An Evaluation of the Chronic Disease Self-Management Program

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AN EVALUATION OF THE CHRONIC DISEASE SELF-MANAGEMENT PROGRAM

A capstone project submitted in partial fulfillment of the requirements for the degree of

Doctor of Nursing Practice

By

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M.S. The Ohio State University, 1979

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ABSTRACT

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The prevalence and costs of chronic disease continue to escalate with the aging of the population and continued advancements in medical care. Self-management of chronic disease may be an alternative approach to care that could assist in moving away from a disease-oriented model to health-oriented one. Outcomes from chronic disease self-management programs are promising but inconsistent across disease entities and populations. Among the Veteran population, chronic disease self-management programs have been implemented in a number of Veteran Affairs facilities. The purpose of this project was to evaluate specific outcomes from the chronic disease self-management program conducted in the five medical centers that comprise the Veterans Integrated Services Network 10. Selected outcome variables included perceived self-efficacy, utilization and cost of healthcare services.

Findings were consistent with some of the evidence noted in the literature review. Although there was not a means of determining significance in perceived self-efficacy measurements by participants after the intervention, as seen consistently in the evidence, there were obvious differences in scores, indicating that for some of the participants the intervention made an impact. No significant reductions in service volumes or costs occurred six months after completion of the workshops. A small decrease was seen in the numbers and costs of outpatient visits. Mean hospital days emergency department visits
and costs increased, but not significantly. However, the sample sizes for both costs calculated six months after the intervention for inpatient care and emergency department visits drawn from the total population were small, leading to the conclusion that any financial impact that could be attributed to the intervention to these outcomes would be considered premature at this time.
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Description of the Problem

Prevalence of Chronic Disease

Chronic diseases are defined as “permanent, nonreversible conditions that may be expected to require a long period of supervision, observation, or care and interfere with a person’s physical, psychological and social functioning” (Nodhturft et al., 2000, p. 507). The prevalence of chronic disease continues to escalate. With improvement in the management of infectious diseases, nutrition, sanitation, and hygiene measures, life expectancy has steadily increased thus increasing the prevalence of chronic disease worldwide (Huber et al., 2011; Lehnert et al., 2011). In 2005, nearly 133 million Americans had at least one chronic disease. By 2020, that number is anticipated to increase by 16% (Bodenheimer, Chen, & Bennett, 2009; DeVol & Bedroussian, 2007). As seen in Figure 1, the prevalence of adults aged 46-64 with two or more chronic illnesses increased 5% between the years 1999-2010. For adults over the age of 65, the increase was 8.1% (Freid, Bernstein, & Bush, 2012).

The increases in chronic disease during this period of time were seen regardless of sex or race (Freid et al., 2012). For those living in poverty, higher increases in prevalence rates were observed among Hispanic adults, blacks, and for individuals between the ages of 45-64 years.
There are several factors that will contribute to the expected increase in the prevalence of chronic disease in the United States. The first is the increasing proportion of the aging population. The number of Americans reaching 65 years and older is expected to reach more than 70 million by 2030 (Boult, C., Green, Boult, L., Pacala, Snyder, & Leff, 2009). Advances in technology, aggressive disease treatments, and early detection or screening efforts have resulted in medical care interventions for individuals with chronic diseases that prolong life (Thorpe & Philyaw, 2012). The availability of treatments, new procedures, or pharmaceuticals to manage diseases has also led to increased utilization of the healthcare system by individuals with chronic disease, with corresponding costs for these therapies (Anderson & Horvath, 2004; Borger et al., 2006; Druss, Marcus, Olfson, Tanielian, Elinson, & Pincus, 2001; Lehnert et al., 2011; Thorpe & Philyaw, 2012).
A second factor contributing to the increase in chronic disease is the presence of risk factors that place individuals at higher risk for the development of chronic disease, particularly in the U.S. (Bodenheimer et al., 2009; Thorpe & Howard, 2006). Three lifestyle behaviors, smoking, inadequate physical activity, and unhealthy dietary practices, have been linked to chronic disease and early mortality (Ford, Bergmann, Boeing, Li, & Capewell, 2012National Center for Chronic Disease Prevention and Health Promotion, 2012). As a major risk factor in the development of chronic disease the greatest concern is obesity. According to Sturm, as cited by Thorpe and Philyaw (2012), the rising prevalence of obesity is “equivalent to 20 years of aging on the number of chronic conditions an individual has” (p. 411). Further, obesity has been related to the increasing prevalence of such chronic diseases as diabetes, heart disease, and hypertension.

Data indicate that cancer; cardiac disease; pulmonary, particularly chronic obstructive pulmonary disease; diabetes; and cerebrovascular diseases remain the most prevalent and costliest chronic illnesses in the U.S. (Bodenheimer et al., 2009; Thorpe & Philyaw, 2012). The current American healthcare system remains fragmented. Healthcare is uncoordinated and results in ineffective management of complex chronic care (Boult et al., 2009). Consequently, as the number of chronic conditions increases, individuals with chronic diseases consume most of the available healthcare resources and utilize more services, all at an increasingly greater cost (Boult et al., 2009; Druss et al., 2001; Lehnert et al., 2011).
Healthcare Costs

Data show that the United States spends the highest dollar amount in the world on healthcare per capita (Bodenheimer et al., 2009; Boult et al., 2009; Thorpe & Howard, 2006). Much of the growth in healthcare spending is related to the care of individuals with chronic conditions. Individuals with five or more chronic conditions, having Medicare as their primary payer source, account for nearly two-thirds of all Medicare spending. The cost burden increases to 80% of Medicare spending when individuals with four or more conditions are added to this group (Boult et al., 2009). Hospital spending has consistently been the largest component of these expenditures (see Figure 2).

Figure 2

2011 Medicare healthcare expenditures (in billions of dollars).


As reported by the Centers for Medicare and Medicaid, the highest rates of hospital admission in 2010 included five chronic conditions.
These conditions are:

- heart failure;
- diabetes;
- chronic obstructive pulmonary disease;
- hypertension; and
- amputations due to diabetes (Squires, 2011).

In 2006-2007, healthcare spending was calculated to be 16%-17% of the gross domestic product (GDP). This figure remained fairly constant for the years 2009-2011. Recently, perceived reductions in the use of medical services have been attributed to the recent recession which resulted in significant efforts by payers to restrict coverage for costly services, efforts by employers to curtail costly healthcare services, and reduced participation in insurance plans (Keehan et al., 2012). Should the population that requires services increase as baby boomers become eligible for Medicare and projections for prevalence of chronic disease continue, the cost of healthcare will grow an average of 6.2% annually and reach nearly 20% of the GDP, or half of the federal budget, by 2021 (Keehan et al., 2012).

**The Veteran Population: Chronic Disease Prevalence and Costs**

Although there are a few studies specific to chronic disease among Veterans, those that were identified indicated that the prevalence of chronic disease burden was similar to the general population (Larson & Welch, 2007; Villa, Harada, Washington, & Damron-Rodriquez, 2003). As with other populations in the country, studies have also indicated that utilization of healthcare services and cost of care has increased with the number of chronic conditions identified by Veterans (Weiss, 2007; Yu et al., 2003).
Depending on age, income, access, and other variables, Veterans may have options other than a Veteran’s medical center for healthcare services (VA). Veterans enrolled in the VA system are assigned to priorities based on their service-connected disability and income. Priorities occur in levels one through eight. Levels seven and eight are Veterans without service-connected disabilities; these individuals are required to provide co-payments for the services they receive. Veterans in the other priority levels have been assessed with some type of a service-connected disability and/or are considered to be low income (Petersen, Byrne, Daw, Hasche, Reis, & Pietz, 2010).

Previous studies of the VA system have indicated that Veterans who rely on the VA medical systems are generally under the age of 65, live near a local medical center, and are usually designated as one of the higher VA-determined priority categories. Additionally, these Veterans are likely to be minorities and of lower income. These same studies indicated that nearly 25% of Veterans over the age of 65 who are Medicare beneficiaries receive their inpatient care at solely VA facilities. As noted by Petersen et al. (2010), Veterans who utilized both Medicare and VA services had more diagnoses than those who utilized VA services exclusively. This supports the supposition that the composition of aging Veterans with chronic disease is comparable to the composition of the aging population in general. Despite access to VA services or other providers for Veterans over the age of 65, there is evidence of higher prevalence of diabetes, arthritis, and cardiovascular disease among this population. According to the experts, Veterans are more likely to report poorer health outcomes than their civilian counterparts (Hoerster, Lehavot, Simpson, McFall, Reiber, & Nelson, 2012).
In August of 2012, the Centers for Disease Control and Prevention (CDC) reported that age-adjusted, elderly Veterans were less likely to be in ill-health than their non-Veteran counterparts. Male Veterans between the ages of 45-64, however, were significantly more likely to report having two or more of nine chronic conditions. Certain lifestyle behaviors found in this Veteran population placed them at greater risk for chronic disease and poorer health outcomes. These Veterans indicated that they were far more likely than the general population to have certain risk factors associated with chronic diseases (Hoerster et al., 2012; Larson & Welch, 2007). Examples of health behaviors included: (a) higher frequency of obesity, (b) less physical activity, and (c) significant use of smoking materials, especially among younger Veterans (Hoerster et al., 2012; Larsen & Welch, 2007; Widome, Littman, Laska, & Fu, 2012).

Additionally, since 1996 groups of Veterans suffering from post-traumatic stress disorder (PTSD) and other mental disorders, alcohol abuse, or substance abuse have presented new challenges in managing the chronic disease burden for this population. Veterans with mental health and/or substance abuse issues, regardless of age, have demonstrated a greater reliance on VA health services, including inpatient care, outpatient provider visits, and pharmaceuticals, than their non-Veteran peers (Petersen et al., 2010).

Between the years 2000-2008 the number of individuals exclusively using services in the VA medical centers for their healthcare needs rose by 40% (National Center for Veterans Analysis and Statistics, 2010). Costs to the VA healthcare system have also been projected to increase dramatically over a similar period of time (U.S. government, Office of Policy and Planning, 2002; Yoon, Scott, Phibbs, & Wagner,
The VA healthcare system is integrated and provides inpatient services, primary care health services, health promotion, and disease prevention in clinics and outreach areas.

The budget for the Department of Veterans Affairs has been funded by Congress and steadily increased by an average of 3.8% annually. From this annual budget, three major service lines are funded including: (a) Veteran Benefits; (b) Cemeteries; and (c) Health Services, which includes medical centers, clinics, and staff. Annually, increases in funding have varied depending on the numbers of Veterans and the conflicts in which the country may be engaged at any given time (Scott, 2012). Total healthcare costs provided for the Veteran population have been projected to continue grow from the current $48 billion to $69 billion in 2020 despite a dramatic decrease in the total numbers of Veterans served, but with a significant increase in minority and female representation (U.S. government, Office of the Actuary 2012; Congressional Budget Office, 2010).

There continues to be a shift from inpatient to outpatient care within the VA system. For 2002-2012, the cost of care in both areas continued to rise. From 2002-2012, acute care admissions increased from 565,000 to 704,000 hospitalizations and outpatient visits nearly doubled from 47 million to 87 million (U.S. government, Office of the Actuary 2012)). Just as other providers in the national healthcare system are struggling with the rising cost of healthcare, the Department of Veterans Affairs healthcare service has been similarly challenged to manage the cost of healthcare within its own network of providers.
Definitions and Conceptual Framework

These trends of rising healthcare costs demonstrate the need for alternative models of care to mitigate the risk factors associated with chronic disease. New approaches are needed to manage chronic disease that will contain or reduce cost and produce value. One promising practice may be the use of self-management programs that are designed and implemented with evidence of positive outcomes (Kass-Bartelmes, 2002; Gordon & Calloway, 2008; Thorpe & Howard, 2006).

Unlike healthcare providers that focus on disease management, self-management programs encourage the patient to become the expert by learning to “manage the symptoms, treatment, physical and psychological consequences and life style changes inherent in living with a chronic condition” (Du & Yuan, 2010, p. 159). Since health is affected by lifestyle and habits adopted by the individual, it is possible to have some control over the factors that affect one’s health (Bandura, 2004). Why, then, do some individuals choose to change behavior and alter or defer negative outcomes of chronic disease and others do not? Among the various theories that offer explanations for behavior change that benefit health, one is based on health promotion and disease prevention by social cognitive means (Bandura, 2004).

Social cognitive theory is based on the belief that behavior is determined by what an individual expects from the consequences of an action or his/her ability to perform a behavior and the perceived value of the outcomes of that behavior by the individual (Rosenstock, Streher, & Becker, 1988). Healthy behavior change is influenced by what the individual believes the consequences to be. An individual adopts changes in health behaviors based on (a) understanding the risks and benefits of those behaviors; (b)
perceived confidence (known as self-efficacy) in believing that those health behaviors can be learned; and (c) expectations that the outcomes, or goals, of the behaviors will be achieved. Since “cognitive processes play a predominant role in the acquisition and retention of new behavior patterns” (Bandura, 1977, p. 192), knowledge of the need for change is necessary for the process to be successful. However, the ability to develop self-efficacy or to achieve necessary behavior change is “central” and “rooted in the core belief that one has the power to produce desired changes in by one’s actions” (Bandura, 2004, p. 144).

For self-management of chronic disease, individuals begin by cognitively learning about disease processes, since this plays an important role in the development and retention of new behaviors (Bandura, 1977). Learning from others is another means of acquiring new health behaviors. Change in behavior is learned through others and can be accomplished through demonstration or feedback from others. As an individual successfully practices new skills or health behaviors, there is an expected increase in the individual’s level of self-efficacy, or “the belief in one’s capabilities to organize and execute the courses of actions required producing given attainments” (Bandura, 1977, p. 3). Incrementally, individuals develop the confidence, or a self-perceived internal state of competence, that they are able to do what needs to be done to achieve health outcomes and manage chronic disease (McKenzie, Neiger, & Thackeray, 2009; Marks & Allegrante, 2005; Pearson, Matke, Shaw, Ridgely, & Wiseman, 2007).

Self-efficacy is typically measured by asking “how confident” the individual is in mastering the tasks and specific skill sets necessary to achieve certain states (Lorig & Holman, 2003). Self-efficacy has been viewed as the “primary determinant for task-
oriented behavior and performance” (Harrison, Rainer, Hochwarter, & Thompson, 1997, p. 79). Change is achieved by different means, but is “induced most readily by experience of mastery arising from effective performance” (Bandura, 1977, p. 191). Accordingly, the more the behavior is experienced, the greater the changes in perceived self-efficacy.

When applied to chronic disease self-management programs, self-efficacy serves as the conceptual framework upon which these programs are based. Self-efficacy is the confidence in one’s ability to make behavioral changes. It determines how individuals “feel, think, motivate themselves and behave” (Bandura, 1994, p. 71). An individual exercising strong self-efficacy and using cognitive processes will choose to make decisions and adopt behaviors that are different to promote health and mitigate the consequences of chronic disease.

Through self-efficacy, individuals approach decisions differently; they see them as opportunities rather than difficulties (Bandura, 1994). Individuals can be proactive, make choices to adapt to changes in life and circumstances, and overcome perceived barriers, rather than simply undergo life experiences and manage stressors (Benight & Bandura, 2004; Weng, Dai, Huang, & Chiang, 2009). Results occur or are increased through learning mastery of self-management tasks, observation of others, persuasion by others, and/or assessment of one’s emotional state (McKenzie et al., 2009).

When new behaviors are adopted or poor health habits are mitigated by a structured self-management program, changes in behavior will also lead to changes in health outcomes. With chronic disease, outcomes may be deferred when healthier habits are adopted. Other outcomes may be affected as well, such as the use of health services and, subsequently, lower costs to the healthcare system, as noted in Figure 3.
Adapted from AHRQ Publication 08-0311, p. 8; Marks and Allegrante, 2005, p. 153).

The Stanford Chronic Disease Self-Management program has produced outcomes that indicate participants have increased their self-efficacy (confidence) in managing chronic disease and reduced their utilization of healthcare resources through fewer emergency department visits and fewer hospitals days (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001b; Lorig et al., 2001a). Reductions in healthcare utilization can reduce the cost of care and allow for use of limited resources for other critical needs.
**Purpose and Goals of the Project**

The Veterans Healthcare system is divided geographically into VISNs, or Veterans Integrated Services Networks. VISN 10 consists of five healthcare facilities in the state of Ohio in the cities of Cleveland, Columbus, Cincinnati, Dayton, and Chillicothe. To support the health of Veterans, prevent further deterioration of chronic diseases, and determine if an alternative care model could affect acute care utilization, the VISN leadership committed to implement the Stanford Chronic Disease Self-Management Program. In addition to purchasing licensing materials, staff members and lay personnel were trained as facilitators for the program, named Healthy U. Although there have been several sessions held for Veterans in VISN 10, there has not yet been an evaluation of outcomes for the program. Further, outcome evaluations reviewed in the literature have not focused specifically on the Veteran population.

The purpose of this project was to conduct an evaluation of the program approved for funding by the VISN 10 leadership. The specific objectives for the program evaluation were (a) to determine whether the program led to a reduction in subsequent acute care costs, as measured by the number of emergency visits, hospital days, and provider visits in the six months prior to the participants’ classes compared to those that occurred six months after completion of the classes; and (b) to assess if the participants felt better prepared to manage their symptoms, as determined by measurement of perceived self-efficacy prior to the intervention and immediately upon completion of an expected four sessions of a total of six sessions of the program.
Acute healthcare for individuals with chronic disease has become a focal point for the healthcare system, as evidenced by the increasing costs of hospital care. The prevalence of chronic disease has continued to grow with the aging of the population, and has been influenced by the availability of new medical therapies, technologies, and medications. Since individuals with chronic illnesses are living longer and requiring greater care for their health, they will consume more resources over their lifetimes (Bodenheimer et al., 2009; Thorpe & Howard, 2006).

As of 2012, the cost of the current care processes had already grown to 17.9% of the national GDP (Keehan et al., 2012). While uncertainties continue to exist with regards to healthcare reform, there can be little doubt that increased demand for care will include increased utilization for individuals with chronic disease as well as increased costs. Additional services will be needed for the elderly. VA medical centers could find themselves positioned as an integrated system that can offer programs to mitigate the expected higher costs of acute care by promoting self-management of chronic disease programs for their population. Evaluation of the Chronic Disease Self-Management Program might assist in this effort by determining the impact of current program outcomes.
Guiding Framework

The purpose of program evaluation relates to the type of evaluation being conducted. In this case, the evaluation was considered to be an impact evaluation, since it focused on “immediate observable effects of a program, leading to the intended outcomes of a program; intermediate outcomes” (Green & Lewis, as quoted in McKenzie et al., 2009, p. 339). This process was not summative since it was not intended to evaluate the entire program. The process was also not intended to seek opportunities for improvement or changes in implementation, which is characteristic of a formative evaluation process. This impact evaluation focused on the need for intermediate program outcomes for a population that had not previously been described (McKenzie et al., 2009).

In 1999, the CDC published a framework for program evaluation that is often used with public health programs and public health education programs (see Appendix A). Based on the model, there are six steps to the evaluation process that should be completed within four specific standards. The six steps outlined for program evaluation include the following:

- engage the stakeholders;
- describe the program;
- focus the evaluation plan;
- gather the credible evidence;
- justify the conclusions; and
- ensure use with lessons learned (McKenzie et al., 2009).
The standards are provided as guidelines to be utilized during the evaluation process. These guidelines are (a) utility standards that are to assure the needs of the user are met, (b) feasibility standards that indicate the evaluation is to be reasonable, (c) propriety standards that address ethics and respect for the rights of all of those affected, and (d) accuracy standards that are intended to assure that procedures are in place so findings are essentially correct (McKenzie et al., 2009).

**Step One: Engage the Stakeholders**

Program evaluation begins with engagement of the original stakeholders, those groups with a vital interest in the program. Stakeholders are the groups or individuals that may (a) increase credibility to the evaluation process, (b) fund or authorize the program and its continuation, or (c) serve to implement program activities (Center for Disease Control and Prevention Model, 2006).

Among these individuals and groups were the Veterans who served as voluntary participants in the program, the master trainers who implemented the initial interventions and subsequently trained additional intervention leaders, and leadership members of the medical centers for VISN 10 who funded the program and set the strategic direction for Primary Care. Additional stakeholders who were identified included members of the Institutional Review Boards and Research and Development Committees for the sites involved in the evaluation.

The settings for the intervention, the Chronic Disease Self-Management Program, included the five facilities already identified and a number of affiliated clinics in VISN 10 in the state of Ohio. Master trainers were responsible for the training of other
workshop leaders and for the quality of the training they received in the Stanford Chronic Disease Self-Management Program.

As noted in the literature, organizational and political environments and relationships of the stakeholders involved in the program can impact the evaluation process (Holder & Zimmerman, 2009). The Chronic Disease Self-Management Program for VISN 10 was originally identified and brought forward to the VISN 10 leadership for approval by the Health Promotion Manager in Dayton. An initial three-year licensing fee was required by Stanford University. Participants may have had a co-payment for the program. As federal funding continues to be a source of concern based on the rising deficit and increasing costs, all programs will be reviewed for their contribution to the Veteran population and to the VA medical system. Given this challenging environment and the expectations of stakeholders within it, measuring outcomes from the self-management program became of paramount importance.

The master trainers for Healthy U in VISN 10 held monthly conference calls. The coordinator for the group was the Health Promotion Manager at the Dayton Veterans Medical Center. The initial three-year funding for the program, class materials, and leader training, was approved by the leadership of the VISN. Salaries for staff trained to serve as leaders were paid by the departments to which each was assigned. The master trainers and the leadership for VISN 10 were advised and supportive of the program evaluation project.

**Step Two: Description of the Program**

A program evaluation model requires a description of the program to be evaluated in the second step.
Specifically, there are three sets of tasks related to the self-management of chronic conditions:

- learning the necessary medical regimen, including medications or diet;
- maintaining or changing behaviors needed to manage the changes in one’s life as result of the chronic disease; and
- dealing with the emotional consequences related to having a chronic condition (Lorig & Holman, 2003).

Specific skills that participants were taught in the self-management programs included (a) problem-solving, (b) decision-making, (c) increasing knowledge of useful and available resources, (d) improving communication and forming relationships with healthcare providers, and (e) taking action (Lorig & Holman, 2003; Pearson et al., 2007).

The initial structured self-management programs were developed by Stanford University and focused on single chronic disease entities, such as diabetes, osteoarthritis, and asthma. Subsequently, Stanford University developed a revised, inclusive program. This program consists of six workshops presented weekly to participants with any chronic disease. The purpose of this program is to build participants’ confidence in managing their health and maintaining active, fulfilling lives and to teach participants the skills of chronic disease self-management. Each participant was provided a copy of a Stanford University book entitled, *Living a Healthy Life with Chronic Conditions: Self-Management of*
Heart Disease, Arthritis, Diabetes, Asthma, Bronchitis, Emphysema & Others (Lorig, Holman, Sobel, Laurent, Gonzalez, & Minor, 2000).

In the six week schedule, the content was covered as indicated from the book utilized as a reference (see Appendix B). Based on the licensing agreement, leaders were not permitted to deviate from the script designed by Stanford University. To demonstrate competency, each leader was expected after completing his/her training to partner with another leader or master trainer and teach two workshops. Other sessions could monitored by a master trainer to assure adherence (accuracy of the standardized information delivered) and competency (ability to “engage the participants effectively”) in the program (Frank, Coviak, Healy, Belza, & Casado, 2008, p. 6). These measures demonstrated the ways in which the program addressed fidelity to proper implementation of the intervention. When fidelity, defined as “adherence or faithfulness to the procedures that compose an intervention” is compromised, testing an intervention and its measured outcomes can be compromised, a reason for incorporating such indicators into program evaluation measures (Frank et al., 2008, p. 5).

Each week, participants learned new skills to manage their symptoms. In particular, in each session participants were expected to practice and apply the steps for problem-solving and action planning. These processes were critical for participants to develop or improve their self-efficacy.

Participants were free to identify a problem that they wished to work on each week. This may have been the most difficult part of the program for some
Participants were asked to select at least one problem, list their ideas to resolve the problem, and choose at least one strategy to try for the coming week. Once selections were made, participants then developed their specific action plans for that week. As noted in the literature, successful action planning is a vital process in the development of self-efficacy since the practice of setting and achieving goals fosters self-confidence.

Action plan steps included (a) what they would do in the coming week to assist with self-management, (b) the amount of time they would devote to the activity they would do, (c) the specific time the activity would be done or where it would be done, and (d) the frequency with which the activity would be done. Participants were then expected to assign their own level of confidence to this action plan based on a scale of one to 10. No scores below a rating of seven were accepted.

Assessing the results of participants’ action plans occurred in subsequent classes. Participants reported on their action plans, including any barriers they encountered, and how they handled these challenges. If the initial approach to the problem was not successful, participants were encouraged to select another approach to the problem or utilize other resources in solving their problem. Participants continued to work on their problem of choice throughout the program. When a participant discovered that particular problems could not be resolved at the time of the program, program leaders suggested that participants select a problem that would be more appropriate to work on while they were in the program (Lorig et al., 2000).
Although the sessions were scripted, they were also interactive. Group members were supportive of one another during the sessions. Exercises included discussions between participants and sharing of results. Additionally, participants identified individuals with whom they could communicate during the week to support them in their self-management efforts and action plans.

**Step Three: Focus the Evaluation Plan**

The evaluation plan was developed with the assistance of the Health Promotion Program Manager at the Dayton Medical Center and presented to the master trainers at the other VA medical centers for input and support. The demographic variables that were included in the evaluation included (a) age, (b) sex, and (c) race.

The outcome objectives for program evaluation were agreed upon by the master trainers to assess the impact of the program. The first outcome, utilization of healthcare services and measured pre- and post-program, was chosen because the program stakeholders were interested in determining whether or not this alternative model of care for the Veteran population would result in cost reductions, thereby preserving resources for the provision of other programs and services. The second objective, measuring participants’ perceived confidence to manage their chronic disease, their perceived self-efficacy, was documented in the literature to be commonly related to successful self-management programs. Perceived self-efficacy was to be measured by a survey developed by Stanford University and administered to participants who had completed four of six program sessions.
Step Four: Gather Credible Evidence and Support

The program evaluation model at this point indicated the need for review of the evidence that supported the program. The literature review included programs that were facilitated by staff and/or lay individuals, all of whom were managing their own chronic diseases. The only program that was reviewed in the literature and was specific to the Veteran population was by Nodhturft et al. (2000). This study did not, however, include measured outcomes in its results.

The VISN 10 Healthy U master trainers selected a strategy to engage Veterans and their caregivers in self-management of chronic disease. Engagement behaviors are defined as “actions that individuals must take to obtain the greatest benefit from their healthcare services available to them” (Holmes-Rovner, French, Sofaer, Schaller, Prager, & Kanouse, 2010, p. 2). Specific behaviors identified as evidence for engagement include health promotion, health prevention, and opportunities to seek health knowledge, all of which are directed to self-management of chronic disease (Holmes-Rovner et al., 2010).

The specific program selected by the Healthy U master trainers in VISN 10 was the Stanford University Chronic Disease Self-Management Program. The program was selected based on data obtained from the Area Agency on Aging, Ohio Department of Aging, National Council on Aging, and Agency on Healthcare Research and Quality reports.
**Literature Review**

A search was initiated to review the evidence; it did not, however, include disease management or patient education programs. As stated by Peterson et al. (2007), “While patient education is necessary, it alone is insufficient” (p. 2). Single disease self-management programs were also eliminated since the program being implemented targeted individuals with any chronic disease or any number of chronic diseases. Dates of studies were irrelevant, but studies were limited to those conducted in the United States, Canada, or Great Britain, since these populations more closely resembled the American Veteran population.

The search was initiated with the following key words: self-management programs, chronic disease self-management programs, self-care, Veterans, outcomes, healthcare services utilization, and self-efficacy. Boolean terms were also utilized. Databases queried included the Cochrane Databases (all), CINAHL, SocINDEX, and PubMed. There were very few hits and many of the same articles were repeated across searches. Extensive searches by hand became necessary based on reference lists of the studies obtained from searches and reports from the Agency of Healthcare Research and Quality.

There were several well-designed studies available regarding the clinical outcomes for single disease self-management programs. For programs in which individuals were taught self-management skills for single diseases, a number of
results reported improvement in clinical outcomes and reductions in costs. Other studies reported less favorable outcomes, as noted in this literature review.

In one narrative review, there were 23 of 27 studies that measured asthma self-management. Clinical outcomes for these studies demonstrated improved asthma symptoms. Studies utilizing action planning tended to have improvements more often than those that did not use action plans (Bodenheimer et al., 2009). Eighteen additional studies were identified and separated into two groups: those offering self-management and those only providing education for osteoarthritis. Of the 18 studies, 12 reported improved clinical outcomes compared to their control groups. All 10 of the self-management groups indicated improvement in clinical outcomes; only two of the patient education groups reported improvement, suggesting a difference between outcomes from self-management programs and those from traditional patient education (Bodenheimer et al., 2009).

In the same narrative review noted above, 15 studies measuring asthma self-management were analyzed to determine the effect on healthcare services utilization and cost. Eight of the 15 studies reported reductions in hospital or emergency department utilization. Ten studies contained data regarding healthcare utilization, of which three reported reductions in physician visits. The remaining seven studies did not report healthcare services utilization. Limitations noted in the review included the difficulty in making generalized statements about the impact of single disease self-management programs since interventions were not standardized (Bodenheimer et al., 2009).
An investigation funded by the Centers of Medicare and Medicaid resulted in a meta-analysis of 53 studies of chronic disease self-management programs. The conceptual model required that interventions assisted patients in self-monitoring of symptoms and management of their diseases. Randomized trials that compared outcomes from self-management intervention to controls for patients with diabetes, osteoarthritis, or hypertension were included. Outcomes evaluated included: (a) hemoglobin A1c, (b) fasting blood sugar, (c) pain, (d) blood pressure, and (e) physical functioning. Thirteen studies addressed self-management of hypertension, 14 studies addressed osteoarthritis, and 26 studies addressed diabetes (Chodosh et al., 2005).

Pooled results from this meta-analysis indicated statistically and clinically significant improvements for participants with diabetes for these single disease self-management programs in reduction of hemoglobin A1c. Reductions in blood pressure were also noted. Although there were statistically significant reductions in pain for participants in osteoarthritis programs, they were determined to be not clinically significant (Chodosh et al., 2005). The authors of this meta-analysis noted that the quality of the studies varied, with some evidence of publication bias. The analysis identified the need for standardizing self-management programs, the essential elements to be defined, and the outcomes to be measured.

Similar results were noted in a structured review of disease-specific self-management programs. Articles containing self-management interventions with concurrent controls and evaluation of outcomes were reviewed. Both randomized and non-randomized studies were included. Seventy-one trials, including five
disease-specific groups, comprised this review, including: (a) arthritis, (b) asthma, (c) diabetes, (d) hypertension, and (e) miscellaneous or generic self-management programs.

A great deal of heterogeneity in the studies was identified. A moderate effect size was detected in reduction of A1c levels for diabetics. Additionally, some improvement in blood pressure was noted as well as fewer asthma attacks. Evidence of publication bias was also noted in this group of studies (Warsi et al., 2004).

A pre- and post-test study for a single disease self-management program reported no clinically significant differences between responders and non-responders but small to moderate increases in self-efficacy and symptom management ($ES=0.43$). However, no changes were found from baseline in healthcare services utilization for nights hospitalized, provider visits, or emergency department visits (Wright, Barlow, Turner, & Bancroft, 2003).

Evidence specific to the heterogeneous, or generic, Stanford Chronic Disease Self-Management Program was limited. The literature most frequently cited was Dr. Lorig and colleagues from Stanford University. In a study funded by the Agency for Heath and Research Quality, randomized trials were conducted with 952 program participants who were over the age of 40 and living in community-based sites. Participants were assessed after six months for improvement in outcomes. Three specific categories for outcomes were assessed, including: (a) health behaviors, (b) health status, and (c) health services utilization.
The tools that were utilized to measure outcomes included the self-rated health scale in the National Health Interview survey, a modified version of the Health Assessment Questionnaire (HAQ) disability scale, a section of the SF-36 and SF-20 tools, and an adaptation of the Medical Outcomes Study that measures pain (Lorig et al., 1999). Participants also reported emergency department visits, provider visits, and hospitalizations.

After six months, program participants demonstrated significant improvements in self-reported health behaviors, including: increased exercise, greater frequency of cognitive symptom management, and improved communication with physicians. Measures of health status and fatigue were also improved. Participants who completed the program also reported fewer nights in the hospital as compared to the control group, which was comprised of individuals who were on a waiting list for the program (Lorig et al., 1999).

Following this study, Lorig conducted a before- and after-cohort study with participants from Kaiser Permanente hospitals. The objective of this study was to evaluate the outcomes of the Chronic Disease Self-Management Program in a “real world setting” (Lorig et al., 2001, p. 256). Six hundred and thirteen patients were recruited and 489 completed the study for baseline data and follow-up in one year. The same outcome measures were assessed utilizing the same tools as the earlier investigation. This study included measurement of the participants’ assessment of their perceived self-efficacy. As previously noted, self-efficacy is the concept upon which the Chronic Disease Self-Management Program is based. It is the personal confidence that must be developed by the
participant to become a knowledgeable individual who can learn responsibility to
set goals for the tasks required to perform the behaviors and develop the attitudes
necessary for management of his or her chronic disease and experience improved
health status (Lorig et al., 1999; Marks, Allegrante, & Lorig, 2005).

Outcomes for measures of health status, health behaviors, and health
services were reported by the participants. Discussion about the psychometric
testing for the tools utilized in the study was also noted in the study. Self-reports
of health utilization were highly correlated to visits recorded in the computerized
medical records.

Outcomes measured at one year for participants completing the program
showed statistically significant improvements in self-reported health status, self-
efficacy, self-reported health behaviors, and mixed results for healthcare
utilization. Statistically fewer emergency department visits were observed and
fewer (but not at a significant level) health provider visits or hospitals days were
documented (Lorig et al., 2001).

Lorig returned to the original 1999 study, Chronic Disease Self-
Management Program database, to conduct a longitudinal follow-up investigating
the retention of program effects (Lorig et al., 2001). In the original six month
study program, there had been 1,140 participants between the wait-listed controls
and those who were randomly assigned to the intervention. After the study, wait-
listed individuals were offered the opportunity to participate, increasing the
sample size. Data were collected for all individuals who completed a
questionnaire upon program entry, at one year, and at two years, resulting in a final sample size of 831.

Three categories of self-reported outcomes were measured by mailed questionnaire: health status, health services utilization, and perceived self-efficacy. Identical tools were utilized from the previous studies with one exception. A social/role activity limitation scale was developed and tested for this study.

No significant differences in baseline characteristics were identified among the participants from the original study. Results in self-reported health status indicated that participants rated some improvement in health status from their original baseline prior to the program despite evidence of increased disability over that same period of time. There was evidence of reduced use of healthcare services but not at a significant level. Reported levels of self-efficacy, however, were statistically significant (Lorig et al., 2001). Additionally, it showed a modest decrease in the use of healthcare services. This study is important because it demonstrates retention to some extent of the intervention despite evidence of continued disability, which is expected with chronic disease.

A randomized controlled study in which the Chronic Disease Self-Management Program was delivered for an Hispanic population produced statistically improved self-reported health behaviors, health status (with the exception of the use of tobacco), and self-efficacy. The purpose of the study was to evaluate the program and its outcomes as a means of addressing the increasing prevalence of chronic disease among Latinos. Prior to the implementation of the
program, focus groups were held with Spanish-speaking individuals with chronic
disease to develop the course in Spanish. The protocol remained standardized,
even though it was taught in Spanish. Additionally, there were some culturally
appropriate adaptations made to the program.

The sample size was 551 Spanish-speaking participants, of whom 327
were program participants and 224 who were in the wait-list control group.
Outcome measures included health behaviors, health status, healthcare services
utilization, and self-efficacy. Tools were translated into Spanish and tested for
validity, and all measures were self-reported.

There were few baseline differences between the participant and control
groups. Initial results were measured at four months and indicated statistically
significant improvements in health behaviors, health status, and self-efficacy and
a trend in reductions in physician visits, however, no difference in hospital days
was observed. Although the results of this study were retrieved in a short period
of time after the conclusion of the program, results were re-assessed after one year
for retention of benefits. By then, the control group had been fully integrated into
the study. Healthcare behaviors and perceived health status indicated that
participants continued to make statistically significant improvements from
baseline. There were significantly fewer emergency visits in the last four months
of the year as compared to the four months before baseline (Lorig, Ritter, &
Gonzalez, 2003). The importance of this study is its cultural adaptation and use of
focus groups prior to implementation as a method to identify the key messages to
be integrated into the curriculum for the population.
Additional studies have addressed self-management programs and included measures of differences in self-efficacy and healthcare utilization. Significant differences were found in measures of participants’ self-efficacy (Farrell, Wicks, & Martin, 2004; Foster, Taylor, Eldridge, Ramsay, & Griffiths, 2009; Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007; Newbould, Taylor, & Bury, 2006). Most of these studies did not report significant reductions in healthcare utilization, but some indicated trends toward decreased utilization. Results varied by study for self-reported health behaviors and self-reported health status of individuals. For studies included in meta-analyses, comments regarding high levels of heterogeneity among the studies were noted. Additionally, some evidence of publication bias was identified.

A review of self-management programs led by lay leaders resulted in a review of 17 randomized controlled trials with 7,442 participants. Seven of the 17 trials were specific to the Chronic Disease Self-Management program. Meta-analyses were performed based on outcomes for 16 of the 17 studies. No statistical improvements were seen in hospital days. In 10 studies, a small but significant increase was seen in perceived self-efficacy. Notations were made that only Lorig’s studies reported reduction in emergency department visits and provider visits. This review is significant because it demonstrates a depth of analysis conducted on the studies with similar interventions. Significant heterogeneity and variation in the quality of the studies was noted in the studies reviewed and some evidence of publication bias was reported (Foster et al., 2009).
A pilot study was conducted in a poor, rural area using a quasi-experimental pre- and post-test design. In this study, a sample of 48 adults participated in the Chronic Disease Self-Management program. The majority of participants were White while 10 were African American. The purpose of the study was to evaluate program outcomes for this specific population. Self-efficacy was measured in terms of managing health, symptoms, disease, and self-management behaviors (Farrell et al., 2004). In this study, the Self-Efficacy Health Cantril Ladder was utilized to measure self-efficacy. The sub scales for this tool measured self-efficacy and self-management behaviors. Cognitive symptom management was measured with a Likert-like scale, and results were self-reported.

Outcome results indicated improvement in performing self-management of symptoms and significant improvement in self-efficacy in managing health. There were significant differences in ages and the number of classes attended by group members. Limitations to the study included short-term follow-up, use of a convenience sample, and small sample size. Strengths included application of the CDSMP to an underserved population and the use of tools based on the self-efficacy concept to measure its effect (Farrell et al., 2004).

Lorig’s work with the Chronic Disease Self-Management program was adapted by the National Health Service of Great Britain and labeled the Expert Patients’ Programme. The National Health Services identified self-care as a priority in its patient-centered approach to care. The Expert Patients’ Programme was implemented as a policy by the National Health Services in 2001. Since its
implementation there has been debate about the diversion of resources to it and whether its results can effectively offset some of the costs of the healthcare services provided by the national program (Griffiths et al., 2007; Newbould et al., 2006). Two studies using the same database and drawn from the Final Report of the National Evaluation of the Pilot Phase of the Expert Patients Program examined the outcomes from the program with a sample size of 659 participants in community settings in England (Kennedy et al., 2007; Richardson et al., 2007).

The purpose of Kennedy’s report from the nationally conducted randomized controlled study was to communicate the results of the effectiveness of the Expert Patients’ Programme compared to the waiting list control group. The sample size from the national report was 629 patients with a variety of chronic conditions who participated in the program based on the generic Stanford Chronic Disease Self-Management. Three specific outcomes were measured: perceived self-efficacy, self-reported healthcare status, and self-reported healthcare services utilization. Data were collected at baseline, six months after completion of the program, and 12 months after the program. The study, however, only reported results from the six month period of measurement. The intervention and control groups completed the collection at rates of 79.2% and 86.4% respectively. There were no significant baseline differences noted between the groups.

Consistent with previous studies, participants demonstrated significant improvement in self-efficacy measures. Specifically, participants noted fewer social role limitations, improved psychological well-being, lower health distress,
more exercise, and better communication with their providers. At the same time, however, results indicated no differences in overall healthcare services utilization. The authors suggested that the lack of effect on utilization might have been due to the short time allocated for follow-up. There was a small effect indicating reduced inpatient utilization, although it was not statistically significant. Regardless, the authors concluded that even a small reduction might have offset the cost of the program itself. The study provided additional evidence that the CDSMP program increased perceived self-efficacy and added a healthcare alternative for patients with chronic disease. There was a small effect on hospital days that could have led to reduction in the cost of acute care (Kennedy et al., 2007).

A recent meta-analysis of the chronic disease self-management program included 18 studies of randomized controlled studies or longitudinal designs that measured health behaviors, psychological health (including measurement of self-efficacy), physical health, and healthcare utilization outcomes. Significant differences were found for symptom management, physical exercise, and psychological outcomes. Consistent and sustained improvements in self-efficacy were recorded and directly associated with self-reported changes in physical function. Small reductions were seen in self-reported healthcare utilization at four to six months after the intervention, but not sustained over 12 months (Brady et al., 2013).

Evidence for the program and its effects on the population of interest, Veterans, was limited to one article, a descriptive pilot study conducted with a small sample in VISN 8 (Florida). The purpose of the pilot program was to
evaluate whether or not implementation of the CDSMP was possible with a Veteran population. The Veteran population was different from the one described in Lorig’s studies in that individuals were predominately male, older, and had a military background. The pilot program was conducted in six hospitals in the network and utilized the Stanford Chronic Disease Self-Management Program. Outcomes were retrieved from VA electronic medical records and responses to self-administered questionnaires. A few centers elected to utilize Lorig’s outcome tools that had previously been tested for validity and reliability. Focus groups were conducted to collect additional information from participants about their personal experiences in the program. Themes derived from the focus groups included:

- Veterans developed empathy with others who had a variety of chronic diseases;
- There were no perceived differences in health behavior changes, regardless of service connection status;
- Discussions focused on highlights of the individual program experiences;
- Participants reached consensus that they would recommend the program to others; and
- Leaders were encouraged to make the program known to as many Veterans as possible.

Limitations to the study included a small sample size (N=43). There were inconsistencies among the centers in how they evaluated the program. Some
centers utilized Lorig’s tools while others only utilized focus groups and feedback from the Veterans. No outcome statistics were reported, but qualitative results indicated enhanced self-efficacy and satisfaction with the quality of life. It was noted that there were slight decreases in use of outpatient provider visits and emergency room visits (Nodhturft et al., 2000). The value of this study is that it describes implementation of the program with the population of interest, Veterans, and within a VISN.

In 2002, the Agency for Healthcare Quality and Research published a summary of Lorig’s research which indicated that the reduction in hospital days could have saved approximately $390.00 to $520.00 per participant due to the use of fewer healthcare resources (Research in Action, 2002). Findings noted on the Stanford University website stated that the program can result in the reduction of healthcare expenditures. Further, the statement was made “with a reasonably high degree of confidence” (Gordon & Galloway, 2008, “Summary of utilization effects,” para. 2).

In 2013, a national study of the Chronic Disease Self-Management programs was sponsored by the National Council on Aging. Results were shared during a webinar. Twenty-two sites were selected across the nation to participate in the study that was designed to assess participants’ outcomes at six and 12 months. At baseline, the sample size was 1,170 participants; at 12 months, the sample size was 825. Outcome measures included symptom management, health status, health behaviors, and healthcare services utilization, specifically hospitalization and emergency department visits. Of the participants, 79%
completed four of the six classes, as expected. Among the outcomes noted, there was a statistically significant difference in self-reported symptom improvement after 12 months. Emergency department visits were also noted to be significantly reduced, with an estimated savings of approximately $740.00 per participant (Whitelaw, Lorig, Smith, & Ory, 2013). Hospitalization rates remained unchanged at both six and 12 months.

Evaluation of the evidence in the synthesis table (see Table 1) is based on the United States Preventative Services Task Force Grade for Strength of Overall Evidence, defined in Appendix C.
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Note:* indicates statistically significant results
The literature that is specific to the generic self-management program designed to assist participants is limited. The quality of evidence may be compromised by the lack of statistical controls or possible publication bias, and two studies had small sample sizes (Farrell et al., 2004; Nodhturft et al., 2000). However, there is evidence to indicate, in many cases, that the Chronic Disease Self-Management Program has provided opportunities for individuals with chronic diseases to develop the ability to increase their confidence and skills to manage their health problems and improve their quality of life (Brady et al., 2013).

Despite the issues identified in this review of the literature, there is compelling evidence from some study results that the Chronic Disease Self-Management Program has had a positive effect for participants related to their self-efficacy. Study participants have reported positive effects on selected self-care behaviors and their health status. Patient education has come to be seen as important, but not a “sufficient contributor to behavior change” (Pearson et al., 2007, p. 2). In order for individuals to increase their skills to manage their chronic disease, they must develop the confidence in their ability to do so. This confidence is measured by the individual’s perceived self-efficacy. As previously noted, self-efficacy is an individual’s belief in his or her ability to perform those tasks necessary for self-management, but more importantly, the belief that the use of the skills will produce “positive, desired outcomes” (Nodhturft et al., 2000, p. 510).

The articles synthesized in Table 1 provide evidence of increased self-efficacy and some evidence of decreased cost. Additionally, there appears to be evidence that the program has reduced healthcare utilization; however, findings are inconsistent and limited to the studies conducted primarily by the founder of the program. Even if the
reductions are not statistically significant, any reductions in cost should be considered. The rising cost of healthcare, even for the VA, remains a challenge. Alternative approaches to helping individuals manage their own health may reduce their use of costly services. If applied to a large number of participants, any potential reductions could amount to significant savings.

**Summary**

VISN 10 implemented the Healthy U program and has conducted several sessions in each of the medical facilities and several of the outlying clinic centers. The Healthy U master trainers agreed upon selection of a program evaluation framework for this process from CDC (see Appendix I). This framework was selected because of its focus on population health and health promotion.

The purposes for program evaluation are several, including: (a) determination of the achievement of program objectives, (b) accountability to the decision-makers and funders for the program, (c) improvement of the program, and (d) contribution to the evidence base for community-based interventions (McKenzie et al., 2009).

There were six steps included in the program evaluation model and standards for its proper implementation. The initial four steps of the program evaluation model have been described. Step five, Justify Conclusion and Recommendations, and step six, Ensure Use and Share Lessons Learned, occurred after project implementation. Step five of the CDC program evaluation model occurred after program outcomes were retrieved, measured, and analyzed. When the evaluation of the selected outcomes was completed, the results were assessed utilizing the standards included in the program evaluation model for utility, feasibility, propriety, and accuracy.
Implementation and Evaluation

Population and Setting

Healthy U, the title given to the Chronic Disease Self-Management Program designed by Stanford University, was offered at the five VA medical facilities in VISN 10 and some of its outpatient clinics. VA Healthcare System of Ohio (VISN 10) is one of 21 Veterans Integrated Service Networks (VISN) of the Department of Veterans Affairs. In addition to the five VA medical facilities, VISN 10 includes 30 community-based outpatient clinics which provide comprehensive inpatient and outpatient healthcare to Veterans in Ohio, Indiana, Kentucky, and West Virginia.

From January 1, 2012, through the end of December, 2013, 296,478 Veterans received healthcare services at one of the medical facilities in VISN 10. Those services may have included inpatient or outpatient care. The range of ages for those served was from 20 to over 100 years. Of this total population, only 8% were female. The population of VISN 10 is predominately male and Caucasian (72.2%). Black or African-Americans are the largest group, or 11.9% of the population. American Indian, Asian, and Native Hawaiian (or other Pacific Islander) racial groups comprised the small remaining entities, 0.3%, 0.1%, and 0.5% respectively. The remaining variance in the total for identification of race indicated that (a) race is not listed on the Veteran’s records (11.7%); (b) race is
stated as unknown to the Veteran (1.1%), or (c) the Veteran declined to answer (2.2%).

Participants who elected to join the chronic disease self-management workshop may have included Veterans of any age. In this project, the average age was 62.3 years, the age range was 28-89 years, and the sample population was predominately male. Participants may have had any chronic disease or any number of chronic diseases. For the purpose of this current study, only Veterans were included as participants since this population has been the subject of limited study. The review of literature identified only two studies that specifically focused on Veterans (Nelson, Wong, & Lai, 2011; Nodhturft et al., 2000). In the first study (Nelson et al., 2011), the principles of self-efficacy were applied to Parkinson’s disease only, and in the second study cited (Nodhturft et al., 2000), there were no measured outcomes documented. The outcomes that were chosen for this study included perceived self-efficacy and healthcare services utilization, which are consistent with those identified in the literature review (Brady et al., 2013; Kennedy et al., 2007; Lorig et al., 1999; Lorig et al., 2001; Lorig et al., 2003; Whitelaw et al., 2013).

**Barriers and Facilitators**

One of the most critical components to successful implementation of the project was identifying and establishing effective communication with the master trainers at each of the sites. With the assistance of the Health Promotion Program Manager at the Dayton VA Medical Center, contact was established with each of these individuals to begin discussions regarding the next steps for implementation.
of the program evaluation. Monthly telephone conferences were facilitated by the Health Promotion Program Manager during which status updates of the project were discussed. This communication and their active engagement in the process facilitated the program evaluation process. Once the master trainers agreed to participate in the project, the next steps for implementation required identification of procedures for approval at each of the medical centers. Despite the study design as a program evaluation, a process for approval to conduct the project was still required. A research proposal describing the program evaluation process was prepared with the expectation that it would be submitted to an Institutional Review Board for expedited review. Although this procedure may be complex for any healthcare organization, this study involved five medical facilities affiliated with the federal government. The Veterans Health Administration outlined its requirements in a handbook through a series of policies addressing research processes and the use of data and data repositories made available for research purposes (U.S. Government, VHA Handbook, 2009). Any one of the Veterans’ medical centers, as an individual healthcare system, is complex in itself. Being part of a larger system such as VISN 10 or the VHA adds a further level of complexity (Porter-O’Grady & Mallach, 2011). VISN 10 is one such complex entity. Further, VISN 10 is part of an even more multifaceted system, the Department of Veterans’ Affairs, a cabinet post in the federal government.

As any healthcare system evolves, it becomes increasingly more complex, with highly networked entities and ordered processes (Clancy, 2007; Clancy, Effken, & Pesut, 2008). The medical centers within the VISN are entities with
unique structures and processes. The approval procedures for the project required extensive communication with additional stakeholders within these systems, and at different points in time, each affecting the implementation process. The structure for Institutional Review Board Approval was governed by rules and regulations outlined by the Department of Veterans Affairs, but were interpreted differently, implemented differently, and consequently involved a variety of additional stakeholders in the decision-making processes (see Appendix D).

**Institutional Review Boards: Human Subject Protection**

VISN 10 did not have a single Institutional Review Board for research requests. Three Institutional Review Boards were involved, only one of which managed requests for more than one facility. The Wright State University Institutional Review Board served in this capacity for the Dayton Veterans Medical Center. The Louis B. Stokes Veterans Medical Center had its own Board. The University of Cincinnati served in this capacity for the Cincinnati Veterans Medical Center, Chillicothe Veterans Medical Center, and the Chalmers P. Wylie Veterans Medical Center. The VHA had previously established procedures to govern operational activities that may be determined to constitute research (U.S Government, VHA Handbook, 2011). In this handbook, research was defined as a “systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge” (U.S. Government, VHA Handbook, 2011, 1058.05, p. 2). Additionally, the handbook outlined policies related to research affecting human subjects noted in other
federal policies, specifically Title 38 Code of Federal Regulations part 16 (38-CFR16).

Expedited review and HIPAA waiver was sought from each of the Institutional Review Boards. The required documents were drafted and forwarded to the Wright State University IRB and included the following: study protocol (see Appendix E), request to conduct research, request for a HIPAA waiver, handout for the participants inviting them to join the study, research security checklists, conflict of interest forms, resumes, and survey instruments to be utilized. Concomitantly, discussion was initiated regarding the documentation required by the Louis B. Stokes Institutional Review Board for the medical center and the University of Cincinnati Institutional Review Board that governed research activities for the Columbus, Cincinnati, and Chillicothe sites.

The project was approved, with revisions, by the Wright State University Institutional Review Board (see Appendices H, I, J, K, L) but was not reviewed by either the University of Cincinnati or the Louis B. Stokes VA Medical Center Institutional Review Boards, both of which determined that the project did not meet their criteria to be considered research (see Appendices F, G). The VHA defines non-research activities as activities that are “not designed to produce information that expands the knowledge based of a scientific discipline or other scholarly field” (U.S. Government, VHA Handbook, 2011, 1058.05, p. 3). It was the determination of these two entities that the study was to be utilized only for internal VA purposes, such as quality improvement activities, and therefore, did not constitute research.
The process for obtaining data for research purposes also changed for all VA sites shortly after these determinations were made. Although only one of the centers had reviewed the project as research, data were to be collected from all VISN 10 facilities, necessitating use of the new process for all data collection. Completion of the request required review of all materials, including all IRB decisions by additional entities within the larger VA system. At the final review step, significant issues arose, including the inconsistencies among the IRB processes in VISN 10. Among the many requirements, the program proposal was to be reevaluated by the Cincinnati and Cleveland IRBs as research. Without completion of these requirements, access to data was not going to be authorized.

As a result of these decisions, in addition to changes in the internal VA processes, project implementation appeared to be compromised. Instead, the request for approval of the project proposal from the Wright State University Institutional Review Board was withdrawn; a closure report was submitted and accepted (see Appendix M). With the study closure, project efforts were directed to program evaluation process, which then provided access to data in an alternative manner.

**Project Implementation and Outcome Measures**

Prior to the previous developments, all of the sites had been prepared to implement the project in spring 2013. Before implementation could begin at any of the facilities, conference calls were held with the master trainers to design the specific procedures for communicating the status, purpose, and objectives of the project. Discussions had been held with the trainers regarding the distribution of
the project survey questionnaires that were to measure perceived self-efficacy (see Appendix N). Additional sessions had been conducted with master trainers who were unable to participate in the original discussion and for other groups of leaders that planned to conduct the classes.

The survey that measured perceived self-efficacy utilized the six-item Chronic Disease Self-Efficacy Scale (see Appendix O) developed and tested by Stanford University for internal consistency and reliability with results at .91 (Lorig, Ritter, Laurent, & Hobbs, 2001).

<table>
<thead>
<tr>
<th>No. of</th>
<th>Observed</th>
<th>Mean</th>
<th>Standard</th>
<th>Internal Consistency Reliability</th>
<th>Test-Retest Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>items</td>
<td>Range</td>
<td></td>
<td>Deviation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>1-10</td>
<td>5.17</td>
<td>2.22</td>
<td>.91</td>
<td>NA</td>
</tr>
</tbody>
</table>

Tested on 605 subjects with chronic disease


As noted on the Stanford University Chronic Disease Self-Management program website, this tool as well as all of the other program tools are not proprietary and have been available at no cost due to funding from the National Institute of Nursing Research. The instrument contains six items and is self-administered. The scale uses a Likert-like rating, ranging from 1 - 10, from “not at all confident” to “totally confident”. Higher scores indicate a higher level of confidence and, therefore, higher levels of self-efficacy. Reliability coefficients reported have been .91 for the total instrument (Lorig et al., 2001), but test-retest
reliability studies have not been conducted on the instrument. Instructions regarding the use of this specific instrument indicated that it measures only self-efficacy and noted that the scale must be utilized in its entirety. Words and scaling factors may not be changed or the scale will be invalidated.

At the first class, all leaders provided informational handouts to the Veterans only, distributed surveys to those willing to participate in the project, and requested that individuals complete the survey. When surveys were completed, they were marked at the top of the page with the letter “A”. At the last class, leaders asked participants if they (a) completed a survey at their first class, and (b) attended four of the six sessions. If any of the participants had, the leaders requested these participants to complete another survey. These surveys were marked at the top of the page with the letter “B”. Pre-addressed envelopes had been sent to master trainers in advance of their workshops. The surveys were subsequently returned to the Health Promotion Manager at the Dayton VA. Aggregate results were to be complied and evaluated to assess differences in mean scores prior to the workshop and immediately upon completion. Survey data collection began on April 2, 2013, and continued for six months until October 31, 2013. The survey collection ceased with the IRB closure and results were reported at that time, on November 15, 2013.

To meet the second objective, whether the program led to a reduction in subsequent acute care services, data were requested from the Division of Support Services, located on the Dayton VA Medical Center grounds (see Appendix P). Specific data elements were identified, including (a) all participants who had
completed four of the six sessions of the workshop; (b) the number of Healthy U sessions attended; (c) the number of emergency department visits, the number of hospital days, and the number of provider visits, all of which would have occurred during the six months prior to their first Healthy U class; and (d) the number of emergency department visits, the number of hospital days, and the number of provider visits during the six months after their last Healthy U class. Dates for collection of data were January 1, 2012, to December 31, 2013, to allow for a larger sample size.

Demographics requested were the age, gender, and race of the participants. The final data requested were the average costs for each of the identified healthcare services. Aggregate results from utilization of healthcare services by participants were to be measured six months after the last class and compared to their utilization of healthcare services in the six months prior to the first class. T-testing was planned to assess differences, if any, in the mean results of healthcare services utilization outcomes. These data were to be retrieved from the Veterans’ electronic medical records and a cost accounting system available at the VA.
Project Outcomes

Findings

The outcomes from the study included both descriptive and quantitative data. Using the same Chronic Disease 6-Item Scale, baseline mean measurement of perceived self-efficacy compared that of perceived self-efficacy mean measurement at the conclusion of the workshop. Quantitative data were retrieved to assess the economic impact of the intervention. Specifically, the number of emergency visits, hospital days, and provider visits in the six months prior to the participants’ classes were compared to those that occurred six months after completion of the classes. These data were to be extrapolated into the costs of healthcare services and assessed for any differences between the mean costs of the services prior to the intervention compared to the mean costs after the intervention.

Data Outcomes and Analysis: Perceived Self-Efficacy

Results were limited in the measurement of perceived self-efficacy. Since the project did not require participant consent, the questionnaire results were not paired. Therefore, statistical testing was limited to any observed differences in the pre and post scores. Statistical significance could not be determined. The questionnaires had been originally distributed upon approval of all Research and Approval committees for each VISN 10 facility or clinic site. Collections had
begun with workshops starting April 2, 2013, through October 31, 2013. Since subsequent organizational circumstances changed, the original study was closed with the IRB and survey collection had ceased October, 2013, resulting in smaller samples. The close-out report provided to the Wright State University IRB included the results of the surveys (see Appendix M).

The sample consisted of 53 anonymous surveys returned to the principal investigator. Descriptive statistical testing only was conducted since the results were not paired. The pre-intervention sample size was 28, and post intervention sample was 25. The survey process did not allow for identification of participants who may have either failed to return on the last day of the workshop, or who may have chosen not to complete a second survey when the second sampling was completed. Therefore, it was not possible to select initial surveys that should have been discarded. Descriptive statistics indicated differences in the results measured post intervention, as noted below:

Table 3

<table>
<thead>
<tr>
<th>Measurement of Differences in Perceived Self-Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timeframe</td>
</tr>
<tr>
<td>Pre-intervention</td>
</tr>
<tr>
<td>Post intervention</td>
</tr>
</tbody>
</table>

Note: Dates of collection: April 2, 2013 - October 31, 2013

After completion of the workshops, 28 participants’ mean perceived self-efficacy scores measured 6.48 prior to their workshop sessions and 25 participants
mean perceived self-efficacy score measured 8.20 after completing at least four of the six sessions. The pre-survey mean scores were two points lower than the average mean post-survey scores, indicating a noticeable difference.

Interpretation of findings is consistent with the evidence presented in the literature review. Although there was no means of determining significance in perceived self-efficacy measurements by participants after the intervention, as seen consistently in the evidence, there were obvious differences in scores. Despite the small sample, the differences in raw scores after the intervention are a clinically important point to note. For some participants, the intervention may have had some impact on their beliefs in managing the symptoms of their chronic diseases. If they believe it did, and it has improved their self-efficacy, they may feel more prepared to manage their symptoms, be more compliant with their medical regimen and deal more effectively with the consequences of their chronic disease.

**Data Outcomes and Analysis: Healthcare Utilization and Costs**

To retrieve data for the health services utilization project objective, consultation was held with staff of the regional Division of Support Services (DSS). The Division of Support Services Office was established as part of the Veterans’ Health Affairs Office of Finance. The regional offices have routinely assisted with data retrieval for research and operations. Staff members extract data from various databases and from the VA cost accounting system. The data obtained may be clinical, program, or financial. As previously indicated, the local staff has been located on the grounds of the Dayton VA Medical Center.
Specific data elements were identified for inclusion were (a) all Veterans Healthy U participants from January 1, 2012, through December 31, 2013, from the five VISN 10 medical centers and any participating clinic sites, (b) the number of emergency department visits, the number of hospital days, and the number of provider visits utilized during the six months prior to their first Healthy U class; and (c) the number of emergency department visits, the number of hospital days, and the number of provider visits utilized during the six months after their last Healthy U class. Demographics requested were the age, gender, and race of the participants. The final data request included the average costs for each of the identified health care services.

The system produced data by individual participant, from all sites, including the actual costs per participant for each of the health services utilized during the time period from six months prior to through six months after completing four of six of their workshops. In discussion with the VA Privacy Officer, the report was altered to eliminate any reference to participant’s unique identifier, age, or dates of service since these data are considered protected by the VA system. The resultant report included a sample size of 139 participants. The second set of findings that focused on the healthcare utilization data was entered into SPSS, version 18, and single sample t-tests were completed. To avoid Type I error, the level of statistical significance was adjusted by applying the Bonferroni correction. This was done because the data being tested were from the same set of data. The level of significance was thus adjusted to be less than 0.0167 (p<0.0167).
Results were initially divided into two groups (a) descriptive and (b) quantitative $t$-tests. Descriptive results are as indicated in tables four and five.

### Table 4  
*Distribution by Gender*

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>17</td>
<td>12.2</td>
<td>12.2</td>
<td>12.2</td>
</tr>
<tr>
<td>Male</td>
<td>122</td>
<td>87.8</td>
<td>87.8</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>139</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

As seen in the tables above, participants were primarily white and male, consistent with the overall utilization pattern seen in the VISN 10 population. The total sample size of 139 Veterans is less than one hundredth percent of the VISN 10 population who sought healthcare services from January 1, 2012 through December...
31, 2013, which is the period of the program evaluation study ($n= .0005$). The ages for both sexes and all races ranged 29-88 years, with a mean age of 62.3 years. This population was somewhat different than that described previously for those in VISN 10 utilizing healthcare services, in that there were slightly more females (12.2%). The racial profile was also different, in that there was a higher percentage of Black and African-Americans in this population (19.4%), about 8% higher than the total percentage using the healthcare system in the VISN.

Prior to running the paired $t$-tests, descriptive testing, including displayed histograms were completed for the dependent means (See Appendices Q, R). The histogram graphs did not indicate a normal distribution, so additional nonparametric statistical testing was completed for each of the means comparisons that were included in those reported (See Appendix S). A review of the results for the paired $t$-test of the means is noted for each of these quantitative objectives for the project in tables six and seven.
Table 6

*Paired Sample: Mean Volumes Pre- and Post-Intervention*

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black or African-American</td>
<td>27</td>
<td>19.4</td>
<td>19.4</td>
<td>19.4</td>
</tr>
<tr>
<td>Declined to answer</td>
<td>4</td>
<td>2.9</td>
<td>2.9</td>
<td>22.3</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>2</td>
<td>1.4</td>
<td>1.4</td>
<td>23.7</td>
</tr>
<tr>
<td>Unsure</td>
<td>2</td>
<td>1.4</td>
<td>1.4</td>
<td>25.2</td>
</tr>
<tr>
<td>White</td>
<td>104</td>
<td>74.8</td>
<td>74.8</td>
<td>100.0</td>
</tr>
</tbody>
</table>

*Mean difference calculated by subtracting post value from pre value. Negative values therefore indicate that the post value was larger than the pre value.

Note: Dates of Collection 1/1/12- 12/31/13

*p < .0167

Results from the paired t-tests indicated that there was no statistically significant reduction in volumes, as measured by these outcomes, for Veterans who had received healthcare services before and after the workshop.
Table 7

*Paired Sample: Mean Costs Pre- and Post-Intervention*

*Dates of Collection 1/1/12- 12/31/13*

<table>
<thead>
<tr>
<th>Project Objectives</th>
<th>n</th>
<th>Pre-Ranges</th>
<th>Post-Ranges</th>
<th>Means Difference*</th>
<th>SD</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Costs</td>
<td>6</td>
<td>1-72</td>
<td>1-75</td>
<td>-$ 8,829.5</td>
<td>$ 1,763.9</td>
<td>.125</td>
</tr>
<tr>
<td>Emergency Department Costs</td>
<td>17</td>
<td>1-8</td>
<td>1-8</td>
<td>-$ 445.7</td>
<td>$ 1,786.7</td>
<td>.309</td>
</tr>
<tr>
<td>Outpatient Costs</td>
<td>138</td>
<td>2-199</td>
<td>1-294</td>
<td>$ 898.5</td>
<td>$ 1,570.0</td>
<td>.503</td>
</tr>
</tbody>
</table>

*Mean difference calculated by subtracting post value from pre value. Negative values therefore indicate that the post value was larger than the pre value.*

Note: Dates of Collection 1/1/12- 12/31/13

\[ p < .0167 \]

Mean hospital days and costs increased but not significantly with mean increased cost indicating $8,230. Mean emergency department visits and costs also increased slightly, although also not at a statistically significant rate. The mean dollar increase ($455.67) was not significant for emergency department visits, since the mean number of visits increased by less than one visit. Provider outpatient visits decreased slightly (by nearly two visits) as did costs, but not at a significant rate. Confidence intervals were somewhat large because of these small sample sizes, particularly for both hospital and emergency department data.
Because the expected assumptions were not met for the dataset, nonparametric statistical testing was completed for each of the means comparisons were completed and noted in the table eight.

Table 8

Results of Nonparametric Tests: Paired Sample

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Days</td>
<td>Related samples Wilcoxon Signed Rank Test</td>
<td>.102</td>
</tr>
<tr>
<td>Hospital Costs</td>
<td>Related samples Wilcoxon Signed Rank Test</td>
<td>.116</td>
</tr>
<tr>
<td>ED Visits</td>
<td>Related samples Wilcoxon Signed Rank Test</td>
<td>.871</td>
</tr>
<tr>
<td>ED Costs</td>
<td>Related samples Wilcoxon Signed Rank Test</td>
<td>.730</td>
</tr>
<tr>
<td>Outpatient Visits</td>
<td>Related samples Wilcoxon Signed Rank Test</td>
<td>.061</td>
</tr>
<tr>
<td>Outpatient Costs</td>
<td>Related samples Wilcoxon Signed Rank Test</td>
<td>.035</td>
</tr>
</tbody>
</table>

Note: $p < .0167$

Results of nonparametric testing affirmed the original results of the paired $t$-tests. There were no significant changes between the pre and post outcomes. Upon completion of these tests, Cohen’s $d$ was calculated to estimate the effect of the paired $t$-test results. Using (a) .2 to indicate small effect, (b) .5 as medium effect, and (c) .8 for large effect, the estimated effect of the intervention on mean costs for each acute care service was noted as indicated in the table below. Inpatient costs may have not have increased significantly, but the effect was perceived to be large. The effect
on both increased emergency and outpatient costs was noted to be small, as were the means cost differences.

Table 9

*Paired Sample: Estimation of Effect: Differences in Costs*

<table>
<thead>
<tr>
<th>Service</th>
<th>Cohen’s $d$</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Costs</td>
<td>7.2</td>
<td>Large</td>
</tr>
<tr>
<td>Emergency Department Costs</td>
<td>.2</td>
<td>Small</td>
</tr>
<tr>
<td>Outpatient Provider Costs</td>
<td>.2</td>
<td>Small</td>
</tr>
</tbody>
</table>


Independent $t$-testing was then completed on the entire sample. Documentation of histograms again indicated lack of normal distribution (See Appendix T). The results of the independent $t$-tests of means for the entire sample are noted in tables ten and eleven.
Table 10

Total Sample Mean Volumes Pre- and Post-Intervention

<table>
<thead>
<tr>
<th>Project Objectives</th>
<th>Pre n</th>
<th>Post n</th>
<th>Pre Mean</th>
<th>Post Mean</th>
<th>Pre SD</th>
<th>Post SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Days</td>
<td>20</td>
<td>15</td>
<td>8.4</td>
<td>14.93</td>
<td>16.22</td>
<td>22.21</td>
</tr>
<tr>
<td>Emergency Department Visits</td>
<td>38</td>
<td>31</td>
<td>2.24</td>
<td>2.68</td>
<td>1.80</td>
<td>2.48</td>
</tr>
<tr>
<td>Outpatient Visits</td>
<td>139</td>
<td>138</td>
<td>42.88</td>
<td>41.88</td>
<td>34.67</td>
<td>40.36</td>
</tr>
</tbody>
</table>

Note: Dates of Collection 1/1/12- 12/31/13

Table 11

Total Sample Mean Costs: Pre- and Post-Intervention

<table>
<thead>
<tr>
<th>Project Objectives</th>
<th>Pre n</th>
<th>Post n</th>
<th>Pre Mean</th>
<th>Post Mean</th>
<th>Pre SD</th>
<th>Post SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Costs</td>
<td>20</td>
<td>15</td>
<td>$33,788</td>
<td>$43,683</td>
<td>$4,933</td>
<td>$8,864</td>
</tr>
<tr>
<td>Emergency Department Costs</td>
<td>38</td>
<td>31</td>
<td>$1,060</td>
<td>$1419</td>
<td>$912</td>
<td>$1,554</td>
</tr>
<tr>
<td>Outpatient Costs</td>
<td>139</td>
<td>138</td>
<td>$17,619</td>
<td>$18,845</td>
<td>$16,907</td>
<td>$19,451</td>
</tr>
</tbody>
</table>

Note: Dates of Collection 1/1/12- 12/31/13

Results of the independent sample $t$-tests were then analyzed with the Mann-Whitney test since the data lacked normal distribution. Results are included in table 12.
Table 12
Mann-Whitney Nonparametric Testing

<table>
<thead>
<tr>
<th>Project Objectives</th>
<th>Pre n</th>
<th>Post n</th>
<th>Pre Mean</th>
<th>Post Mean</th>
<th>Pre SD</th>
<th>Post SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Costs</td>
<td>20</td>
<td>15</td>
<td>$33,788</td>
<td>$43,683</td>
<td>$4,933</td>
<td>$8,864</td>
</tr>
<tr>
<td>Emergency Department Costs</td>
<td>38</td>
<td>31</td>
<td>$1,060</td>
<td>$1,419</td>
<td>$912</td>
<td>$1,554</td>
</tr>
<tr>
<td>Outpatient Costs</td>
<td>139</td>
<td>138</td>
<td>$17,619</td>
<td>$18,845</td>
<td>$16,907</td>
<td>$19,451</td>
</tr>
</tbody>
</table>

Note: p< 0.0167

Once again the results indicate no significant difference in the utilization of healthcare services by the Veterans in entire sample (139 participants), six months after the workshop. The results for the participant group was consistent with the paired samples in that no significant difference was perceived in the utilization of acute care health services in the six-month period following their workshop. Fewer participants utilized acute care services. However, the costs of those services were higher, primarily due to an increase in hospital days and/or possibly an increase in resources utilization during the hospital stay. Little cost increase was observed in outpatient visits, and, despite fewer individuals utilizing the emergency department, a small increase in costs was also observed.

Six months after the intervention these documented healthcare utilization outcomes indicated results mirroring some of those noted in the evidence (Foster et al., 2009; Kennedy et al., 2007; Lorig et al., 2003). The described evidence included studies in which six months after intervention, emergency department visits were
reduced, but hospital days were not affected. Mean outpatient visits were often decreased, but not at a statistically significant level (Brady et al., 2013; Lorig et al., 2001; Lorig et al., 2003; Whitelaw et al., 2013).

**Step V Justify the Conclusions**

This evaluation was conducted to assess the impact of the Healthy U program known as Chronic Disease Self-Management Program in VISN 10. The original intent had been to determine the effect on the participants’ perceived self-efficacy after completion of the workshop and to determine if the intervention affected their utilization of healthcare services six months after completion of the intervention, as compared to their utilization six months prior to the intervention. At the outset of the project data requested had included more specific information about the participants including the presence of specific co-morbidities identified to be the most frequent among the Veteran population including: (a) diabetes, (b) heart disease, (c) hypertension, (d) depression, and (e) arthritis (Hoerster et al., 2012). Also requested had been the percentages of Veterans who had one of these diseases and those who had three or more of these diseases. These data had been requested so that that there might be the possibility of ascertaining a relationship between participants with co-morbidities and their utilization of healthcare services. With the revisions in the study necessitated by organizational circumstances and processes, these data were not available at that time.

Veterans who utilize the VA system, as previously discussed, generally mirror the needs of the aging population with chronic disease in the country (Petersen et al., 2010). Three of the diseases that precipitated the highest rates of hospital admissions
were among the co-morbidities found in the Veteran population (Hoerster et al., 2012; Squires, 2011). Veterans over the age of 65 years have reported having more chronic diseases and poorer health than non-Veterans (Hoerster et al., 2012). Studies have indicated that increases in healthcare costs are noted with additional chronic conditions (Lehnert et al., 2011; Machlin & Soni, 2013).

If the data regarding the prevalence of these chronic diseases among this study population had been available, they might have assisted in the evaluation of the utilization of healthcare services among this population, particularly hospital days. A review of the raw data indicated wide variation, with a few participants requiring significant hospital days. Participants with several chronic diseases or in later stages of their disease certainly would have required a greater intensity of resources with resultant increases in costs.

In this step (justify the conclusions) of the framework for program evaluation, an evaluation of the standards provided as guidelines to be utilized during the process should be included. There were four standards within the program evaluation framework that were initially identified in the report: (a) utility, (b) feasibility, (c) propriety, and (d) accuracy.

The utility standard was noted as necessary to assure the needs of the user are met. The quantifiable project objectives were specifically designed to address two purposes, to meet the requirements for completion of an academic degree and to lay the foundation for routine reporting of outcomes for the Healthy U program. Although limitations to the study have been identified, ongoing reporting of program
outcomes is expected. There may be opportunities for improvement but this standard for program evaluation has been satisfied.

Despite barriers throughout the process, the program evaluation design eventually was identified to be reasonable. A framework for program evaluation was selected and determined to appropriate to meet the standard for feasibility.

During the evaluation process, consultation was held with the Research and Development staff at the VISN 10 centers to follow all appropriate procedures to assure and protect the rights and privacy of the Veterans involved. These steps were taken to assure compliance with propriety standards within the program evaluation framework.

Great care and attention to detail was paid to assure accuracy in requesting, clarifying, reporting, displaying, interpreting, and analyzing these program data. Clarification was sought when duplication of data elements, specifically racial identification, occurred in the data report. Since participants update their information, staff at the DSS center indicated that original data may not be removed from the system. Therefore, when racial identity was missing duplicate data without racial identification was removed from the database. Participants who did not complete at least four of the six sessions were also removed from the study database. These individuals were identified by the number of notes made by the Healthy U leaders in their records and pulled into the report by the electronic system. Findings have been carefully reviewed in the context of accepted statistical procedures to avoid error and misinterpretations as well as to identify limitations to meet expectations for the accuracy standard (McKenzie et al., 2009).
Study Limitations

There are several limitations to this study. Because informed consent was not obtained, the survey utilized to measure perceived self-efficacy was not a paired sample and no statistical testing was completed. Participants were volunteers for the interventions, which might have influenced the results, particularly for the surveys. There is indication that some participants attended more than one workshop which might have influenced outcomes as well.

Participant data obtained for healthcare utilization were not randomized but received from all sites and in whatever order they were pulled from the listing of codes entered by DSS staff. Duplicate descriptive data received from the DSS staff and noted in the report regarding race were deleted based on information obtained from staff that follow-up registrations subsequently corrected omitted or inaccurate data elements. Data obtained were limited, in that no specific information was available about participants. There are no data known or available on their specific chronic disease, their medical plan of care, or any support systems that may have affected their compliance to self-management regimen. This may be significant because any additional data regarding participants’ health and/or the state of their chronic diseases may have been very useful in the assessment of utilization of acute care services.

Although the cost for services has been calculated for the services provided through the VA cost accounting systems, the specific methodology utilized has not be identified or explained, so the calculations and results cannot be clearly explained or verified.
The paired sample sizes for both inpatient care and emergency department
visits drawn from the total population size (139), were small, six and 17 participants,
respectively. The total sample size of 139 Veterans, represents a small contingent of
those who sought services from the health care centers in VISN 10 from January
2012 through December 2013. Given these small sample sizes and wide variation in
results, preliminary conclusions cannot be drawn at this time, without the possibility
of error. The timeframe (six months) within which outcomes were assessed is
relatively short; research studies have recommended longer periods of time or
sequential periods of time for ongoing measurement of these same outcomes.

**Step VI Ensure Use with Lessons Learned**

Project findings were summarized and reported to the principal investigator. A
report will be prepared for the VISN leadership, the major stakeholders, who
approved the program and its expenditures. The report will also be shared with the
master trainers who provided so much support to the study. Plans are to continue to
add to the database and monitor these same outcomes to assess impact of the program
on its participants and its contribution to VISN 10. As the Healthy U program
continues to expand within VISN 10 and additional participant data are added,
seeking additional data regarding participants’ health, the number and the state of
their chronic diseases may be helpful in the assessment of utilization of acute care
services. These data could be useful in predicting service needs, utilization, and
resource allocation within the VA system in general and VISN 10 in particular.
Recommendations

There are already plans for continuing data collection for the Healthy U program to assess its effect on its potential economic outcomes. The investment made by the VISN requires careful evaluation of the resources already deployed. Continued study of the results from the program evaluation data may assist in planning for future program needs in the management of chronic disease among the Veteran population. Additional recommendations for consideration might include maintenance of the participant data base so that additional meaningful data can be managed, monitored and reported. Data should be maintained and analyzed annually, at a minimum, and at time intervals, 12 months, 18 months and 24 months, to assess improvement and/or retention of benefit for the participants. Data collected should include continued measurement of the means for acute care days, emergency department visits, and provider visits prior to and after the identified time period.

Mean cost data should also be included in the ongoing data collection, but there should be ongoing dialogue with the DSS staff to assure that the methodology for ascertaining cost does not change from one data collection period to the next, in order to assure consistency in interpretation of results.

In addition to the data analyses already described, the master trainers should consider using some of the other tools available to them from Stanford
University that will allow the assessment of perceived clinical outcomes, such as pain or mobility. Measurement of clinical results such as A1c or tidal volumes may also be outcomes of interest for selected populations or clinics.

Feedback from veterans regarding their ability to manage their chronic disease is an important outcome from self-management programs. Ongoing measurement of perceived self-efficacy with the use of paired samples is recommended to determine to assess if differences exist prior to the intervention and afterwards. Feedback from Veterans about this program and what they perceive they have learned or experienced is important to provide to the VISN. To receive meaningful feedback regarding perceived self-efficacy, the survey must be paired. This will require some means of identifying the participants. The master trainers will need to ascertain if this effort may require authorization from their IRBs and informed consent, since informed consent will also require those obtaining it to complete Citi training required by the VA.

Meaningful data regarding the Veterans’ perception of the program is necessary and should be collected in an appropriate manner. For this reason, narrative feedback from the participants may be both useful and clinically significant. Qualitative data may allow themes to be extracted from either interview with participants or written comments. The data supplied can be shared with the decision-makers to provide insight into what the participants believe they have achieved from the program.

In summary, the sample for this project is so small, the confidence intervals so imprecise, and differences and effect relatively small, with the
exception of the inpatient costs. The inpatient sample, however, is also small and
inpatient costs may vary widely, depending on the participants’ healthcare
problems or needs. Consequently, it would be premature to evaluate the Healthy
U program based on these findings. Instead, it is more important to continue to
collect data and amass a larger sample to assess the program’s continuing impact
on the Veteran population in VISN 10.
Conclusion

The prevalence and burden of chronic disease in the U.S. is continuing to grow and place heavy demands on the entire healthcare system (Anderson & Horvath, 2004). The number of individuals with chronic disease increases with the aging population. With the advancement of medical technology, the population is living longer and requiring care longer in life. With the increase in the number of individuals needing care, as well as the increase in services they demand or require, healthcare costs will continue to drive government, private payers, and individual’s financial responsibilities upward. Despite the decreasing number of Veterans, these same demographic factors are affecting Veterans’ healthcare services. The burden of resulting costs is being exacerbated by Veterans with one or more chronic diseases.

Chronic disease self-management programs are among the few alternative models of care that can create value for participants by increasing their confidence in managing their health problems and reducing cost so that limited resources can be used more effectively. These programs shift the focus from the old authoritarian provider model of simply adhering to medical guidance to learning the knowledge and skills they need to “incorporate the psychological and social management of living with a chronic illness” (Newman, Steed, & Mulligan, 2004, p. 1523).
References


for the Institute of Medicine’s “Retooling of America” report. *Journal of the American Geriatrics Society*, 57(12), 2328-2337.


United States Department of Health and Human Services, Centers for Medicare and Medicaid.
United States Department of Veterans Affairs, Veterans Health Administration. (2011). *VHA handbook 1058.05* (VHA operations activities that may constitute research). Retrieved from http://www.research.va.gov/resources/policies/oro-120811.cfm


APPENDICES
Appendix A

Centers for Disease Control Framework for Program Evaluation

STANDARDS
Utility
Feasibility
Propriety
Accuracy

Note: McKenzie et al., 2009, p. 34
### Appendix B

**Workshop Overview**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Week 1</th>
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<th>Week 5</th>
<th>Week 6</th>
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<td>Using your mind to manage symptoms</td>
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Note: CDSMP T-T Manual Appendix 1 2010; Chart Summary, p. 3.
Appendix C

United States Preventative Services Task Force: Hierarchy of Research Design

<table>
<thead>
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<th>Evidence obtained from at least one properly-designed randomized controlled trial</th>
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<tr>
<td>II-1</td>
<td>Evidence obtained from well-designed trials without randomization</td>
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<tr>
<td>II-2</td>
<td>Evidence obtained from well-designed cohort or case controlled analytic studies, preferably from more than one center or research group</td>
</tr>
<tr>
<td>II-3</td>
<td>Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940’s) could also be regarded as this type of evidence</td>
</tr>
<tr>
<td>III</td>
<td>Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees</td>
</tr>
</tbody>
</table>

Note: United State Library of Medicine, National Institutes of Health, U.S. Preventive Services Task Force: *Appraising the evidence*. 2008
Appendix D

Institutional Review Board and Study Approval Processes


Appendix E

Study Protocol

**Study Summary**

This study will evaluate the impact of the Stanford University Chronic Disease Self-Management Program (CDSMP) on volunteer participants. This licensed and scripted program, developed by Stanford University, consists of a series of six weekly sessions conducted by two trained lay leaders and/or healthcare professionals. During these sessions, participants learn strategies for dealing with chronic conditions, practice self-management skills, and provide/receive peer support for their efforts. Researchers at Stanford University and other sites have documented program outcomes that include decreased disease symptoms, increased self-efficacy, and decreased utilization of healthcare resources.

All VISN 10 VA facilities implemented the program in FY12 and plan to expand it in FY13. Because there are limited data about outcomes for the CDSMP among Veterans, this evaluation is being done to assess the effect of the program in VISN 10.

**Background and Significance**

The prevalence of chronic diseases is rising. In 2005, nearly 133 million Americans had at least one chronic disease. By 2020, that number is anticipated to increase by 16% to 150 million or more. Many Veterans have more than one chronic illness. Symptoms of chronic illnesses - including pain, fatigue, muscle tension, shortness of breath, and depression - can be debilitating and interfere with normal life activities. Although medical treatments and medications are crucial in the management of chronic disease, disease outcomes are heavily impacted by the decisions that patients make every day about physical activity, food intake, stress management, and adhering to a medical plan of care.

Individuals with chronic conditions consume a lot of healthcare resources, and they have been found to utilize more services, at greater expense, as the numbers of their chronic conditions multiply. Much of the growth in health care spending is related to the care of individuals with chronic conditions.

There are few studies specific to prevalence of chronic disease in Veterans using the VA system, but the chronic disease burden is estimated to be similar if not greater than the general population. Utilization of healthcare services and costs of care for Veterans increases with the number of identified chronic conditions.

The CDSMP is one of several self-management programs have been designed to help patients make healthy decisions, manage symptoms using self-care strategies, work with their healthcare team, and use the healthcare system more efficiently. Approaches like these, if effective, could help contain or reduce costs, and also improve the quality of life for those with chronic diseases. The Chronic Disease Self-Management Program was developed in 1996 by Stanford University with a grant from Agency for Healthcare Research and Quality.

**Method of Subject Identification and Recruitment**

Individuals, male or female who have signed up to participate in the Chronic Disease Self-Management Program (known as Healthy U) at the Dayton Veterans Affairs
Medical Center over a period of six months will be invited to participate in evaluating the program. The invitation will be written in a handout describing the program evaluation process and containing the pre-program assessment survey. Individuals, male or female who have signed up to participate in the Chronic Disease Self-Management Program (known as Healthy U) at the Dayton Veterans Medical Center during a six-month period of study will be included in the program evaluation. Although class participants may include Veterans and non-Veteran family members, only Veterans will be asked to complete surveys before and after the program. Both male and female Veterans will be recruited for participation. It is estimated that 60 Veterans will be recruited in the six month period.

**Inclusion Criteria**

- Subjects must
  - Be Veterans
  - Be 21 years or older
  - Signify willingness to participate in the evaluation by completing the survey
  - Complete the program by attending at least four of six sessions of a workshop within the six-month study period

**Exclusion Criteria**

- Chronic Disease Self-Management Program participants not meeting the inclusion criteria

Data for Veterans who do not complete the survey will be excluded by removal from the list of participants that is provided to the Division of Support Services for data collection by means of encrypted e-mail.

**Study Design and Methods**

This protocol describes a program evaluation process focused on 1) a self-report of self-efficacy before and after the CDSMP workshop, and 2) a comparison of utilization of healthcare resources in the six-month period before the workshop and the six-month period after the workshop. Self-efficacy was chosen as an outcome variable to determine if the participants experienced an increase in their confidence in managing their chronic conditions after completion of the program. Healthcare utilization data were selected as outcomes to determine whether the program was associated with cost reductions. Data about each participant will be extracted from electronic patient records and provided in a report to the researchers without any patient-identifiable information. These demographic variables will be reported to describe the participants:

- age
- sex
- marital status
- VA medical center where the course was provided
- presence and documentation by ICD-9 code of any of the following at the time of hospital discharge: hypertension, diabetes, heart disease, depression, and arthritis.

Outcome variables were selected to assess the impact of the program on the participants’ perceived self-efficacy, which is the confidence to manage their chronic disease, and an
outcome determined to be related to successful self-management programs. Utilization of healthcare was chosen because there is interest in determining if this alternative model of care for the Veteran population might result in cost reductions, preserving resources for the provision of other programs and services. The measurements of self-efficacy will be done using the six-item Chronic Disease Self-Efficacy Scale (attached). This scale was developed and tested by Stanford University (internal consistency reliability of 0.91). The Stanford University website grants permission for use of this tool. Program leaders will provide the tool to Veteran participants at the first class and at the completion of the final class; participants' names will not be attached to the surveys. Mean scores will be calculated for the two survey points, using a test-retest design for the mean. The willingness of the participants to complete the tool will be assumed to be their consent.

Aggregate results from utilization of healthcare services by the participants will be measured six months after the last class and compared to their utilization of healthcare services in the six months prior to the first class. Healthcare utilization data will be obtained from a report generated by Division of Support Services without any patient identifiable information:

- numbers of visits to emergency departments or urgent care centers within the Veterans medical centers in the six month period before the first Chronic Disease Self-Management Program session
- numbers of visits to emergency departments or urgent care centers within the Veterans medical centers in the six month period after the last Chronic Disease Self-Management Program session
- number of hospital days in the six month period before the first Chronic Disease Self-Management program session
- number of hospital days in the six month period after the last Chronic Disease Self-Management Program session
- number of number of visits to outpatient healthcare providers in the six month period before the first Chronic Disease Self-Management Program session
- number of visits to outpatient healthcare providers in the six month period after the last Chronic Disease Self-Management Program session

Pooled results of the means of utilization of healthcare services by the participants will be measured six months after the last class and compared to their utilization of healthcare services in the six months prior to the first class. Lists of participants who have agreed to be included in the study will be provided to the Division of Support Services by means of encrypted e-mail. Data for participants electing not to participate will be excluded by removal from this list of participants that is provided to the Division of Support Services. Data will then be extracted from the electronic record by the Division of Support Services and provided to the investigators in a table that will display the demographic variables, including age, gender, marital status, and chronic conditions. No personally identifiable data will be displayed. Consequently, no personal health or identifiable information will be connected to the participants. To track the number of subject records collected, the
Subject number column in the data collection tool will be numbered from 1 to the end of the data collected.

**Risks:** Risks to patients in this study will be minimal as no active interventions are proposed and study data will be pre-existing. The main risk of this study would be patient confidentiality. However, every effort will be made to study data in a confidential manner. All data will be stored on a password protected computer in a secure location with limited access only to the study staff in the locked office on medical center premises. Risk would be added if consent were to be obtained; copies would need to be maintained.

**Benefits:** There are no direct benefits to the participants in this study. The benefits to be clarified are cost benefits. However, the additional benefits of doing this study is to assess potential program outcomes for a health oriented intervention that is patient-centered empowering the patient to assume responsibility for managing his or her health and chronic conditions.

**Data Analysis and Data Monitoring**
Perceived self-efficacy outcomes will be measured by statistical testing using t-tests of the means. Data will be aggregated by measuring the means of all scores from the questionnaire pre-tests and compared to the means of all scores for the questionnaire post-test. For healthcare services utilization outcomes, repeated single analyses of variance will be used to compare the mean participant emergency department utilization, hospital bed days, and provider visits six months prior to the first class of the program and six months after the completion of the program.

---

We are so glad you have joined us for our classes and hope you are looking forward to the next six weeks. You should learn a lot about living with health problems. We are doing a study to see what difference this course can make in Veterans’ health. So we
are asking you to fill out a survey on the first day and another one on the last day. The survey is the only difference in the course. After your course has ended, we will use information from your electronic record to learn about your health.

Please do not write your name on the survey.

You do not have to take the survey. Just tell your course leader and your information will not be used in the study. Your Healthy U course will be the same either way.

Thank you!
## Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know *how confident* you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

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Not at all confident

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Totally confident

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
References


United States Department of Health and Human Services, Centers for Medicare and Medicaid.


Appendix F

Approval for Exemption - University of Cincinnati

<table>
<thead>
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<th>UNIVERSITY OF Cincinnati</th>
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<td>Shari Altman</td>
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<td>TITLE OF STUDY</td>
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<td>DESCRIPTION OF</td>
<td>This study will evaluate the impact of the Stanford University Chronic Disease Self-Management Program (CDSMP) on volunteer participants.</td>
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<tr>
<td>RESEARCH, INCLUDING</td>
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<td>THE PURPOSE:</td>
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- The activity involves research because all of the following are true:
  - The activity is a systematic investigation, including research development, testing and evaluation
  - Either of the following is true:
    - The activity is designed to develop generalizable knowledge.
    - The activity is designed to contribute to generalizable knowledge.

- The activity involves human participants because both of the following are true:
  - The data the investigator is planning to obtain are about living individuals
  - Either or both of the following is true
    - The investigator plans to obtain the data through one or more of the following:
      - Physical procedures performed on those individuals
      - Manipulation of those individuals
      - Manipulation of those individuals' environments
      - Communication with those individuals
    - The information to be obtained is both:
      - Private, because either of the following is true
        - The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
        - The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)
      - Individually identifiable, because either of the following is true:
        - The identity of the participant is or may readily be ascertained by the investigator
        - The identity of the participant is or may readily be associated with the information

Note: Research VIA Operation Activities

The activity is designed and implemented for internal VIA purposes.

The activity is not designed to produce information that expands the basis of a scientific discipline.

Version 08-03-2008

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## Research for which FDA regulations may apply

- The activity involves an FDA regulated test article because one or more of the following is true:
  - The activity involves the use of a drug, other than the use of an marketed drug in the course of medical practice.
  - The activity will involve the use of a drug, meaning one of the following:
    - An article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them
    - An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals
    - An article (other than food) intended to affect the structure or any function of the body of humans or other animals
    - An article intended for use as a component of any article specified in the above items
  - Either of the following is true:
    - The drug is NOT approved by the FDA for marketing
    - The drug is NOT being used in the course of medical practice
  - The activity involves the use of a medical device, other than the use of an marketed medical device in the course of medical practice.
    - Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
    - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals
    - Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes
  - Either of the following is true:
    - The medical device is NOT approved by the FDA for marketing
    - The medical device is NOT being used in the course of medical practice
  - The activity is otherwise subject to FDA regulation:
    - Data from the activity will be submitted to, or held for inspection by, the FDA.
    - The activity involves an FDA-regulated article one or more of the following:
      - Infant formula
      - Biological product for human use
      - Electronic product for human use
      - Other article subject to the FD&C Act
    - The test article will be used on one or more humans
      - The test article is a medical device
      - The medical device will be used on human specimens
      - The activity is being done to determine the safety or effectiveness of the device
      - Data from the activity will be submitted to, or held for inspection by, the FDA.

---

**For IRB Office Use Only**

[Signature]

Dated 12/3/13

Version 08-03-2006

100
Appendix G

Exemption Decision - Louis B. Stokes

IRB #: __ IRB Use Only

Katherine Baczewski MS, RD, LD, CDE

Form Directions: Form is protected (user has limited access to the fill-in fields). Use the tab key or mouse to navigate the fill-in fields. Formatting is limited in the text fields (no bulleted lists, numbering, etc). In the event that the user is unable to navigate through the protected document or would like to format a document, the user can disable the "protected" feature (select "Review" then "Protect Document" then "Restrict Formatting and Editing" then "Stop Protection"). Please do not delete or modify questions.

Louis Stokes Cleveland Department of Veterans Affairs Medical Center
Request for EXEMPTION from IRB Review

Please submit this completed form to the IRB and when accessing or collecting identifiers submit a HIPAA Waiver Request. Please contact the IRB office if you have any questions at (216) 791-3800 ext. 4658.

EXEMPT research includes research activities in which the only involvement of human subjects is in one or more of the categories listed in Section 3 (38 CFR 16.101(b).) The exempt status must be determined by the Institutional Review Board (IRB) Chair or Vice Chairperson.

Section 1 – General Information

1. Date: 2/11/13
2. Title of Project: An Evaluation of the Chronic Disease Self-Management Program
3. Principal Investigator (name & degree): Katherine Baczewski MS, RD, LD, CDE
   E-mail: Katherine.baczewski@va.gov
   Pager Number/Cell Phone Number: (216) 739-00700 Ext. 1313; Cell: 216-701-0764

Signature: __________________________ Date: 2/11/13

Section 2 – Summary

4. Please provide a brief summary of the proposed project. Include how data will be accessed and if identifiable private information will be used. Submit a HIPAA Waiver Request when accessing or collecting identifiers.

LSCDVAMC
March 2011

Exemption Request
Page 1 of 7

101
This study will evaluate the impact of the Stanford University Chronic Disease Self-Management Program (CDSMP) on volunteer participants. All VISN 10 VA facilities implemented the program in FY12 and plan to expand it in FY 13. Due to the limited data regarding outcomes for the CDSMP among Veterans, this evaluation is being done to assess the effect of the program in VISN 10.

In addition, this study will add to the body of research that has been conducted on the Stanford University Self-Management Program. The CDSMP was developed in 1996 by Stanford University with a grant from the Agency for Healthcare Research and Quality. Outcomes from this research has produced evidence as decreased disease symptoms, increased self-efficacy, and decreased utilization of healthcare resources. This study is focused on outcomes that include 1) a self-report of self-efficacy at the beginning and end of the CDSMP workshop, and 2) a comparison of utilization of healthcare resources in the six-month period before the workshop and the six-month period after the workshop.

Individuals, male or female, who have signed up to participate in the Chronic Disease Self-Management Program (known as Healthy U) at the Veterans Affairs Medical Centers over a period of six months will be invited to participate in evaluating the program. The invitation will be written in a handout describing the study and containing the first survey. Although class participants may include Veterans and non-Veteran family members, only Veterans will be asked to complete surveys before and after the program. Names of all participants in the workshops are routinely kept electronically on secure VA servers. For study purposes, the workshop leaders will note the names of participants who complete a survey, implying consent to participate in the study, and will submit those names (using secure electronic transmission) to the VHA Decision Support Service (DSS) for inclusion in the study report. Both male and female Veterans will be recruited for participation. Both male and female Veterans will be recruited for participation. Ages will vary, from 18 and older. Ethnicities will vary as well. Demographic variables will be reported to describe the participants, including age, sex, marital status, VA medical center where the workshop was provided and documentation by ICD-9 code of any of the following at the time of clinic visits or hospital discharge: hypertension, diabetes, heart disease, depression, and/or arthritis. Request for HIPAA waiver is attached.

The measurement of self-efficacy will be done using the six-item Chronic Disease Self-Efficacy Scale (attached). This scale was developed and tested by Stanford University, which has an internal consistency reliability of 0.91. The Stanford University website grants permission for use of this tool. Program leaders will provide the tool to Veteran participants at the first class (labeled "A") and at the completion of the final class, assuming completion of at least four of the six classes (labeled "B"). Participants’ names will not be attached to the surveys. Surveys will be mailed to the Dayton center and will be aggregated by the co-investigator by calculating a mean for all scores from the pre-tests and a mean for all scores for the post-tests. Perceived self-efficacy outcomes will be measured by statistical testing using t-tests of the means. The measurement of self-efficacy will be done using the six-item Chronic Disease Self-Efficacy Scale (attached). The Stanford University website grants permission for use of this tool. Program leaders will provide the tool to Veteran participants at the first class and at the completion of the final class; participants’ names will not be attached to the surveys. Data will be aggregated by calculating a
mean for all scores from the pre-tests and a mean for all scores for the post-tests. Perceived self-efficacy outcomes will be measured by statistical testing using t-tests of the means.

Healthcare utilization data were selected as outcomes to determine whether the program was associated with cost reductions. The PI will send the names of participants who have completed surveys, implying their consent, by means of encrypted e-mail to the Division of Support Services. Variables about each participant will be extracted from electronic patient records and provided in an electronic report to the researchers. Repeated single analyses of variance will be used to compare the means for participant emergency department utilization, hospital bed days, and provider visits six months prior to the first class of the program and six months after the completion of the program.

The data will be provided in a table that displays the socio-demographic variables, age, gender, marital status, and co-morbidities will be retrieved for each Veteran participant. The paper surveys utilized will not contain any names or personal or protected information. Reports produced from the electronic file by the VA Decision Support Service will not contain any names, or personal or protected information. Data will be maintained on the VA server and the investigators will work on a VA computer in a locked office on the VA premises.

Section 3 – EXEMPTION Categories

Please check all applicable categories below:

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

☐ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. If the research involves children as participants, the procedures are limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed. The research is not FDA regulated and does not involve prisoners as participants.
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<td>3.</td>
<td>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Attach to this application a copy of any questionnaire or survey to be used. The research is not FDA regulated and does not involve prisoners as participants.</td>
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<td>4.</td>
<td>Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. <em>(Specimens must be preexisting.)</em> The research is not FDA regulated and does not involve prisoners as participants.</td>
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<td>5.</td>
<td>Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: Public benefit or service programs; Procedures for obtaining benefits or services under those programs; Possible changes in or alternatives to those programs or procedures; or Possible changes in methods or levels of payment for benefits or services under those programs. Such projects must be conducted pursuant to specific federal statutory authority, there must be no statutory requirements for IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of subjects, and the exemption must be invoked only with authorization or concurrence by the funding agency. <strong>NOTE:</strong> 1) This determination must be made by the Under Secretary for Health on behalf of the Secretary of Veterans Affairs, after consultation with the Office of Research and Development, the Office of Research Oversight, the Office of General Counsel, and other experts, as appropriate. The research is not FDA regulated and does not involve prisoners as participants.</td>
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<td>6.</td>
<td>Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.</td>
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FOR IRB USE ONLY  Evaluation of Exemption

Research may be exempt from review when the only involvement of human subjects in the research falls into one of the following categories.

**Indicate all of the categories which apply:**

- **Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

- **Category 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior; unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Attach questionnaire(s) and/or surveys. If the research involves children as participants, the procedures are limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed. The research is not FDA regulated and does not involve prisoners as participants.

- **Category 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Attach to this application a copy of any questionnaire or survey to be used. The research is not FDA regulated and does not involve prisoners as participants.

- **Category 4:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (Specimens must be preexisting.) The research is not FDA regulated and does not involve prisoners as participants.

- **Category 5:** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be
conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.

☐ Category 6: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

DETERMINATION

The research meets the following ethical standards for exempt research:

- Research holds out no more than minimal risk ☐ Yes ☐ No
- Selection of subjects is equitable ☐ Yes ☐ No
- Confidentiality and Privacy provisions adequate ☐ Yes ☐ No
- HIPAA Waiver submitted ☐ Yes ☐ No
- Consent Form/Script suggested* ☐ Yes ☐ No

*The consent process will disclose:
- That the activities involve research
- The procedures to be performed
- That participation is voluntary
- Name and contact information for the investigator

☐ Exempt
☐ Not Exempt. Submit application for Expedited Review.
☐ Not Exempt. Submit application for Convened (Full) Review.
☐ HIPAA Waiver Request approved

Comments if NOT exempt:

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? If yes, please do not perform the review and contact the IRB Office at (216) 791-3800 ext. 4658. ☐ Yes ☐ No
NOTE: All research must be reviewed and approved by the Research & Development Committee, prior to initiating any study activities. Contact R&D Committee Coordinator at x3646.

You must notify the IRB office if your research changes after approval because the exemption may no longer apply. Please refer to the LSCDVAMC Human Research Protection Program Standard Operating Procedures for additional information and examples of what qualifies as exempt research. (See also VHA Handbook 1200.05; 38 CFR 16.101(b); 45 CFR 46.101(b))
Appendix H

Wright State University – Approval with Restrictions

DATE:  February 21, 2013
TO:  Beth Cameron, DNP, PI
      Health Promotion
      Joan S. Majers, RN, Doctoral Student
FROM:  Bette Sydelko, M.S.L.S.,  Facilitator, WSU-ERAC
SUBJECT:  SC# 5041
      'An Evaluation of the Chronic Disease Self-Management Program'

The above human subjects study was approved by Expedited Review on the condition that you respond to the review comments. Please note that the activities covered by this action may ONLY be initiated when all restrictions have been received and accepted.

In order for us to remove the conditions, please respond by sending a cover letter explaining the additions or changes along with a copy of any revised pages and/or consent document (with changes highlighted) as indicated.

Send your response to Jodi Blackledge, Program Facilitator, 201J University Hall. If you have any questions concerning the condition(s), please contact her at 775-3974.

Thank you!

Enclosures
PLEASE RESPOND:

*NOTE: When responding, please highlight the requested changes made to your revised document(s). Unless otherwise noted, only one (1) copy of the requested item (s) needs to be submitted for your response.

Please be aware that the activities covered by this action may not be initiated until all restrictions have been removed and subsequent final approval has been recommended.

**Recommended for approval provided the following conditions are met:

a. Submission of a revised petition in which the following changes have been made:
   1. First page: please give your highest degree earned under “Academic Title” and include a fax number if one is available to you.
   2. Q# 5: mark “Yes” as there is some concern with privacy and confidentiality.
   3. Q# 14: mark “No”.
   4. Q# 15b: please clarify any training involved with the study staff on how to conduct the study.
   5. Q# 24: mark “No”. (the costs aren’t part of the study)

b. Please clarify how the surveys will be matched to the participants if no names or identifiers will be included on the survey. How will the pre and post surveys be linked to the medical information?

c. Please clarify why there is a request for a waiver of informed consent. Is there a reason these people can’t be informed of their rights? The informed consent you use could be a cover letter with no signature in which case you can ask for a waiver of the documentation of IC. If you decide to use a cover letter, then response to petition q. 27 changes to yes, 27.a no, then respond to q.28 (which you already have). Also then remove responses from q.29. Respond to q.30 all parts.
Appendix I

Revised Petition

Petition for Approval of Research Involving Human Subjects

Office of Research and Sponsored Programs (RSP)
201J University Hall
Wright State University
Dayton, OH 45435
(937) 775-2425 – Voice / (937) 775-3781 - Facsimile

The attached petition is to be used when requesting review for approval of research protocols involving human subjects by the Wright State University Institutional Review Board (IRB). This petition is to be used for either full board or expedited (Expedited Review Advisory Committee) review. A separate form is used for submitting amendments to approved protocols. This form, which includes instructions for use, can be found on the RSP web site (www.wright.edu/rsp/subjects.html).

INSTRUCTIONS

Review by the Full Institutional Review Board:
Research activity involving more than minimal risk to the subject (see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102 for definition of minimal risk) must be reviewed by the full Institutional Review Board (IRB). If this project falls under full board review, submit 24 collated copies of the completed petition and all supporting documents (one copy must contain original signatures of principal investigator, co-investigator(s) and, for a student PI, the faculty advisor). Supporting documents may include: 1-2 page summary, consent form(s), cover letter(s), agency permission documents, questionnaires, interviews, debriefing material, advertisements, etc. In addition, submit 4 copies of the complete research protocol, 4 electronic copy (PDF) of the complete research protocol (sent to Robyn.Wilks@wright.edu), 4 copies of the PI’s CV (and CV of faculty advisor for students), 2 copies of the grant proposal (if applicable) and 4 copies of the investigator’s brochure (if applicable). If this is a funded study and the sponsor (incl. DHHS/NIH) has approved the human subjects protocol and consent form, submit one copy of these documents as approved. Do not include the instruction page with your submission. Submit all documents to the Institutional Review Board, c/o RSP.

Expedited Review:
Research activity involving no more than minimal risk to the subject (see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102 for definition of minimal risk)
may be eligible for expedited review. If this project falls under expedited review, submit 10 collated copies (1 single-sided original and 9 double-sided copies) of the completed petition, CV of PI (and faculty advisor for students) and all supporting documents (one copy of the petition must contain original signatures of principal investigator, co-investigator(s) and, for a student PI, the faculty advisor). Supporting documents may include: summary (max of 4 double-spaced pages), consent form(s), cover letter(s), agency permission documents, questionnaires, interviews, debriefing material, advertisements, etc. Do not include the instruction page with your submission. In addition, submit 1 copy of the research protocol, if available. Submit all documents to the Expedited Review Advisory Committee, c/o RSP.

**Exempt Research:**
Eligibility of protocols for exemption under current NIH guidelines (see the six items in paragraph b. of http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101) is determined by the IRB Chair. To request an exemption for your project, complete the petition and submit 1 copy of the appropriate documents as described under Expedited Review by the Expedited Review Advisory Committee.

Please TYPE and SIGN before submitting. Copies should be individually stapled, clipped or banded, with no covers. If you have any questions concerning the petition or meeting dates, please contact the IRB Coordinator at 775-4462.

**Note:** Deadline dates for submission of petitions to RSP may be found on the human subjects web page at: http://www.wright.edu/rsp/subjects.html
Title of Research Project: An Evaluation of the Chronic Disease Self-Management Program

Requested Review Assignment (NOTE: Research and Sponsored Programs will determine the actual review designation. Therefore, you may be required to provide additional copies)

- [ ] Full Board Review
- [X] Expedited Review [see http://www.hhs.gov/ohrp/policy/expedited98.html]
- [ ] Exempt Research [see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101]*

*you must provide the appropriate citation for this exemption request:  

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**PRINCIPAL INVESTIGATOR INFORMATION:**

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<tr>
<th>Principal Investigator</th>
<th>Academic Title</th>
<th>Phone</th>
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<tr>
<td>Beth Cameron</td>
<td></td>
<td>937-268-6511</td>
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<tr>
<th>Department</th>
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<tr>
<td>Health Promotion</td>
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<tr>
<th>Address</th>
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<tr>
<td>4100 W 3rd St Dayton, OH 45428</td>
<td><a href="mailto:Beth.Cameron@va.gov">Beth.Cameron@va.gov</a></td>
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<th>Contact person to receive study correspondence. Include name &amp; phone no.</th>
<th>Contact E-mail</th>
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<tbody>
<tr>
<td>Beth Cameron – 268-6511, ext 2527</td>
<td><a href="mailto:Beth.Cameron@va.gov">Beth.Cameron@va.gov</a></td>
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Position (check one):

- [ ] Faculty
- [X] Student/Resident
- [ ] Staff
- [X] Other (specify):  

Indicate the names of other investigators participating in the research. If a student is listed as principal investigator, specify a faculty advisor. If study-related healthcare decisions are to be made and the PI does not have a license to practice medicine in Ohio, a qualified clinician must be listed. Indicate academic titles, if any, for all investigators.

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<th>Name</th>
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<tr>
<td>Joan Sevy Majers, MS, RN</td>
<td>WSU doctoral student</td>
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(WSU only) Check here to indicate that Principal Investigators/Advisor (exempt protocols) or all investigators/advisor (expedited and full board) have completed the required human subjects protection training offered by Collaborative Institutional Training Initiative (CITI) through Wright State University—see http://www.citiprogram.org/ and IRB Policy P.5. (found in the IRB Charter at http://www.wright.edu/rsp/IRB/irb_charter.html).
X(Other institutions) Check here to indicate that Principal Investigators/Advisor (exempt protocols) or all investigators/advisor (expedited and full board) have completed the required human subjects protection training offered by Collaborative Institutional Training Initiative (CITI) through another institution. Please attach a copy of the CITI report for each investigator listed on the study.

FUNDING INFORMATION:

Indicate the category of the sponsor (if applicable):

- [ ] Industry (other than pharmaceutical)
- [ ] State Government
- [ ] Local Government
- [ ] Pharmaceutical Company
- [ ] Non-Profit Organization
- [ ] Federal Agency
- [ ] Internal Grant Program
- [ ] Other (specify)

X No Funding

INVESTIGATOR POTENTIAL FINANCIAL CONFLICT(s) OF INTEREST:

1. Does the investigator or co-investigator(s) have a vested interest in any actual or potential commercial enterprise/business associated with any aspect of this protocol (other than patents)?

   - [ ] Yes
   - [X] No

   If yes, fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process:

2. Are there financial issues that may be of concern to potential subjects? If no, please certify this for all investigators by checking the following boxes to indicate that the investigator(s):

   - [X] Does not have ownership interest, stock options or other financial interest related to the research whose value, when aggregated for immediate family, represents ≥5% interest in any one single entity
   - [X] Will not receive compensation related to the research whose amount is affected by the outcome of the research
   - [X] Has no equity interests in the sponsor of this study greater than $10,000 (when aggregated for the immediate family), or does not have ownership interest, stock options, or other financial interest related to the research of any value whose value could not be determined through reference to publicly available prices
   - [X] Does not have Board or executive relationship related to the research, regardless of compensation
   - [X] Is/are receiving no payments by the sponsor greater than $10,000 to the investigator’s performing organization(s) exclusive of the costs of conducting the study
   - [X] Will receive no payments by the sponsor directly to the investigator(s), their spouses or dependent children
   - [X] Has no financial interests (other than patents) in any non-sponsored research

If all boxes above cannot be checked, please describe below (or in a separate attachment) how such financial arrangements will not adversely affect the interests of the research subjects, and how subjects will be given any information which may be material to potential subjects’ decision-making process.
PROTOCOL INFORMATION

Attach a concise description summarizing the following areas (specifically address the subject’s role in the research). This will be provided to all IRB members for review. [Note: for expedited or exempt review protocols, submit a MAXIMUM of 4 double-spaced pages; descriptions exceeding this limitation will be returned for re-writing.]

- Purpose of research
- Background and hypothesis
- Procedures
- Risks
- Potential benefits
- Inclusion and exclusion criteria
- For all DHHS studies, a copy of the DHHS-approved sample consent document and the complete DHHS protocol must be submitted.

In addition, provide (1) copy of all documents to be given to subjects during the research.

Please answer the following questions about the protocol:

3. Indicate all that apply to the research:

☐ Investigational new drug use
☐ FDA approved drugs
☐ Humanitarian use device
☐ Investigational new device
☐ Gene therapy
☐ Chart review*
☐ Telephone interview
☐ Retrospective study**
☐ Other (describe) [ ]

☐ FDA approved drug being used for unapproved use
☐ FDA approved drug – new route of administration
☐ FDA approved drug – new formulation
☐ Tissue banking
☐ New drug delivery system
☐ In-person interview**
☐ Self-administered questionnaire**
☐ Public dataset without identifiers***

*Note: For chart reviews or retrospective studies, copies of the data collection instruments must be provided. **Copies (see instructions for number) of any interview, surveys, or questionnaires must be submitted along with documentation that permission has been obtained to use any copyrighted materials in your research. X Please check here to indicate that appropriate permission has been obtained. ***For public datasets without identifiers, a copy of the data review form must be provided.

4. Does the research involve a drug or device for which an investigational new drug (IND) or investigational device exemption (IDE) has been filed? ☐ Yes ☐ No

If yes,

Provide the IND or IDE number: [ ]

Who holds the IND or IDE? [ ]

Please provide documentation verifying the IND or IDE number, such as a letter from the sponsor or a copy of FDA correspondence.

If no and the research involves the use of drugs or devices, please answer the following questions

114
Device Studies

☐ Yes ☐ No  Is the device intended as an implant?
☐ Yes ☐ No  Does the device present a potential for serious risk to the health, safety or welfare of a subject?

Drug Studies

☐ Yes ☐ No  Will study results be reported to the FDA in support of a new indication for use; OR to support any other significant change in the labeling of the drug(s); OR to support a significant change in the advertising for the product(s)?
☐ Yes ☐ No  Will the study involve a route of administration, dosage level, use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the drug product?

Please list all study drugs or devices by generic name only (if no name, list sponsor’s study drug number)

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RISK ASSESSMENT:

5. Does the study involve any risk to the subjects? Examples of risks/discomforts include: dizziness, nausea, embarrassment, social stigma (shame or disgrace), psychological distress, loss of employment, invasion of privacy and breach of confidentiality. ☐ Yes  ☑ No

If yes:

a. Indicate where these risks are described in the protocol and consent form/cover letter.

b. Are the risks/discomforts reasonable in relation to anticipated benefits (if any)? ☐ Yes ☑ No

c. Indicate how risks to subjects have been minimized where possible. For example:

☐ Subjects have received 24-hour emergency phone numbers
☐ More frequent health exams or diagnostic tests are being performed to monitor for known or anticipated risks
☐ Emergency equipment is available for use if needed
☐ Specimens/samples already collected for standard treatment are used for research purposes
SAFETY MONITORING:

A plan for data safety monitoring should be provided in any situation in which participants might be at greater than minimal risk of harm, including when a drug or device is being tested for safety or effectiveness for marketing approval, or in placebo-controlled trials, or when marketing drugs are being tested for another indication or compared for safety or effectiveness. A plan is required for all clinical trials, including the development or evaluation of clinical laboratory tests (e.g. imaging or diagnostic tests) if the test will be used for medical decision-making for the subject, or if the test itself imposes more than minimal risk for subjects. Guidelines regarding drafting this plan can be found in Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, of the U.S. Department of Health and Human Services Public Health Service Grant Application (PHS 398) instructions at <http://grants.nih.gov/grants/forms.htm>.

6. Does the protocol require a safety data monitoring plan?  □ Yes  ❌ No. If yes:
   • Indicate where the description may be located within the protocol □
   • If not described within the protocol, attach a copy of the plan. Copy attached?  □ Yes  □ No
   • If there is no plan, please explain why there isn’t one. □

7. When applicable, will medical or psychological resources be made available to participants after their completion of the study, if the research produces consequences in which these services are required?  □ Yes  □ No  ❌ N/A. If yes:
   • Indicate where the description may be located within the protocol: □
   • If not described in the protocol, attach an explanation of resources. Explanation attached?  □ Yes  □ No
   • If there are no resources, please explain why there aren’t any. □

CONFIDENTIALITY AND PRIVACY:

8. Indicate the procedure for assuring confidentiality of the data (e.g. responses kept in locked safe, restricted access to information, etc.) or for assuring the anonymity of the subjects (e.g. no names on instrument, no personal identifiers linked to instrument, any in-person interviews/videos, etc.) Please note that student investigators must store study records or data in a Wright State location (i.e. not at home).

   Paper survey to be utilized will not contain any names or personal or protected information. Reports produced from the electronic file by the VA Division of Support services will not contain any names, or personal or protected information. Socio-demographic variables, age, gender, marital status, and co-morbidities will be retrieved. Data will be maintained on the server and the co-investigator will work on a VA computer in a locked office on the VA premises.

9. Indicate the procedure for assuring that method(s) used during data collection protect the privacy of the participants (for example, recruitment, obtaining of consent, or obtaining of data will be done in a private location or manner). Note: this does not refer to the confidentiality of the data. No identifiable data will be available in the reports.
The data collected on the questionnaires will contain no names or any other individually identifiable data. The reports available will contain no personally identifiable data that can be connected back to the individual participants.

10. Does the protocol involve immediate or future testing of genetic material and/or pedigree studies?

☐ Yes  X No

If yes, briefly describe any additional means (other than those described in 8) that will be used to protect the confidentiality or anonymity of the subjects. In addition, standard wording must be added to the consent document that cautions prospective subjects about the hazards of identifiable genetic findings toward future insurability and/or employability. See suggested wording in “Cover Letter/Consent Form Guidelines” (http://www.wright.edu/rsp/IRB/Consent_Guide.doc). In addition, wording should be added indicating compliance with the Genetic Information Nondiscrimination Act (GINA). See http://www.wright.edu/rsp/IRB/GINA.pdf for further information.

Request for waiver of consent is made because the proposed study cannot be practicably conducted without a waiver of authorization. Consent would be a document which would subsequently link subjects to the study, increasing the risk to their privacy. The study is being conducted at several sites, which would also require secure transport of materials.

11. Have adequate safeguards been taken to protect against identifying, directly or indirectly, any individual subject in any report of the research project? X Yes  ☐ No  If No, provide further information.

12. Is identifiable medical information (Protected Health Information or PHI) being collected during the study?

X Yes  ☐ No  Refer to http://www.wright.edu/rsp/IRB/Policies/P_19%20Using%20Provided%20Health%20Information%20In%20Research.docx for a list of PHI.


☐ Yes  ☐ No

If the consent document does not follow the HIPAA requirements, is a waiver of the HIPAA privacy rule being requested? (Note: this is most commonly requested with studies limited to chart review) X Yes  ☐ No

If a waiver is being requested, all of the following questions must be completely answered:

a. Explain why the research cannot reasonably be conducted without the waiver of authorization.

Consent would require collection of data about participants which would subsequently link them to the study, increasing the risk to their privacy. The study is being conducted at several sites, which would also require secure transport of materials.

b. Explain why the research cannot reasonably be conducted without access to and use of identifiable health information.

There is no identifiable information being collected.
c. Briefly describe the PHI (Protected Health Information) for which use and/or disclosure has been determined necessary.

There is no identifiable protected health information being collected.

d. Describe the reasonable safeguards to protect identifiable information from unauthorized use or re-disclosure.

There is no identifiable information being collected. Reports will be secured on the computer in a locked office in the VA. The reports and data will be destroyed upon completion of the study.

e. Describe the reasonable safeguards to protect against identification, directly or indirectly, any patient in any report of the research.

No names or any identifiable information will appear on any questionnaire or report since all data will be utilized in an aggregate manner.

f. Describe the plan to destroy the identifiers at the earliest opportunity, consistent with the research. If there is a health or research justification for retaining identifiers, or if the law requires you to keep such identifying information, please provide this information as well.

The reports and data will be destroyed upon completion of the study.

g. Provide written assurance that identifiable information will not be reused/disclosed to any other person or entity, unless such use is required by law, for oversight of the research study, or for other research permitted by law.

No data will be utilized for any purpose other than this study.

13. Will a Certificate of Confidentiality be requested from NIH? □ Yes X No

- If yes, does the Consent Form advise the subjects of situations where the PI may voluntarily comply with state laws? □ Yes □ No
- If yes, has the standard confidentiality statement been modified to be consistent with Confidentiality Certificate protections? See http://grants.nih.gov/grants/policy/coc/index.htm. □ Yes □ No

STUDY SITE RESOURCES:

14. Is this study a multi-center study for which the PI at WSU is the lead investigator or WSU is the coordinating site of the study? X Yes □ No

If yes, are there procedures in place for the PI or WSU to adequately manage the protection of human subjects (such as Adverse Events (AEs), modifications and progress reports) at all the research sites? X Yes □ No. If no, please explain

15. You may either answer the following questions or attach a separate page (check here if a separate page is attached) □

a. State where you will be conducting the research study (e.g. Wright State University (WSU), Veterans Administration (VA), Good Samaritan Hospital (GSH), Miami Valley Hospital (MVH), etc.)

Include the address for any site not affiliated with WSU
• Name of site(s): Veterans Administration Medical Center-Dayton, Louis Stokes Veterans Administration Medical Center; Cincinnati Veterans Administration Medical Center; Chalmers P. Wylie Ambulatory Care Center; Chillicothe Veterans Administration Medical Center

• If other than WSU, Dayton Clinical Oncology Program (DCOP) or hospital facility, describe the facility where the study will be conducted

b. How will the PI ensure that all research staff for the study are adequately informed of the research-related duties and functions? The co-investigator has completed CITI training

c. Are there adequate resources to complete the research study? X Yes  □ No

d. Is there access to a population that will allow recruitment of the required number of participants? X Yes  □ No  If no, explain how subjects will be recruited in item 17, below.

e. If previously collected deidentified data is being used in the research (for example, publicly available datasets), briefly describe the source (leave blank if non-applicable)
RECRUITMENT:

16. Will this research study recruit any subjects from the following “Vulnerable” categories? Check all that apply.

☐ Cognitively Impaired
☐ Fetuses
☐ Pregnant Women
☐ Prisoners
☐ Healthy Volunteers (applies only to more than minimal risk protocols)
☐ Others vulnerable to coercion (e.g. employee of research site or sponsor, students of investigator). Describe:

☐ Minors (<18 years of age)

For research involving minors, please indicate which of the categories listed below accurately describes this protocol (refer to the appropriate section of 45CFR46, Subpart D)

☐ Not involving greater than minimal risk (46.404)
☐ Involving greater than minimal risk but of direct benefit to individual subjects (46.405)
☐ Involving greater than minimal risk, no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject disorder or condition (46.406)
☐ Involving research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of minors (46.407)

17. Describe the population from which the researcher will recruit (or data source from which data will be obtained):

Individuals attending the workshop will decide whether to allow their data to be utilized in the study.

Note: if subjects are being recruited at a non-WSU site (e.g. local schools, prisons etc.) provide a copy of the permission to use that site signed by an institutional official, or, equivalently, approval from their IRB.

18. How will participants be recruited for this study? Attach copies of any materials given to prospective subjects and/or scripts of any oral communication used to recruit subjects.

Individuals attending the workshop will decide whether to allow their data to be utilized in the study.

19. What type of advertising will be used for this study? Check all that apply.

Note: If an advertisement is to be used, WSU policy requires prior written approval from the PI’s department chair and dean. A copy of the advertisement with approval of the chair or dean must be submitted with this application for IRB review.

☐ No advertising will be used
☐ Newspaper
☐ Poster
☐ Brochure
☐ Web Site
☐ Patient Recruitment Letter
☐ Internet
☐ E-mail
☐ Radio or TV (script)
☐ Other (describe) A handout will be provided by the class leader to recruit participants, a copy of which is attached to the protocol
20. State the approximate expected number and age range of participants to be enrolled. List each group, arm, cohort, etc. if applicable, including control groups, on separate lines. If only one group, description would be “All.” Check “N/A” if the only data used in the study will come from a previously existing, deidentified data source. N/A □ (Note: This applies to exempt studies only)

<table>
<thead>
<tr>
<th>Group</th>
<th>NUMBER OF SUBJECTS</th>
<th>AGE RANGE OF SUBJECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All sites for</td>
<td>All other sites All</td>
</tr>
<tr>
<td></td>
<td>which you are</td>
<td>sites for which</td>
</tr>
<tr>
<td></td>
<td>the PI</td>
<td>which you are the PI</td>
</tr>
<tr>
<td>Dayton</td>
<td>30-80</td>
<td>30-80</td>
</tr>
<tr>
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<td>30-80</td>
<td>30-80</td>
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<tr>
<td>Cleveland</td>
<td>30-80</td>
<td>30-80</td>
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<tr>
<td>Cincinnati</td>
<td>30-80</td>
<td>30-80</td>
</tr>
<tr>
<td>Chillicothe</td>
<td>30-80</td>
<td>30-80</td>
</tr>
</tbody>
</table>

a. Are subjects who might otherwise benefit from the research excluded from participation? Yes X No. If yes, provide scientific and ethical reasons for excluding these subjects.

b. Is the subject population representative of the population base from which subjects could be selected with respect to gender representation (see NIH guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). X Yes □ No. If no, please explain.

c. Is the subject population representative of the population base from which subjects could be selected with respect to minority representation (see NIH guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). X Yes □ No. If no, please explain.

21. Will subjects be paid or otherwise compensated? □ Yes X No □ N/A. If yes:

a. What is the amount of the compensation?

b. If not monetary, what will be used for compensation?

c. What is the reason for compensation?

d. If subjects are to be remunerated, indicate how this remuneration will be prorated over the course of their participation.

22. Will the research involve the intentional use, of or introduction into, subjects of:

a. Biohazards (e.g. rDNA, microorganisms, biological toxins) requiring approval by the Institutional Biosafety Committee?
□ Yes X No

b. Radioisotopes, radiation, or x-rays requiring approval by the Radiation Safety Committee:
□ Yes X No
c. Hazardous chemicals (not covered elsewhere in this petition) requiring approval of Environmental Health and Safety?

☐ Yes  X No

23. Does the protocol involve exposure to human blood or body fluids by study personnel?  ☐ Yes  X No

If yes, have study personnel received appropriate training?  ☐ Yes  ☐ No  (If no, describe the steps that will be taken to ensure that training occurs _ ).

24. Are there anticipated costs to study participants?  X Yes  ☐ No  ☐ N/A. If yes, describe and justify the costs:

Some participants, depending on their VA eligibility, will pay a co-payment for each class session. This is not related to the study.

INFORMED CONSENT:

25. Is the short form process for obtaining consent going to be used in the study (if the short form for consent will be used, the complete process that will be followed for obtaining short form consent must be described and attached. See WSU Standard Operating Procedures, Policy 12 – Obtaining Informed Consent in Human Subjects Research at www.wright.edu/rsp/subjects.html).  ☐ Yes  X No

26. Is deception being used in the study (which prevents the full purpose of the study from being disclosed in the consent document)?  ☐ Yes  X No

If Yes, then a waiver of informed consent must be requested (by responding to question 29).

27. Will there be a consent document used in this study? (A consent document is usually a signed consent form, but may also be a cover letter or an introduction to a survey).  ☐ Yes  X No  If No, a waiver of informed consent must be requested (by responding to Question 29).

   a. If yes, will the consent document be signed?  ☐ Yes  ☐ No  If No, then a waiver of informed consent documentation must be requested (see question 28)

   b. If the consent document is going to be signed, who will be signing? (Indicate all that may apply):

      ☐ Participant (adult)
      ☐ Participant (minor, signing an assent) with parent or guardian signing permission
      ☐ Legally authorized representative for participant
      ☐ Next of kin for participant (emergency research only)

28. For unsigned consent documents (e.g. when the consent information is found in a cover letter or a survey introduction) please indicate the rationale for waiving the documentation of informed consent by checking the appropriate box below. Also, please be sure that you have included a rationale for using an unsigned consent document in your research protocol. The waiver of documentation can only be approved if it meets one of the following two categories:

   X The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

   or

   The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
29. If there will not be a consent document used in the study (e.g. as in studies limited to retrospective studies such as chart reviews), or if the consent document will not include all the required elements of informed consent (Refer to http://www.wright.edu/rsp/IRB/NewProtocolReviewChecklist.doc) (which is the case if deception is being used in the study) then a waiver of consent must be requested by answering the following questions. A waiver can be granted only if the answer to all of the following questions is “Yes”.

   a. The research involves no more than minimal risk to the participants. X Yes ☐ No
   b. The waiver or alteration will not adversely affect the rights and welfare of the participants. X Yes ☐ No
   c. The research could not practicably be carried out without the waiver or alteration. X Yes ☐ No
   d. The research is not subject to FDA regulation. X Yes ☐ No
   e. If deception is used, the subjects will be debriefed after participation. ☐ Yes ☐ No X N/A
   f. That for any person for whom consent has not been obtained, whenever appropriate, additional pertinent information will be provided after participation. ☐ Yes ☐ No X N/A

30. Informed consent involves more than obtaining the subject’s signature on a consent form. It is a process between the investigator and the subject that involves sharing information and addressing questions and concerns to allow the subject to fully understand what they are agreeing to. For complicated protocols, or for subjects with limited comprehension, it is often appropriate to include an assessment of comprehension as part of the consent process.

Please describe the process by which informed consent will be obtained and documented by answering the following questions. This section does not need to be completed if a waiver of informed consent has been requested and informed consent will not be sought from study participants.

   a. The consent interview (the opportunity for the subject to discuss the protocol with the investigator or designee) will be conducted by:
      ☐ Study staff ☐ Investigator or co-investigator ☐ Other (describe) ☐ N/A (e.g. if the consent process does not involve contact between the investigator and the subject)

   b. Will subjects have an opportunity to ask questions prior to signing the consent document? ☐ Yes ☐ No ☐ N/A

   c. Will comprehension be assessed in some fashion (e.g. through use of a verbal or written assessment test)? Note: This is not required for all protocols, but is appropriate for very complicated protocols, or for protocols involving subjects with limited comprehension. ☐ Yes ☐ No ☐ N/A

   d. Is there a waiting period between the consent discussion and the signing of the consent document? ☐ Yes ☐ No ☐ N/A

   e. Will participants be allowed to review the consent document at home prior to signing? ☐ Yes ☐ No

   f. Are there procedures in place to minimize the possibility of coercion or undue influence?
Yes □ No. If No, please explain: □

g. Will the language to be used in the informed consent document and/or consent interview be understood by the potential participants? □ Yes □ No

h. If consent will be obtained from adults who are cognitively impaired on a temporary basis at the beginning of the research, is there an opportunity (if appropriate) for these participants to provide consent after recovery of cognitive function? □ Yes □ No □ N/A

i. Will a copy of the informed consent document be provided to the participant? If no, please provide a justification.
□ Yes □ No Justification if “No” □

SIGNATURES AND CERTIFICATIONS

By signing and submitting this application, the Principal Investigator agrees that he/she:

1. Accepts responsibility for the scientific conduct of the project, that the scientific portion of the protocol is original and contains no false, fictitious, or fraudulent statements or date. Signature certifies that all listed investigators have reviewed the proposal and that the research will be conducted in full compliance with WSU policies and federal regulations.

2. Has provided the IRB with all the information on the research project necessary for its complete review.

3. Will submit progress reports to the IRB for review in a timely manner in order to obtain appropriate continuing review to maintain the approval status of the protocol.

4. Will submit all changes in the study to the IRB for review and approval before implementing those changes.

5. Will submit anticipated problems (including adverse events) to the IRB for review in a timely manner.

6. Will not put this research project into effect until final IRB approval is received.

7. Has completed the required modules in the CITI training program, which can be found at http://www.citiprogram.org/ (see also IRB Policy P.5.)

If this protocol involves more than minimal risk AND the research is or is proposed to be funded by an external grant/contract, you must include two (2) copies of the external grant/contract proposal. [NOTE: Grant/contract or proposals for external funding that is to be administered by Wright State University must be processed through Research and Sponsored Programs.] One of the following two boxes must be checked:

□ More than minimal risk AND externally funded; two copies of the proposal are included
X Not applicable

*DCOP protocols are assumed to be conducted under the umbrella NCI grant, a copy of which is provided to the IRB separately. Thus copies of the DCOP/NCI grant proposal are not required to be submitted with DCOP petitions.

Signature of Principal Investigator Date

All other Investigators and/or Faculty Advisor listed on the cover of this petition (if any) must sign to acknowledge their participation in this project:
<table>
<thead>
<tr>
<th>Signature of Faculty Advisor</th>
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<td>Signature of Co-Investigator</td>
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<td>Signature of Co-Investigator</td>
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Appendix J

Letter to Participants – Dayton Only

Welcome to the Healthy U Class.

Purpose of Study
My name is Dr. Beth Cameron and I am the Health Promotion Program Manager at the Dayton VA Medical Center. I am inviting you to take part in a research study about the Healthy U class. The purpose of this study is to see if there is a difference in how you feel about managing your chronic disease before and after completing the workshop. The Dayton VA Medical Center and the Wright State University Institutional Review Board have given my team permission to conduct this study. The research team includes Healthy U leaders and a graduate nursing student from Wright State University.

Description of Study
As many as 100 Veterans may agree to participate in this study. We are conducting the study at all the VA centers in Ohio. If you agree to be part of it, we will ask you to do these following things:

- Complete a survey of six questions on the first day of your Healthy U class. This will take you about five or ten minutes.
- Take the same survey of six questions a second time, but only if you have attended four of the six sessions of the class and the last class.
- Give permission to the VA Division of Support Services, which is part of the VA system, to get certain information from your medical record. We want to know these things about the Veterans who take this class:
  - Your age
  - Your marital status
  - Your gender
  - Whether you have heart disease, high blood pressure, diabetes, depression or arthritis
  - How many times you have visited a VA medical center or CBOC

Confidentiality
We will make every effort to keep your personal information private. We will not ask you to put your name on any of the surveys. The Division of Support Services will get information from your records electronically after receiving your name from the class leader by VA-protected email.

We will not use your name or any personal information that can identify you in any reports or published papers that may result from the study. The study reports will not have names on them. We will not be able to trace information back to any individual person. We will keep all information in locked files at all times. Only we will have access to these files.
**Risks and Benefits**

There are no risks to you from this study. There are no direct advantages to you if you agree to be part of this study. We hope that the results from this study will make more self-management programs like this one possible.

**Your Rights**

It is your decision if you would like to be part of this study. Your decision will not change your Healthy U classes or your care in the VA system in any way. You may decide that you do not want to be part of the study at any time. You do not have to give a reason for not participating. Making that choice will not affect your care or classes in any way. If you have questions about this study, you may contact me at 268-6511, Ext. 2527. You may also contact:

- Joan Sevy Majers, the WSU graduate nursing student, at 937-768-5559;
- The Wright State University Institutional Review Board, at 937-775-4462.

Thank you for taking the time to read this information. If you are willing to be part of this study, please complete the attached survey and return it to your class leader.
Appendix K

Final Approval - Dayton

DATE: April 10, 2013
TO: Beth Cameron, DNP, PI
    Health Promotion
    Joan S. Majers, RN, Doctoral Student
FROM: B. Laurel Eider, Ph.D.
      Chair, WSU-IRB
SUBJECT: Sci 5041

'An Evaluation of the Chronic Disease Self-Management Program'

This memo is to verify the receipt and acceptance of your response to the conditions placed on the above referenced human subjects protocol/amendment.

These conditions were lifted on: 04/10/2013

This study/amendment now has full approval and you are free to begin the research project. If this is a VA proposal, you must still receive a letter of approval from the Research and Development Committee prior to beginning the research project. If this is a MVH proposal, you must still receive a letter of approval from the Human Investigation and Research Committee (HIRC) prior to beginning the research project. This implies the following:

1. That this approval is for one year from the approval date shown on the Action Form and if it extends beyond this period a request for an extension is required. (Also see expiration date on the Action Form)

2. That a progress report must be submitted before an extension of the approved one-year period can be granted.

3. That any change in the protocol must be approved by the IRB; otherwise approval is terminated.

If you have any questions concerning the condition(s), please contact Jodi Blackledge at 775-3974.
Thank you!
Enclosure
RESEARCH INVOLVING HUMAN SUBJECTS

ACTION OF THE WRIGHT STATE UNIVERSITY
EXPEDITED REVIEW
Assurance Number: FWA00002427

Title: 'An Evaluation of the Chronic Disease Self-Management Program'

Principal Investigator: Beth Cameron, DNP, PI
Jean S. Majers, RN, Doctoral Student

Department:

Expedited Category: 5, 7

The Institutional Review Board has approved the use of human subjects on this proposed project with conditions previously noted. The conditions have now been removed.

REMINDEIR: FDA regulations require prompt reporting to the IRB of any changes in research activity, changes in approved research during the approval period may not be initiated without IRB review (submission of an amendment), and prompt reporting of any unanticipated problems (adverse events).

NOTE: This approval has been assigned an "SC" number in our system, which means it has been approved by Expedited Review for a protocol involving no more than minimal risk.

Signed Chair, WSU-IRB

Review Date: January 25, 2013
IRB Meeting Date: May 20, 2013

This approval is effective only through: January 25, 2014

To continue the activities approved under this protocol you should receive the appropriate form(s) from Research and Sponsored Programs (RSP) two to three months prior to the required due date. If you do not receive this notification, please contact RSP at 775-2425.
Appendix L

Approval - Dayton Research and Development Committee

DEPARTMENT OF
VETERANS AFFAIRS

Date: April 25, 2013
From: Coordinator, Research and Development Service
Subj: Approval of Proposal
To: Beth Cameron (11P)
     Joan Sevy Majers

1. The Research & Development Committee reviewed:
   A. Study name: "An Evaluation of the Chronic Disease Self-Management Program"
   B. Proposal number: 552-13-006, SC 5041
   C. On (date): April 23, 2013

Your proposal was approved.

2. You may begin your research study. Please note this approval is effective only through January 25, 2014. This approval will automatically expire on this date unless you submit a "continuing review" request at http://www.wright.edu/rsp/IRB/CR_sc.doc and send this document to the Research Office.

3. If you have any questions, please contact the Research Office at x1156.

Jack M. Bernstein, M.D.
## Appendix M

IRB Close-Out Report

Wright State University Research and Sponsored Programs  
Human Subjects Protection, Institutional Review Board

**FINAL STUDY CLOSE-OUT REPORT FORM**

### INSTRUCTIONS
- **Use this form** to close out any WSU IRB-approved study.
- **Submit this completed form within 30 days** of completion or termination of all research activity for a study, even if the current approval period has expired.
- **Do not close out a study** if any of the following six conditions apply. Such studies must remain active and continue to receive ongoing IRB review and approval.
  1. Enrollment at the WSU-approved site is ongoing.
  2. Research-related interventions and/or follow-up at the WSU-approved site is ongoing.
  3. Participant follow-up at the WSU-approved site is ongoing.
  4. Biological specimens containing personally identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed.
  5. Data analysis or manuscript preparation is ongoing.
  6. If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.
- **Return one hard copy of this form and any supporting materials to:**  
  WSU IRB  
  201 University Hall  
  Wright State University  
  Dayton, OH 45435
- **Contact IRB office if you have any questions.**
  - Call the IRB staff at 937-775-4462 or email robyn.wilks@wright.edu
  - Refer to the full procedure for Project Closures, Suspensions, and Terminations on the WSU RSP web page  
    (http://www.wright.edu/rsp/IRB/Policies/P_10%20Suspensions%20and%20Terminations.doc)

### A. PROTOCOL INFORMATION:

<table>
<thead>
<tr>
<th>Currently Approved Principal Investigator</th>
<th>Beth Cameron, DNP,RN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title</td>
<td>An Evaluation of the Chronic Disease Self-Management Program</td>
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<tr>
<td>WSU IRB #</td>
<td>SC-5041</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>1/25/14</td>
</tr>
</tbody>
</table>

### B. STUDY STATUS AT CLOSE OUT:

1. Provide the reason for closing the study at WSU:
   - [ ] Study was completed. *(Please complete sections B through G.)*
   - [X ] Study was started but closed prior to completion *(Please complete sections B through G.)*
2. Please explain why the study was not started or was closed prior to completion.

The Veterans Affairs Health System implemented a new process for access to the outcome data required for the study. These new requirements resulted in procedures that made these data unavailable to the researchers.

3. Did the study involve the collection, storage, or use of any human biological specimens? If yes, please explain what will happen with the specimens at the close of this study.

4. Which institution is this study being transferred to? What parts of the study are being transferred? Be sure to work with your Department to make sure everything you need to do to transfer the study has been or will be completed.

C. SUMMARY OF STUDY RESULTS:

1. Please summarize the results of this research project.

42 participants completed the initial survey prior to the workshop; 39 completed the survey after the workshop. The surveys were totally anonymous. Statistical significance could not be measured, since the results were not paired, but the average mean perceived self-efficacy measured prior to the workshops was 6.09. After completion of the workshops, participants’ mean perceived self-efficacy measured and measured 8.167. The pre-survey mean results were two points lower than the average mean post-survey, indicating a definite difference.

2. Have there been any presentations or publications resulting from this study since last continuing review. If yes, please describe and cite references.

D. SUBJECT RECRUITMENT AND ENROLLMENT since last initial or continuing review:

1. Was there any participant contact since the date of the last review? If no, skip sections E through F. If yes, answer the questions below in this section only for subjects since the last initial or continuing review.

2. Number of subjects enrolled since the last continuing review (if there has been no continuing review, please record the number of subjects enrolled during the study).

3. Approximately how many potential subjects have refused participation?

4. How many subjects have voluntarily withdrawn from participation?

5. How many subjects have been withdrawn from participation by the PI?

6. If applicable, provide a brief summary below of any difficulty obtaining/retaining subjects, or obtaining informed consent since the last continuing review.
Participants were invited to complete a pre-survey at the first workshop class. To be included in the final sample, they would have had to have attended four of the six sessions and to have completed the second survey. Of the 42 original participants who completed the initial survey, 39 completed the second. It is not known if they failed to attend the four of six sessions, did not attend the last session to complete the last survey, or chose not to complete a final survey.

### E. SIGNIFICANT FINDINGS AND REPORTABLE EVENTS

1. Have there been **any significant new findings** (recent literature or other relevant information) that may affect the risks or benefits associated with the research that should be disclosed to subjects who have participated in the study?  
   If yes, please describe below and describe how you will notify research participants. Submit copies of any materials that you use to notify participants.  

   | [ ] Yes | [X] No |

2. FOR BIOMEDICAL OR HIGH RISK BEHAVIORAL STUDIES ONLY: Reporting and Summary of 10-Day Reportable Adverse Events and Other Safety Information:

   a. Are you submitting any new or missed Adverse Event Reports now?  
      | [ ] Yes | [ ] No |

   b. Are you submitting any new or missed DSMB or other multi-center oversight reports now that were not submitted previously?  
      | [ ] Yes | [ ] No |

   c. Were there any other unexpected safety developments that the IRB should know about?  
      If yes, please explain below.  

      | [ ] Yes | [ ] No |

3. Reporting and Summary of Protocol Violations, Deviations and/or Incidents:

   a. Are you submitting any new or missed 10-day Violation, Deviation or Incident Reports now?  
      | [ ] Yes | [X] No |

   b. Were there any other unexpected developments in study conduct that the IRB should know about (e.g., problems with study activities or participant complaints)?  
      If yes, please explain below.  

      | [ ] Yes | [X] No |

### F. STUDY ACTIVITY AFTER IRB APPROVAL EXPIRATION:

Please answer the following questions only if the WSU IRB approval has expired.

If the WSU IRB approval for this study has expired, did any research-related activity(ies) occur during the lapse in approval?  
If yes, answer the questions below.  

| [ ] Yes | [ ] No |

If the WSU IRB approval for this study has expired, did any research-related activity(ies) occur during the lapse in approval?  
If yes, answer the questions below.  

| [ ] Yes | [ ] No |

1. Were any participants enrolled during the lapse of approval period?  
   | [ ] Yes | [ ] No |

2. Did any other research-related activity(ies) continue during the lapse of approval period?  
   | [ ] Yes | [ ] No |

3. Why did the approval lapse occur?  

4. What will be done do to prevent this from happening in the future for other studies?  

5. If yes to either questions #1 or 2, please describe all research-related activities that continued, including number of participants involved and any adverse events, violations, deviation or incidents that occurred during the period of protocol lapse:
G. PRINCIPAL INVESTIGATOR’S CERTIFICATION:

I certify that all study activity involving participant contact, or use or access to individually identifiable information has ceased and the information provided in this report is complete and correct.

Principal Investigator’s Signature

Date
Appendix N

Study Information for Healthy U Trainers

Purpose of the study: This study will evaluate the impact of the Stanford University Chronic Disease Self-Management Program (CDSMP) on volunteer participants. All VISN 10 VA facilities implemented the program in FY12 and plan to expand it in FY 13. Because there are limited data about outcomes for the CDSMP among Veterans, this evaluation is being done to assess the effect of the program in VISN 10. The study is focused on outcomes that include 1) a self-report of self-efficacy at the beginning and end of the CDSMP workshop, and 2) a comparison of utilization of healthcare resources in the six-month period before the workshop and the six-month period after the workshop. During the first class, please identify the Veteran participants and provide them with a copy of the study handout (sample attached).

1. If the Veteran chooses to participate in the study, provide them with a copy of the study survey and ask them to complete the six questions. It is important to remind them not to place their name or any other personal information on the survey (sample attached).

2. Collect the surveys and mark each with the letter “A”.

3. Place the surveys in the addressed envelope that has been provided and keep it with your class materials until the last class.

4. At the last class, ask the Veteran participants who completed the first survey and attended at least four of the six classes if they would complete another survey.

5. If the Veteran completes this second survey, please remind them again not to place their name or any other personal information on the survey.

6. Collect the surveys and mark each of these with the letter “B”.

7. Place these surveys in the same envelope with the previous surveys marked “A”. Seal the envelope and either return it to your master trainer or place it in the outgoing VA mail.

8. From the class list, delete the names of the individual participants who:
   a. Elected not to participate in the study by not completing an initial survey
   b. Are not Veterans
   c. Completed an initial survey, but did not attend at least four of six sessions
   d. Elected not to complete a second survey

1. Send that class list with names and the last four digits of their social security numbers, or amended class list, via encrypted e-mail, to beth.cameron@va.gov. Participants may ask you how and why we are accessing their medical records and how we are protecting their privacy and confidentiality. The names are sent being sent by encrypted e-mail through the VA firewall. The researchers are looking for characteristics of the class participants that can be pulled from their electronic medical records, such as age, marital status and their chronic diseases. However, the report that will be generated by the Division of Support Services (a VA department) will have no names or any identifiable information on it. Since the surveys also do not have any names on them, there will be no way the researchers can link these results back to any of the individual study participants either.
Appendix O

Survey Tool

Self-Efficacy for Managing Chronic Disease
6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

<table>
<thead>
<tr>
<th>Not at all Confident</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Totally Confident</th>
</tr>
</thead>
</table>

1. How confident are you that you keep the fatigue caused by your disease from interfering with the things you want to do?

   1 2 3 4 5 6 7 8 9 10

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

   1 2 3 4 5 6 7 8 9 10

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

   1 2 3 4 5 6 7 8 9 10

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

   1 2 3 4 5 6 7 8 9 10

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

   1 2 3 4 5 6 7 8 9 10

6. How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

   1 2 3 4 5 6 7 8 9 10
IMPORTANCE
Chronic disease impact

The prevalence of chronic diseases is rising. In 2005, nearly 133 million Americans had at least one chronic disease. By 2020, that number is anticipated to increase by 16% to 150 million or more. Many Veterans have more than one chronic illness. Symptoms of chronic illnesses - including pain, fatigue, muscle tension, shortness of breath, and depression - can be debilitating and interfere with normal life activities. Although medical treatments and medications are crucial in the management of chronic disease, disease outcomes are heavily impacted by the decisions that patients make every day about physical activity, food intake, stress management, and adhering to a medical plan of care.

Individuals with chronic conditions consume a lot of healthcare resources, and they have been found to utilize more services, at greater expense, as the numbers of their chronic conditions multiply. Much of the growth in health care spending is related to the care of individuals with chronic conditions. The burden of chronic disease in the veterans Affairs health system is estimated to be similar if not greater than in the general population. Utilization of healthcare services and costs of care for Veterans increases with the number of identified chronic conditions.

Self-management program expectations
The CDSMP is one of several self-management programs have been designed to help patients make healthy decisions, manage symptoms using self-care strategies, work with their healthcare team, and use the healthcare system more efficiently. Approaches like these, if effective, could help contain or reduce costs, and also improve the quality of life for those with chronic diseases.

PROGRAM DESCRIPTION
CDSMP description
The Chronic Disease Self-Management Program was developed in 1996 by Stanford University with a grant from Agency for Healthcare Research and Quality. The program consists of six structured workshops presented weekly to participants with any chronic disease. The purpose of the program is to build participants’ confidence in managing their health and to teach them the skills of chronic disease self-management.

• VISN implementation description
• Collaborations

Association with VA mission & objectives, other initiatives at VA
The Department of Veterans Affairs continues to pursue excellence in the delivery of care and services. In its proposed strategic plan for 2014-2020, goals have been identified to achieve success. Goal one, states” Empower Veterans to improve their well-being” and includes achieving outcomes from “preventative care and healthy lifestyle changes”.

PROGRAM GOAL(S)
• Attendance, # leaders trained, # classes
• Affecting ability to self-manage care, changing the responsibility
TARGET AUDIENCE: All participants from the program inception who have attended at least four of the six sessions of the workshops

Data elements:
   a. Demographics: age, race, gender, marital status
   b. Hospital days, ED visits, provider visits six months prior to the first workshop day (identified by the Healthy U note)
   c. Hospital days, ED visits, provider visits six months, after the last workshop day (identified by the Healthy U note)

PROGRAM IMPACT
   • Description of population/attendees, trainers trained
   • Attendance
   • # workshops, # sites, # workshops per site, # leaders trained
   • # participants & their demographics
   • Resource utilization data points – another decision point for DSS questions
   What unanticipated issues arose?

ADMINISTRATION
   • Cost, including time & staff investment in project
   • Source of funding
   • Management – personnel needs
   • Marketing effectiveness – publicity, promotion, advertising
   • Conflicts with other programs?

DECISIONS
   • Are we reaching the target population?
   • Suitability for VA sites
   • Is the program cost effective?
   • Should we continue the program?
   • Should we alter the program?
<table>
<thead>
<tr>
<th>Participant number (sequential)</th>
<th>Gender</th>
<th>Age</th>
<th>Marital status</th>
<th>Ethnicity</th>
<th># of sessions attended</th>
<th>Date of 1st session attended</th>
<th>Date of last session attended</th>
<th># of hospital visits</th>
<th>Cost of average hospital day</th>
<th># of ED visits</th>
<th>Cost of average ED visit</th>
<th># of provider visits</th>
<th>Cost of average provider visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the six months prior to first session</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For the six months after the last session</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix Q

Tests for Normality, Paired Sample

Case Processing Summary

<table>
<thead>
<tr>
<th>Cases</th>
<th>Valid</th>
<th>Missing</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Percent</td>
<td>N</td>
</tr>
<tr>
<td>post_ER_cost</td>
<td>7</td>
<td>5.0%</td>
<td>132</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>post_out_cost</td>
<td>7</td>
<td>5.0%</td>
<td>132</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>prior_in_cost</td>
<td>7</td>
<td>5.0%</td>
<td>132</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Histogram

Mean = $43,682.50
Std Dev. = $34,226.851
N = 15
Histogram

Mean = $1,622.16
Std. Dev. = $1,012.00
N = 7

Histogram

Mean = $44,263.90
Std. Dev. = $33,856.14
N = 7
### Appendix R

**Paired Sample Statistics**

<table>
<thead>
<tr>
<th>Pair</th>
<th>Paired Differences</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>95% Confidence Interval of the Difference</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>prior_ADMITS - post_admit</td>
<td>-0.667</td>
<td>.816</td>
<td>.333</td>
<td>-1.524 - .190 -2.000 5</td>
<td>.102</td>
</tr>
<tr>
<td>prior_cost_bdoc - post_cost_bdoc</td>
<td>-$1.38565E4</td>
<td>$5,656.9012</td>
<td>$1.55536</td>
<td>$1.35295 - 1.179 5 5 8.65</td>
<td></td>
</tr>
<tr>
<td>prior_in_cost - post_in_cost</td>
<td>-$1.17639E4</td>
<td>$4,802.5822</td>
<td>$2.11749</td>
<td>$3,515.9132 - 1.838 5 5 12.5</td>
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</tr>
<tr>
<td>prior_LOS - post_LOS</td>
<td>-2.500</td>
<td>36.215</td>
<td>14.785</td>
<td>-40.505 35.505 - .169 5 5 8.72</td>
<td></td>
</tr>
<tr>
<td>prior_ER_visits - post_ER_visits</td>
<td>-.529</td>
<td>2.741</td>
<td>.665</td>
<td>-1.939 .880 - .796 16 5 4 38</td>
<td></td>
</tr>
<tr>
<td>prior_ER_cost - post_ER_cost</td>
<td>-$1.786.7360</td>
<td>$433.34714</td>
<td>$1.37433</td>
<td>$462.98047 - 1.052 16 5 .309</td>
<td></td>
</tr>
<tr>
<td>prior_OUT_visits - post_OUT_visits</td>
<td>1.978</td>
<td>23.267</td>
<td>1.981</td>
<td>-1.938 5.895 .999 137 5 3.20</td>
<td></td>
</tr>
<tr>
<td>prior_out_cost - post_out_cost</td>
<td>$898.529</td>
<td>$1.57000E4</td>
<td>$1.356.4746</td>
<td>$3,541.3159 - 1.74426 137 5 5.03</td>
<td></td>
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</tbody>
</table>
Appendix S

Paired T-Test: Nonparametric Tests

### Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The median of differences between prior ADMITS and post_admit equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.102</td>
<td>Retain the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .05.

### Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The median of differences between prior_in_cost and post_in_cost equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.116</td>
<td>Retain the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .05.

### Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The median of differences between prior_ER_visits and post_ER_visits equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.871</td>
<td>Retain the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .05.
### Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The median of differences between prior_ER_cost and post_ER_cost equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>0.730</td>
<td>Retain the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is 0.05.

### Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The median of differences between prior_OUT_visits and post_out_visits equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>0.061</td>
<td>Retain the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is 0.05.

### Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The median of differences between prior_out_cost and post_out_cost equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>0.035</td>
<td>Reject the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is 0.05.
Appendix T

Total Sample: Tests for Normality
## Appendix U

**Total Sample: Group Statistics**

<table>
<thead>
<tr>
<th>Group Statistics</th>
<th>pre_post</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>admits</td>
<td>pre</td>
<td>139</td>
<td>.19</td>
<td>.537</td>
<td>.046</td>
</tr>
<tr>
<td></td>
<td>post</td>
<td>139</td>
<td>.19</td>
<td>.680</td>
<td>.058</td>
</tr>
<tr>
<td>los</td>
<td>pre</td>
<td>20</td>
<td>8.40</td>
<td>16.223</td>
<td>3.628</td>
</tr>
<tr>
<td></td>
<td>post</td>
<td>15</td>
<td>14.93</td>
<td>22.212</td>
<td>5.735</td>
</tr>
<tr>
<td>inpatient_cost</td>
<td>pre</td>
<td>20</td>
<td>$33,787.87</td>
<td>$22,061.494</td>
<td>$4,933.100</td>
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<tr>
<td></td>
<td>post</td>
<td>15</td>
<td>$43,682.50</td>
<td>$34,328.852</td>
<td>$8,863.672</td>
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<tr>
<td>cost_bdoc</td>
<td>pre</td>
<td>20</td>
<td>$11,439.49</td>
<td>$8,772.736</td>
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<td></td>
<td>post</td>
<td>15</td>
<td>$7,456.53</td>
<td>$7,821.891</td>
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<tr>
<td>ER_visits</td>
<td>pre</td>
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<td>1.807</td>
<td>.293</td>
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<td></td>
<td>post</td>
<td>31</td>
<td>2.68</td>
<td>2.482</td>
<td>.446</td>
</tr>
<tr>
<td>ER_cost</td>
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<td></td>
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<td>$1,419.31</td>
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<td>cost_per_ER_visit</td>
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<td>38</td>
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<td>$121.764</td>
<td>$19.753</td>
</tr>
<tr>
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<td>post</td>
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<td></td>
<td>post</td>
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<td>41.17</td>
<td>40.360</td>
<td>3.436</td>
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<td>$16,906.576</td>
<td>$1,433.997</td>
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<td>post</td>
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<td>$16,845.19</td>
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<td>$1,655.816</td>
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<td>$202.029</td>
<td>$17.136</td>
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<tr>
<td></td>
<td>post</td>
<td>138</td>
<td>$392.45</td>
<td>$323.599</td>
<td>$27.547</td>
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</table>