comparison ($)
Total Cost of VHA-Provided Services	80,477	42,325**
Hospital	32,387	17,788**
Outpatient Total	48,063	24,533**
VHA HBPC	17,667	--
Non-VHA Provided Inpatient Care	5,329	2,508**
Grand Total	85,808	44,833**
Age 85 & Older		
Total Cost of VHA-Provided Services	61,231	31,399**
Hospital	21,922	14,394**
Outpatient Total	39,298	17,002**
VHA HBPC	20,332	--
Non-VHA Provided Inpatient Care	4,049	2,566**
Grand Total	65,280	33,966**
Two or More Comorbidities		
Total Cost of VHA-Provided Services	84,837	47,299**
Hospital	34,847	19,921**
Outpatient Total	49,959	27,377**
VHA HBPC	18,017	--
Non-VHA Provided Inpatient Care	5,362	2,575**
Grand Total	90,202	49,875**
Recipients of Palliative Care		
Total Cost of VHA-Provided Services	89,908	78,009**
Hospital	**34,165**	**44,642****
Outpatient Total	55,710	33,345**
VHA HBPC	27,171	--
Non-VHA Provided Inpatient Care	5,071	5,797
Grand Total	94,983	83,807**

*p < .05; **p < .001
Bold indicates the treatment group having significantly lower costs.
Data Source: VHA DSS Inpatient and Outpatient Data Files and Purchased Care Files, FY 2009-2012.

Among VHA HBPC palliative care recipients, costs were $34,165 compared to $44,642 for the comparison group recipients of palliative care ($p < .001$). There was a non-significant difference in cost between groups for hospital care over the duration of the study among those ages 85 and older ($p = .07$ for VHA and $p = .29$ for non-VHA).

The average cost of nursing home care over the duration of the study was $976 for those in VHA HBPC and $1,134 for those in the comparison. These numbers are skewed due to the low utilization rate of nursing home services (VHA HBPC: 2.67%, comparison group: 1.62%) which is likely why the models for nursing home care did not converge, and thus, significance is not reported.
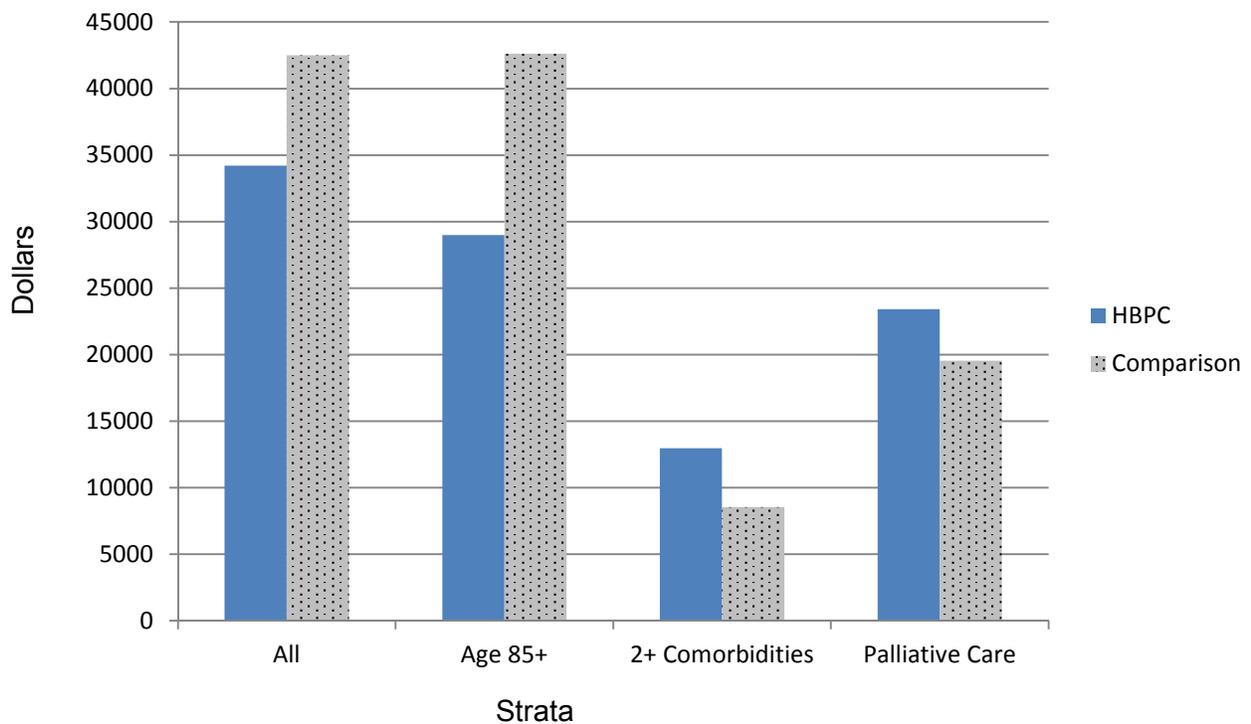
Figure 8. Average Nursing Home Cost Over the Duration of the Study for Those with Greater Than $0 Costs
Data Source: VHA DSS Outpatient Data Files, FY 2009-2012.

When restricting the sample to only those who utilized nursing home care, the average was $34,201 for those in VHA HBPC and $42,492 for the comparison group over the duration of the study. Figure 8 illustrates the difference in average costs between groups for only those with greater than zero costs. In general, and among

those ages 85 and older, VHA HBPC seems to reduce the cost of nursing home care. However, for those with two or more comorbidities and for recipients of palliative care, average nursing home costs are higher among those in VHA HBPC. Significance levels are not reported since models did not converge.

The hypothesis that VHA HBPC would be associated with an overall lower cost of healthcare for VHA-paid services was not supported. Costs were generally higher among those in VHA HBPC with the exception of the costs associated with VHA acute hospitalizations among palliative care recipients.

Aim 3

The objective of Aim 3 was to examine if there was a survival differential

associated with participation in VHA HBPC. A total of 25,884 (62.79%) patients in VHA

HBPC died during the study period compared to 17,834 (43.28%) patients in the

comparison group (*p* < .001). As Table 8 shows, findings reveal that the risk of death

was significantly higher among those in VHA HBPC (RR = 1.45, 1.43 – 1.47) relative to

the comparison group.

Table 8. Relative Risk of and Time to Death Among Those in VHA HBPC and the Propensity-Matched Comparison Group, FY 2009-2012

	RR /Hazard Ratio	95% CI
Died		
Relative Risk	**1.45**	**1.43 – 1.47**
Survival Time	**1.89**	**1.86 – 1.93**

RR = Relative Risk; CI = 95% Confidence Interval.
Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Outpatient Data Files and Vital Status Files, FY 2009-2012.

A Cox proportional hazards model with a robust variance estimator to account for

clustering was fit to the matched sample to determine if there was a significant

difference between groups in time to death. The model contained exposure to VHA

HBPC and quintiles of the logit of the propensity score as predictors since covariate

adjustment was already applied to the sample. The average time to death was 979

days (SD = 534), or just over two and a half years from initial treatment date for those in

VHA HBPC, and 1,226 days (SD = 414), or three and a quarter years from initial

treatment date for those in the comparison group. This difference was statistically

significant at *p* < .001. The hazard ratio for mortality among those who participated in

VHA HBPC was 1.89 (CI 1.86 – 1.93). This indicates that those in VHA HBPC died

sooner, on average, than those who died in the comparison group. This relationship is

graphically displayed via Kaplan-Meier survival curves in Figure 9, below. The solid

blue line represents the survival estimates over time for the control group, which is

significantly more favorable in comparison the survival estimates for those in VHA

HBPC, represented by the dashed red line indicating sooner time to death.
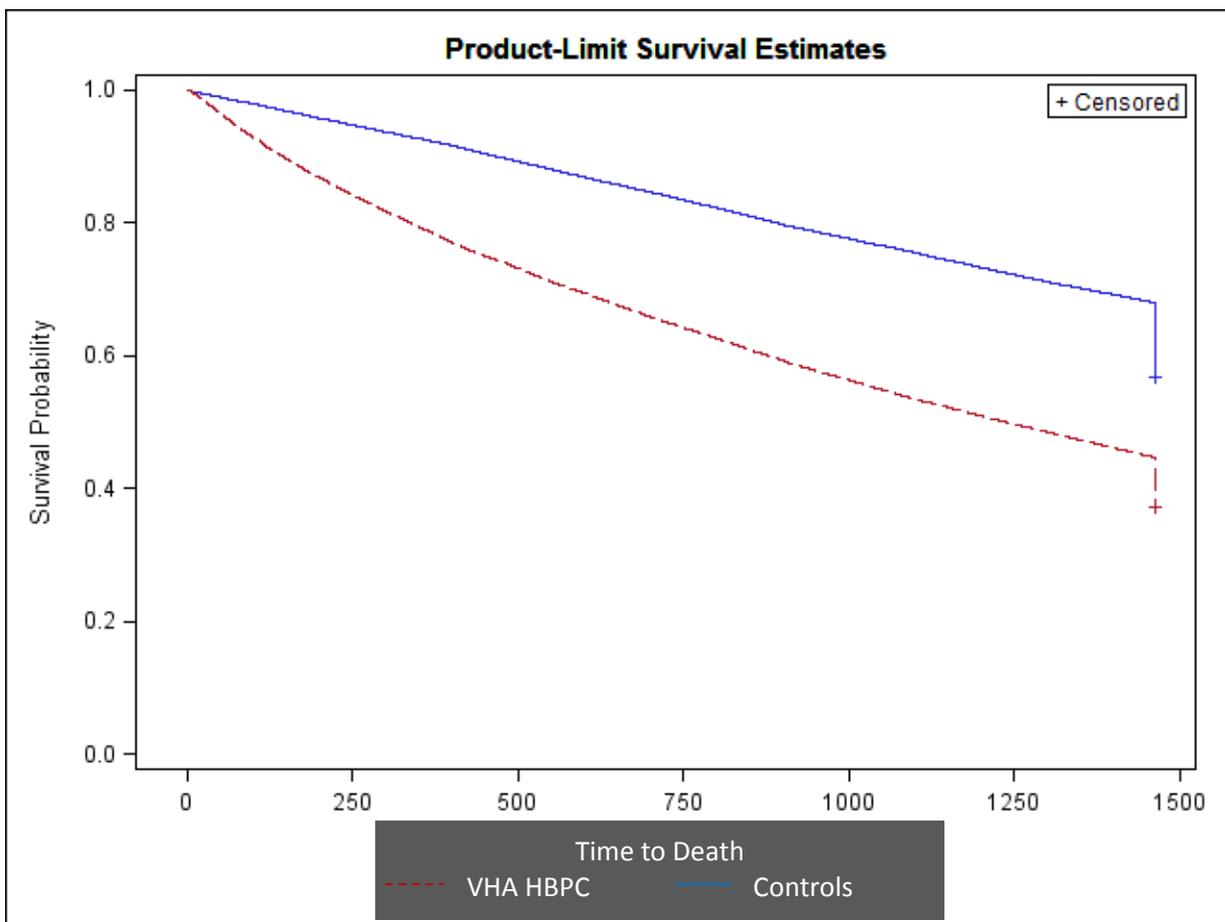
Figure 9. Survival Time From Initial Treatment Date Among Those in VHA HBPC and the Propensity-Matched Comparison Group, FY 2009-2012

Also revealed by the Cox proportional hazards model was the significance of the propensity score quintiles in predicting time to death. All quintiles were significant predictors, and the higher the quintiles, the sooner death occurred (quintile 1: reference; quintile 2: HR = 1.84, 1.78-1.92; quintile 3: HR = 2.39, 2.31-2.48; quintile 4: HR = 3.08, 2.97-3.19; quintile 5: HR = 4.64, 4.48-4.80). This suggests that there is an association between time until death and the likelihood of VHA HBPC treatment.

Post-hoc analyses were conducted to determine if the risk of death varied by subgroups (Table 9). Results indicate that the rate of death was higher among those in the VHA HBPC subgroups of adults ages 85 and older (80.50% vs. 66.13%, $p < .001$) and those with two or more comorbidities (62.34% vs. 43.03%, $p < .001$) compared to the same subgroups in the comparison group. Among recipients of palliative care, the comparison group had a higher rate of death (89.77%) compared to VHA HBPC (86.54%, $p < .001$). Accordingly, the relative risk was higher among VHA HBPC recipients who were ages 85 and older (RR = 1.45, CI 1.43 – 1.47) and those with two or more comorbidities (RR = 1.22, CI 1.20 – 1.24). However, among those who received palliative care, VHA HBPC recipients had a slightly lower relative risk of death (RR = 0.96, CI 0.95 – 0.98).

Table 9. Post-Hoc Sensitivity Analyses to Examine Relative Risk of Mortality Among Those in VHA HBPC and the Propensity-Matched Comparison Group, FY 2009-2012

	RR	95% CI
Age 85 & Older	**1.45**	**1.43 – 1.47**
Two or More Comorbidities	**1.22**	**1.20 – 1.24**
Recipients of Palliative Care	**0.96**	**0.95 – 0.98**

RR = Relative Risk; CI = 95% Confidence Interval.
Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Outpatient Data Files and Vital Status Files, FY 2009-2012.

In sum, the results indicated that the hypothesis of a survival differential between VHA HBPC and the comparison group was supported by the evidence. Recipients of VHA HBPC, in general, were at a higher relative risk of death and on average died significantly sooner relative to the comparison group. The only exception was among recipients of palliative care, those in VHA HBPC survived slightly longer than those in the comparison group. Considering the results of the three aims varied from expectations, several sensitivity analyses were conducted.

Sensitivity Analyses

Multiple iterations of sensitivity analyses were conducted to either validate the reported findings or to better describe the effect of VHA HBPC taking into account the implications of the previously reported findings. The first sensitivity analysis selected a new comparison cohort 100% unique from the original. These results were nearly the same as the first and are not discussed here.

The second sensitivity analysis used the original cohorts but redefined the treatment group as those in VHA HBPC for six months or more. The third sensitivity analysis modified the original matching algorithm by replacing 'the number of past hospitalizations' with the 'time since last hospitalization'. In this cohort, there were 40,368 matched pairs. Approximately 9% (3,630) of controls are the same cases between the first and third validation cohorts, but none are the same as the original control cohort (i.e., the third validation cohort was 100% unique from the original sample of controls).

From the original comparison cohort to the fourth comparison cohort there was 71% overlap in the control group. This cohort was selected by refining the matching algorithm further to include time to death and additional comorbidities and selected the sample based on the occurrence of an inpatient hospitalization. This group was comprised of 29,471 matched pairs. Finally, the fifth round of sensitivity analyses used the fourth cohort but restricted the VHA HBPC cohort to only those that utilized the program for six months or more.

The results for the relative risk of hospitalization and nursing home use are presented in Table 10. From the original analysis to the second sensitivity analysis, the

results were very similar to the original. The only difference in significance was among

recipients of palliative care in VHA HBPC who had a significantly lower risk of non-VHA

hospitalization compared to recipients of palliative care in the comparison group from

the second sensitivity cohort. With one exception, all other analyses of risk for hospital

or nursing home use remained significant, and in cases where there was an increased

risk for hospitalization, the degree of increased risk lessen from the degree of risk in the

original cohort to the second sensitivity cohort. This indicates that the risk of the use of

these services remains higher than the comparison group but the risk is tempered over

time since the second sensitivity cohort only looked at the use of services among those

in VHA HBPC for six or more months.

Data for non-VHA hospitalizations were not available for the third sensitivity

analyses. Nevertheless, the results for the third sensitivity analyses suggest that the

number of days since prior hospitalization did not change the results of the risk of

service use, overall. The risk for VHA hospitalization remained at levels indicated in the

original cohort and the risk for nursing home services that were significant in the

original cohort remained significant in the third sensitivity analyses, but to a lesser

degree than the original cohort.

The fourth and fifth sensitivity analyses suggest that refining the matching

algorithm by adding time to death and additional comorbidities, in addition to only

including those with a baseline inpatient VHA hospitalization, impacts the effect of VHA

HBPC on service use. While the risk of VHA hospitalization remained higher for the

VHA HBPC enrollees relative to the comparison group in general in the fourth sensitivity

cohort, the risk of nursing home utilization was significantly less for VHA HBPC

enrollees overall and among VHA HBPC enrollees in the age strata of 85 years and older. Among those with two or more comorbidities, the relative risk changed from significantly higher among VHA HBPC enrollees in the original cohort to significantly lower in the fourth cohort. After restricting the fourth cohort to only those in VHA HBPC for six or more months (i.e., the fifth cohort), the lower risk of nursing home use among VHA HBPC enrollees from the fourth cohort was even lower in the fifth cohort. Additionally, the fifth cohort was the only cohort that showed significantly lower risks for VHA and non-VHA hospitalization relative to the comparison group. This remained true for all strata examined. The results indicate that time to death, selection based on hospitalization, and additional comorbidities are necessary when examining the risk for service use among VHA HBPC participants. Additionally, these results indicate that the effect of VHA HBPC cannot be determined immediately, and six months after the initial treatment, different results should be expected.

Table 11 describes the results of the sensitivity analyses for expenditures. Expenditures for the third sensitivity cohort were not examined since the use of services was very similar to the original cohort. The results from Table 11 show that VHA HBPC enrollees incur significantly higher costs overall compared to a matched comparison group. The only evidence of lower expenditures is in the fifth sensitivity cohort for VHA hospitalization, but this savings was not enough to produce lower expenditures overall among VHA HBPC enrollees relative to the matched comparison group.

Table 10. Relative Risk of Hospitalization Comparing the Original Cohort to Sensitivity Cohorts, Including Subgroup Stratification, FY 2009-2012

	Original Cohort		Second Cohort (Original, 6 mo.)		Third Cohort (+Days Last Hospital)		Fourth Cohort (+Death time & Comorbidities)		Fifth Cohort (+Death time Comorb., 6 mo.)	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Any Hospitalization (VHA & non-VA)	**1.53**	**1.51 – 1.56**	**1.36**	**1.34-1.39**			**1.25**	**1.23 – 1.27**	**0.91**	**0.90-0.92**
VHA Hospitalization	**1.50**	**1.47 – 1.52**	**1.35**	**1.32-1.38**	**1.47**	**1.45 – 1.50**	**1.41**	**1.38 – 1.45**	**0.89**	**0.88-0.90**
Age 85 & Older	**1.47**	**1.42 – 1.52**	**1.35**	**1.30-1.41**	**1.47**	**1.42 – 1.52**	**1.42**	**1.35 – 1.50**	**0.82**	**0.80-0.85**
Two or More Comorbidities	**1.40**	**1.37 – 1.42**	**1.25**	**1.22-1.37**	**1.37**	**1.34 – 1.40**	**1.39**	**1.35 – 1.42**	**0.89**	**0.88-0.90**
Recipients of Palliative Care	**0.84**	**0.81 – 0.87**	**0.75**	**0.71-0.79**	**0.81**	**0.78 – 0.84**	1.06	0.99 – 1.12	**0.74**	**0.71-0.77**
Non-VHA Provided Inpatient Care*	**1.94**	**1.87 – 2.00**	**1.52**	**1.47-1.58**			1.02	1.00 – 1.04	**0.88**	**0.86-0.90**
Age 85 & Older	**1.65**	**1.53 – 1.78**	**1.39**	**1.28-1.50**			1.02	0.98 – 1.07	**0.88**	**0.84-0.92**
Two or More Comorbidities	**1.82**	**1.75 – 1.89**	**1.43**	**1.37-1.50**			**1.03**	**1.01 – 1.05**	**0.89**	**0.87-0.91**
Recipients of Palliative Care	0.94	0.87 – 1.03	**0.74**	**0.67-0.82**			0.99	0.92 – 1.06	**0.88**	**0.82-0.95**
Nursing Home Utilization	**1.65**	**1.50 – 1.81**	**1.59**	**1.44-1.76**	**1.42**	**1.30 – 1.56**	**0.88**	**0.80 – 0.97**	**0.74**	**0.67-0.81**
Age 85 & Older	**1.27**	**1.09 – 1.46**	**1.23**	**1.06-1.44**	0.99	0.87 – 1.14	**0.62**	**0.53 – 0.73**	**0.54**	**0.45-0.64**
Two or More Comorbidities	**1.73**	**1.54 – 1.94**	**1.64**	**1.45-1.86**	**1.48**	**1.32 – 1.66**	0.90	0.81 – 1.01	**0.76**	**0.68-0.86**
Recipients of Palliative Care	1.08	0.76 – 1.54	0.97	0.66-1.43	0.92	0.65 – 1.29	1.15	0.79 – 1.69	0.77	0.50-1.17

This data were not available for all cohorts.
RR = Relative Risk; CI = 95% Confidence Interval.
Bold indicates statistical significance at p < .05.
Data Source: VHA DSS Outpatient and Inpatient Data Files, and Purchased Care Files, FY 2009-2012.

Table 11. Average VA Expenditures Among Those in Original Cohort Compared to Sensitivity Cohorts

	Original Sample		Second Validation (Original: 6-mo.)		Fourth Validation (+Death time & Comorbidities)		Fifth Validation (+Death time & Comorbidities, 6 mo.)	
	HBPC	Comparison	HBPC	Comparison	HBPC	Comparison	HBPC	Comparison
Total Cost of VHA-Provided Service	80,477	42,325**	80,000	42,325**	107,950	69,125**	89,761	85,371**
Hospital	32,387	17,788**	23,348	18,111**	51,010	32,454**	**46,107**	**48,693****
Outpatient Total	48,063	24,533**	34,563	24,700**	56,935	36,659**	43,680	36,659**
Non-VHA Provided Inpatient Care	5,329	2,508**	4,354	2,617**	13,008	13,198	11,071	13,198
Grand Total	85,808	44,833**	87,294	46,121**	123,748	84,315**	103,358	100,519**

*** p < .001*
Bold indicates the treatment group having significantly lower costs.
Data Source: VHA DSS Outpatient and Inpatient Data Files, and Purchased Care Files, FY 2009-2012.

Chapter 4: Discussion

Summary

The VHA characterizes quality care as: the right type of care; care that results in the best outcome; patient-centered care; and care free from harm and hazards (U.S. Department of Veterans Affairs, 2014). As a central component to providing quality of care, the VHA strives to focus on what matters to the patient. Thus, VHA HBPC remains a critical alternative to institutional care or care dependent upon caregivers by bringing health professionals to the patient. By enabling patients to remain in their homes and receive care that they might otherwise forgo, the VHA is assisting patients in achieving their health-related goals.

This study found that without accounting for critical factors (i.e., time to death, baseline hospitalization, and an additional array of comorbidities), VHA HBPC appeared to be associated with higher risk for hospital and nursing home use, higher expenditures, and higher risk of death. However, the findings that indicated that VHA HBPC is associated with likelihood of death should be accounted for in analyses that assess the impact of VHA HBPC. This is a major contribution of this study. This is supported by other research suggesting that homebound individuals have a higher risk of death within two years compared to non-homebound individuals and suggest that homebound status should be considered an indicator of frailty (Herr, Latouche, & Ankri, 2013). This difference in the original analyses and several of the early sensitivity analyses could explain why the program was not producing the expected results.

After accounting for time to death, baseline hospitalization, and additional comorbidities, the results were closer to the hypothesized outcomes. Specifically, VHA HBPC can affect the relative risk of hospitalization after a certain period of longevity in the program. In this study, six months was used as the point in time in which the relative risk was assessed. After six months (and after the inclusion of additional comorbidities, time to death, and hospitalization as inclusion criteria), VHA HBPC participants had a lower risk of hospitalization and nursing home use relative to a comparison group, albeit higher total expenditures.

Prior to the refinement of the matching algorithm and inclusion criteria, VHA HBPC recipients of palliative care had lower acute care utilization overall and immediately prior to death compared to a similar group of patients not receiving VHA HBPC. Additionally, VHA HBPC recipients of palliative care survived longer than the comparison group. These findings are highlighted because VHA HBPC participants have a high rate of death. In this study, more than 62% of VHA HBPC participants in the original cohort died over a three year period. Even after the refinement of the matching algorithm, recipients of palliative care generally had a lower rate of VHA hospitalization, overall.

The question should be raised as to whether VHA HBPC is an end-of-life program. The program seems effective in keeping participants receiving palliative care out of the hospital, especially during the 30 to 60 days prior to death in all cohorts, but further research is needed to better understand this association. Moreover, the findings here are underscored by a previous study (Hughes et al., 1992) that similarly found that

VHA HBPC was effective in keeping patients home for longer in the time prior to death compared to a comparison group.

Relation to Other Evidence

The findings here are supported by those in the Hughes et al. (2000) study which found that those in VHA HBPC had higher costs than a randomized control group. A difference between these results and the Hughes study is in the service utilization associated with costs. In the Hughes study, only outpatient services were significantly reduced and home-based care and nursing home costs were significantly higher. The results from this study suggest that outpatient services were not reduced, and generally, VHA HBPC participants had higher service use and cost across the board. The differences in the details of costs are not surprising given the general inflation of healthcare costs over time. Nevertheless, the "bottom line finding" regarding total costs was the same between studies: VHA HBPC did not reduce overall cost of care when compared to a similar control group.

Previous studies finding reduced cost associated with VHA HBPC should not be overlooked. Studies of VHA HBPC that found cost savings (Cummings et al., 1990; Hughes et al., 1992) were from the 1980's and before a time when aggregated cost records were kept in administrative databases that would allowed for large scale analyses, like that conducted here. A more recent cost analysis was conducted for Medicare's Independence at Home program and suggested that participants had significantly lower costs, especially among the most frail (De Jonge et al., 2014). However, these two programs generally operate in two different systems of care, and although service utilization overlap occurs, direct comparisons between programs are

difficult. A closer look at the most frail VHA HBPC recipients is warranted, but measures of frailty are difficult using administrative data.

Based on the original analysis and early sensitivity analyses, this study did not support others that found a general reduction in hospital utilization associated with VHA HBPC or similar home-based primary care programs (Chang et al., 2009; Edes et al., 2014; Hughes et al., 1992; Wajnberg et al., 2010). However, these previous studies used pre-post enrollment designs. For example, reduced utilization is what Edes et al. (2006) and Edes et al. (2014) found in their smaller study of the Missouri VHA HBPC program and a more recent, larger study of VHA and Medicare. Specifically, VHA HBPC was considered cost effective from the perspective of the expected cost of VHA HBPC participants (based on pre-enrollment service use) compared to the observed cost (based on post-enrollment service use).

The current study did not determine if there were service use reductions and cost reductions after admission to VHA HBPC compared to prior to VHA HBPC, as the aforementioned studies concluded. The service use and cost trajectory could have been changed due to participating in the program, as previous evidence suggested, but this type of comparison was not the goal of the present study. This study adds to the evidence base that, when compared to a similar group of patients receiving usual care, VHA HBPC does not reduce the relative risk of hospitalization initially, and VHA HBPC should not be characterized as lowering expenditures.

In addition to the difference of a pre/post design versus comparative analyses, other differences in study designs exist that could explain the differences and similarities in findings between past research findings and those described here. A

handful of studies examined disease specific populations rather than the entire program

population, as was done in this study. Edwards et al. (2014) examined enrollees with

diabetes and found decreased hospital use. Hughes et al. (2000) investigated those

with two or more functional impairments, congestive heart disease, or chronic

obstructive heart disease and found lower hospital readmission rates at six months.

Edes et al. (2006) examined end stage heart and lung disease patients and found lower

use and cost. These findings are similar to those in the Medicare Independence at

Home Demonstration that found the program effective for the frailest group of

participants (De Jonge et al., 2014). Similar to the findings presented here, Chang et

al.'s (2009) study utilized a six-month post enrollment design, and like this study, found

lower hospital use.

The findings here that evidenced a lower relative risk of death among those

receiving VHA HBPC and palliative care are similar to the findings in a study examining

the effect of palliative care on patient-reported outcomes and end-of-life care among

patients with a new diagnosis of non-small-cell lung cancer (Temel et al., 2010). In

Temel et al.'s study, the mean survival time was 11.6 months for those receiving

palliative care compared to 8.9 months for those receiving usual care (p = 0.02). Other

positive findings have been associated with the receipt of palliative care among complex

patients. For example, among Medicaid patients with cancer, palliative case

management was associated with lower inpatient admissions, lower intensive care unit

admissions, longer average days on hospice, and lower rate of death in the hospital

compared to those in the comparison group (Wang, Piet, Kenworthy, & Dy, 2015). The

overall favorable findings regarding VHA HBPC and palliative care warrant further investigation.

Andersen's Behavioral Model

Andersen's behavior model was adapted for VHA HBPC was used to develop the conceptual model for this study. Predisposing factors (i.e., age, race, and sex) were generally balanced between the control and treatment groups. Proposed enabling factors in this study included geographic location, the receipt of palliative care, insurance status, and receipt of the VHA HBPC. It was determined through *t*-tests that there was not a geographic difference between the treatment and control group in terms of miles from individual's residences and the VA medical center providing VHA HBPC. Therefore, geographic location likely did not impact the effects of the program on outcomes, overall. Also balanced was the proportion of those service eligible which was the proxy for insurance status. Due to data limitations, examining the effect of hospice was not enabled but it was determined that VHA HBPC recipients of palliative care had better outcomes in terms of lower service utilization than did the control group who received palliative care. This effect was generally true across cohorts, and without more analyses, it is difficult to disentangle the effects of the program from the effects from receiving palliative care.

Two factors from Andersen's Health Behavior Model likely influenced the results which were the receipt of VHA HBPC (an enabling factor) and need for care. While diagnoses were used to account for comorbidity (as a proxy for need for care), the level of disease severity (and therefore, the precise level of need) was indiscernible. After accounting for confounding by controlling for time to death, two groups that were more

similar in terms of likelihood for mortality-related processes (and possibly need for care) were created. Therefore, need for care played a confounding role in the results in the first set of analyses, but after creating a control group that likely reduced residual variance, the enabling factor of receiving VHA HBPC had an effect by decreasing the risk of service use relative to the comparison group. The strong influence of need was also described by others who found it to have influential effects in a Veteran population (Elhai et al., 2008).

Interpretation, Limitations, and Future Research

Given the higher average number of utilizations and higher relative risk of acute hospitalization relative to the comparison group in cohorts that did not restrict to six months of program enrollment, it is likely that there are one or more subgroups of VHA HBPC recipients who could be considered "frequent fliers". Past research has led to suggestions that those who experience complicated transitions from one setting to another after an acute hospitalization are more likely to be those who are more vulnerable and suffer disproportionately during care handoffs (Coleman, 2007). If this is the case for VHA HBPC recipients, further research is critical to enhance the quality of care provided to these patients. Future analyses should focus on high utilizers and transitional care for those in VHA HBPC.

The results of high resource utilization are not surprising. More care, in this case provided by VHA HBPC, can often lead to even more care, which in turn leads to higher costs. A possible explanation for these findings are that, given that VHA HBPC recipients are in a program of care, their care could be monitored more closely than that of the comparison group yielding a "surveillance bias". This phenomenon is one

suggesting that the more you look, the more you find. Since those in VHA HBPC are being provided care regularly, they may have a higher likelihood of receiving additional needed services. Another scenario, not necessarily an alternate explanation, but perhaps additional possibility, is that VHA HBPC recipients are experiencing more emergency department utilizations. The reason for this suggestion is based on the nature of the administrative data used in this study. Emergency department utilizations are categorized as outpatient services. Although the cost of emergency services are accounted for by the data, the actual type of outpatient service utilized is limited by not being able to determine emergency services and is an area for further investigation.

The findings from this study could be limited by an averaging effect. While focusing on between-patient outcomes, the effects of intra-individual differences are minimized with the assumption that all individuals follow a similar pattern. Within-person differences likely exist in this population given the proportion of the individuals who were near death. Specifically, terminal decline, or the decrements in individuals' functional capacities that span the time from months to years before death, has intra-individual variation that is a within-person process (Gerstorf & Ram, 2013). However, these differences become masked in between-person analyses, such as those conducted in this study. However, some of the within-person variation is accounted for in the later analyses that controlled for time to death since time to death can serve as a proxy for unnamed mortality-related casual processes (Gerstorf & Ram, 2013).

Additionally, program variation is likely and should be examined in relation to service use and cost (Olsan et al.). Program leaders have suggested that variation in the duration and intensity of services exist across programs. Some programs operate

on a shorter-term acute basis, where others implement the program as long-term and continuous. Additionally, program leaders have suggested that future work should examine differences in outcomes based on the programs that focus on primary care versus those that implement an interdisciplinary care approach.

In terms of intensity, the average VHA HBPC caseloads are between 20 to 30 patients to each registered nurse (or licensed practical nurse), 80 to 105 per social worker, 85 to 155 per rehabilitation therapist, and 95 to 125 per dietician. Given these high caseloads, future research would be behooved to examine whether the size of the caseloads effect outcomes. Perhaps more staffing results in better care and improved outcomes such as preventing avoidable service use (e.g., hospitalizations) and lowering expenditures. Increased staffing levels have been associated with positive outcomes in other studies, for example, in acute care hospitals (Kane, Shamliyan, Mueller, Duval, & Wilt, 2007), nursing homes (Konetzka, Stearns, & Park, 2008), and in assisted living facilities (Stearns et al., 2007). In this study, an intent-to-treat design was utilized in that service intensity (referred to as a proxy for staffing) was not a requirement in order to determine the effects of the program on the outcomes.

Although this study refined the matching algorithm and inclusion criteria to an extent, other areas for future research include further refinement to the matching method and should consider other frailty indices, alternative matching techniques, and further restriction of the matching caliper. It would be advantageous if measures related functional limitations, cognition, and the availability of caregiver assistance were available for matching in future studies.

The inability to control for patient frailty is a limitation of this study. Other studies examining the effect of VHA HBPC found that those with the highest frailty scores had lower costs suggesting that this group has the greatest potential for savings (De Jonge et al., 2014). Although further investigation into frailty indices may be warranted, others have suggested that diagnoses using ICD-9-CM codes, as was done in this study, compared to the use of measures of functionality, were better predictors of mortality among a frail population (Levy et al., 2015).

Another limitation of this study is that propensity scores are generated from observed covariates, therefore, if there are associations between unobserved factors and probability of treatment, these are not accounted for and such residual differences could exist. Additionally, there is inherent subjectivity in deciding which propensity score method to use (e.g., matching, adjustment, inverse weighting). Since the propensity score approach involved two models, if either model is incorrect, biased estimates of the causal effect are possible (Vittinghoff et al., 2012).

Other limitations include the dichotomized nature of the service eligibility variable. A more nuanced approach to examining service eligibility could provide a better understanding of the effect of VHA HBPC compared to how different levels of service eligibility effect service use. A notable limitation is the lack of Medicare data. A complete picture of the effect of VHA HBPC would be provided by merging Medicare files with VA files. However, this study was restricted to VA data. The presence of advance directives was not accounted for which could affect service use. Finally, measures of quality of care were not accounted for in this study due to the nature of the data.

Strengths of the study include the use of population-based, longitudinal VHA data, and the study design which addressed statistical challenges including selection bias and yielded relatively well-matched comparison cohorts to draw conclusions regarding the effect of VHA HBPC. Ethical considerations limit the ability to conduct randomized controlled trials to determine the effect of any healthcare delivery models. Thus, this study used matched comparison groups to understand the effect of VHA HBPC on service utilization, cost, and survival.

Policy Recommendations

Several policy recommendations can be made based on the findings from this study. First, more research should be supported in order to better understand the effectiveness of VHA HBPC. First, program variation is likely and understanding how programs different and how such a differences effect outcomes would be advantageous to the program's longevity. Additionally, research support should be provided to gain a better understanding into the effects of VHA HBPC recipients who receive palliative care. The research from this study suggests that VHA HBPC recipients receiving palliative care could possibly be an effective subgroup to target for optimal outcomes. These findings are not surprising given past research suggesting that participating in palliative care following hospitalization can have a beneficial effect on service use, cost, and satisfaction with care (Brumley, Enguidanos, & Cherin, 2003; Gade et al., 2008). Understanding how palliative care and VHA HBPC work in conjunction to produce positive outcomes is warranted.

Another policy recommendation is to develop a method to identify an appropriate group of VHA HBPC participants that would benefit from palliative care. Given the

findings from this research and others, palliative care can have a multitude of beneficial effects. It would be justified to provide clinical guidance in terms of identifying patients in VHA HBPC who could benefit from such services. A checklist could be implemented such as the ones developed by The Center to Advance Palliative Care's Consensus Panel which developed two checklists to screen patients for unmet palliative care needs (Weissman & Meier, 2011). Palliative care services can be provided in conjunction with restorative care. Therefore, this recommendation is not specific to end-of-life care.

To address end of life, it is recommended that training in end-of-life care be provided for the clinicians and staff of VHA HBPC. Given the high rate of death of program participants, it is likely that end-of-life issues arise frequently whether they be related to clinical care or psychosocial issues. Therefore, specialized, continuous end-of-life care trainings for all those involved with VHA HBPC patient-care should be provided.

The final policy recommendation is to develop clinical guidelines and/or best practices for which VHA HBPC programs can utilize. This patient population is vulnerable and complex and providing care in one's home likely presents situations that clinic-setting professionals do not confront. Therefore, in order to optimize the effectiveness of the program, guidelines should be provided to clinicians serving patients in VHA HBPC. Additionally, these guidelines should be updated as research on the program evolves.

Conclusions

Past research found that, among a sample of VHA patients, interactions with the health-care system and with providers were major concerns and presented significant obstacles to self-care (Noel, Frueh, Larme, & Pugh, 2005). For those that have significant difficulty with getting to the clinic to receive care, VHA HBPC provides an option to alleviate access barriers such as transportation, mobility, and the general difficulty in navigating the system by bringing services into the patient's home. Some have even gone as far as to suggest that advances in medicine and technology allow complex care to be delivered to certain patients in their homes and is comparable to being treated in the hospital (Boling et al., 2013). While this study did not address the comparability of hospital care to home care, the results of this study – at least in terms of those in the program for six or more months and palliative care recipients - underscore the idea that successful home-based programs, such as VHA HBPC, should be maintained to address the unmet needs of patients and Veterans who need care provided in the home, albeit the need for further examination on program effectiveness.

Although this study did not find lower expenditures as a result of VHA HBPC participation, reduced nursing home use and hospitalization can be expected after six months of program participation. Though not captured in this study, patient and caregiver satisfaction have been reported elsewhere (Beck, Arizmendi, Purnell, Fultz, & Callahan, 2009; Cummings et al., 1990; Edes et al., 2014; Hughes et al., 2000) and as others have suggested, favorable outcomes are not always correlated with high patient satisfaction (Kennedy, Tevis, & Kent, 2014). Factors outside of desired outcomes seem to influence patient satisfaction and this appears to be the case for those in VHA HBPC.

Although VHA HBPC only serves a fraction of the VHA patient population, recipients of VHA HBPC are a vulnerable population who have multiple chronic conditions that are often characterized as costly and account for a disproportionate level of resource utilization, as evidenced through this study. However, this does not mean that the program is not effective in meeting the needs of these patients or doesn't assist in keeping patients independent for longer than otherwise expected, although the findings here cannot speak to this effect. A modest impact on resource use with little to no impact on expenditures has been reported in other programs that attempt to manage patients with complex, chronic conditions in the community (Agency for Healthcare Research and Quality, 2013a; Peikes, Chen, Schore, & Brown, 2009; Weinberger, Oddone, & Henderson, 1996). Like these, this study should not undermine the value of the program to the patient, but should be used to improve care by providing insight as to where improvement and research efforts should focus.

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Appendix: Original USF IRB Approval Letter

USF
UNIVERSITY OF SOUTH FLORIDA

10/31/2013

Robert Campbell, J.D., Ph.D. James A.
Haley Veterans' Hospital 13000 Bruce
B. Downs Blvd Tampa, FL 33612

RE:	Expedited Approval for Initial Review
IRB#:	Pro00013863
Title:	Impact of Veteran's Home Based Primary Care on Health Services Use and Expenditures at the End of Life

Study Approval Period: 10/31/2013 to 10/31/2014

Dear Dr. Campbell:

On 10/31/2013, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below. **Approved Item(s):**

Protocol Document(s):

Protocol 189 10 25 13

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

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Your study qualifies for a waiver of the requirements for the process of informed consent as outlined in the federal regulations at 45CFR46.116(d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent.

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45CFR164.512(i) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI. A waiver of HIPAA Authorization is granted for this retrospective chart review of Veterans Administration patients seen at a VA hospital or clinic between October 1, 2006 and September 30, 2012. This waiver allows the study team (or its honest broker) to obtain medical records for the above cohort from the Veterans Integrated Health Systems and Technology Architecture (VISTA) system and/or the Decision Support System.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment. We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

VJorgensen MD

E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board