

Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic

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Abstract

Nationally, heart failure (HF) is the leading cause of disability, hospitalizations, and death among veterans. Health care providers continue to struggle to maximize the quality of life and functional status of their patients. A significant amount of research is available on the topic of HF clinics; however, the unique patient population and staffing issues at this facility have made prior attempts to implement national recommendations unsuccessful. A nurse practitioner (NP)-led HF clinic was created in 2009 without any formal planning, treatment criteria, or outcome measures. Intuitively, the clinic seemed to be decreasing hospitalizations and improving symptom management. However, no data existed to prove success or to guide expansion. This clarificative evaluation attempted to step back from the daily operation of the NP HF clinic and verify the value of the current program. A mixed method design, retrospective chart reviews as well as semi-structured interviews with employee and veteran stakeholders, was used to broaden the understanding of clinic performance. Significant findings included: majority male population, lower left ventricular ejection fraction (LVEF), higher rates of systolic HF, higher rate of co-morbidities, and greater distance traveled to clinic visits of veterans enrolled in NP HF clinic as compared to national average. Standards of care were being met in terms of medical management. The NP HF clinic is reducing ED visits without increasing burden on non-acute resources. Qualitative findings revealed a need to improve communication and collaboration as well as suggestions for improving basic mechanics of the clinic.

Background and Significance

More than 5 million Americans have heart failure (HF), and the prevalence is increasing due to the aging of the population, the increasing incidence of ischemic heart disease, and the decreasing mortality associated with myocardial infarction (Libby, Bonow, Mann, & Zipes, 2007). HF is the leading cause of disability, hospitalization, and death among veterans (U.S. Department of Veterans Affairs, 2008). More money is spent for the diagnosis and treatment of HF than for any other diagnosis. HF is the most common Medicare diagnostic-related group (Hunt et al, 2009), and more than 50% of all patients discharged with a diagnosis of HF will require re-admission within six months (Libby, Bonow, Mann, & Zipes, 2007). Significant advances have been made in the last decade in the treatment of HF; however, the progress has also rendered clinical decision making more complex. The interest in high quality care of HF goes beyond the patients and their families. Government and third-party payers are interested in the efficient use of health care resources and prevention of hospitalizations related to HF (Hunt et al., 2009).

When compared to the population at large, veterans have several characteristics that increase the frequency and severity of HF. They are more likely to smoke (Office of Actuary and Office of Policy and Planning, 2007), to consume excessive amounts of alcohol (Abramson, Williams, & Kumholz, 2001), and to have been exposed to toxic chemicals (Dao, 2009), which are all risk factors for HF. While the majority of veterans are white, a disproportionate number of veterans receiving VA services are minorities who qualify based on low income (National Center for Veterans Analysis and Statistics, 2010). Ischemic heart disease, diabetes mellitus and hypertension, the most common causes of HF, are more common in minority groups. Ninety-two

percent of veterans are male (Office of Actuary and Office of Policy and Planning, 2007), and HF is more common and occurs at a younger age in males (Hunt et al., 2009). More than 41% of the veterans enrolled in the VA health care system live in rural or highly rural areas of the country. Many patients live greater than 50 miles from a medical facility and often 100 miles from a VA regional medical facility (ORH, 2011) making medical management and the prompt assessment of changes in symptoms difficult.

The G.V. Sonny Montgomery VA Medical Center (VAMC) is located in Jackson, Mississippi and is the only regional VA facility in the state. The majority of the veterans with HF are managed in the primary care clinics secondary to limited availability of cardiology services. One cardiologist staffs all clinical consults and diagnostic services. On average, the workload consists of 20 outpatient consults, 10 inpatient consults, and 10 diagnostic studies per day. A teaching clinic staffed by cardiology fellows meets once a week with a total of only 24 slots. A daily cardiology nurse practitioner (NP) clinic was created in 2005 for pre-procedure, post-procedure, and post-hospitalization acute coronary syndrome (ACS) evaluation. In 2009, the cardiologist unilaterally started filling all open NP clinic slots for HF management creating a NP HF clinic. The verbally described goals of the clinic were to offer frequent visits for medication titration and to increase patient education on lifestyle modifications and symptom management. No formal planning, treatment guidelines, or outcome measures were established. No input from providers within or outside of the department was solicited. The cardiologist who created the clinic has retired, and no succession planning was done to facilitate the new cardiologist's understanding and collaboration with the clinic. Without a clear mission or vision for the clinic, changes to the clinic seemed haphazard. Confusion was at an all-time high, and the cardiology

staff were concerned that missed opportunities for timely treatment and prevention of acute exacerbations abound.

Purpose of the Capstone Inquiry

The first goal of this capstone inquiry was to conduct a clarificative evaluation (Owen, 2007) of the NP HF clinic at the G.V. Sonny Montgomery VAMC in order to accurately understand the quality of care provided by the clinic. Frequently, programs are created in which problems arise that could not have been anticipated even with the best planning. Stopping the program for re-evaluation would create additional problems or could result in never getting the program re-started again. Clarificative evaluation is a method designed to assess a functioning program in order to improve processes and to overcome barriers to effective provision of care. Evidence to assess the program relies on document analysis, interviews, and observation. Efforts are aimed at establishing the feasibility of the program, encouraging consensus among stakeholders, and overcoming deficiencies that become apparent in practice (Owen, 2007). Based on an enhanced understanding of HF care in the current clinic, recommendations for program improvement are provided that address the unique needs of the population and are practical for this specific facility.

Nationally, the Veterans Health Administration (VHA) has committed substantial resources to HF by establishing a Quality Enhancement Research Initiative (QUERI) dedicated to chronic HF care (Heidenreich, 2009). On a local level, the G.V. Sonny Montgomery VAMC has struggled to meet national performance goals for admissions related to HF. Prior attempts to improve HF management have resulted in short-term gains or failed outright. Based on personal knowledge, the lack of success seemed more likely a result of the organizational culture as opposed to the competence of the providers. Historically, the executive administrators have

focused on “fix it” solutions that lack a true understanding of the unique needs of the population and the importance of generative relationships among stakeholders. These solutions also emphasized the importance of immediate improvement in performance. Leadership has viewed adaptations to a program after implementation as a failure in planning. A lack of systems thinking has discouraged the evolution of established projects (Cabrera, Colosi, & Lobdell, 2007). This clarificative evaluation process may serve as a model for stakeholders at this specific facility for transformation. Therefore, while the primary goal of this inquiry was instrumental use for the purpose of informed change, a secondary goal was process use to create change as a result of the process itself.

The main questions addressed were:

1. Did the G.V. Sonny Montgomery VAMC NP HF clinic’s current patient population significantly differ from the general population, which may have an effect on the access and/or delivery of HF care?
2. Was the NP HF clinic adhering to standards of care?
3. Did the NP HF clinic result in a change in the use of health care resources?
4. In what ways could stakeholder input be utilized to improve performance of the NP HF clinic?

Review of Literature

While much literature exists regarding HF clinics, most simply include a description of services provided at a self-identified clinic or academic center. Most published articles do not describe standards of care processes, structural elements (Hauptman et al, 2008), outcome measures, or recommendations (Gustafsson & Arnold, 2004). The American College of

Cardiology/American Heart Association (ACC/AHA) and the Heart Failure Society of America (HFSA), the leading authorities on HF, published clinical practice guidelines advocating the usefulness of HF clinics, but they did not provide details about the nature of the clinics themselves (Hunt et al., 2005; Hunt et al., 2009; Adams et al., 2006; Lindfield et al., 2010). In response to numerous requests, the Quality of Care Committee of HFSA published a consensus statement for HF clinics to identify the components most likely to improve the adherence to guidelines with the secondary benefit of optimizing patient outcomes. The HFSA working group openly admits that many of the domains have not been proven effective due to a lack of controlled trials, standardization of design, and adequate follow up (Hauptman et al., 2008).

Overall, studies regarding HF clinics emphasize the need for close follow up and easy accessibility of providers to prevent exacerbations and admissions (Hauptman et al., 2008). Most studies use a multi-disciplinary team approach; however, no consensus exists regarding which providers are essential or who should lead the HF clinic. Many studies support nurse-led HF clinics (Thompson & Dykeman, 2007; Kasper et al., 2002; Krumholz et al., 2002; Hebert et al., 2008). However, whether the supervising physician needs to be an internist (Hernandez et al., 2010; Jaarsma, Haaifer-Ruskamp, Sturm, & Van Veldhuisen, & 2005; Weinberger, Oddone, & Henderson, 1996) or cardiologist (Doughty et al, 2002; McDonald et al., 2002; Capomolla et al., 2002; Whellan, Hasselbard, Peterson, O'Connor & Schulman, 2005) remains unclear.

Other types of interventions have also been studied. The most popular intervention is frequent telephone contact as a way to increase access to providers and treat changes in symptoms quickly (Riegel et al., 2002; Grancelli et al., 2005; Krumholz et al., 2002; Laramie, Levinsky, Sargent, Ross, & Callas, 2003). Similarly, telephone-monitoring devices have also been studied (Soran et al., 2010). Home visits have also been shown to decrease the frequency

of hospitalization (Naylor et al, 1999; Stewart & Horowitz, 2002). The number and extent of educational interventions has also been shown to reduce admissions (DeWalt et al., 2009).

The vast majority of studies include multiple interventions, which were not well described and often oversimplified. Frequently, researchers categorize their programs by one main characteristic, such an intervention or type of provider, without commenting on the smaller interventions that may have been just as important in influencing success. Little research is available on long-term effects of programs since most trials only follow patients for 9 to 12 months (Clark, Savard, &Thompson, 2009). Due to the wide variety of strategies, health care settings, and populations, recommendations are not easily generalized (Whellan et al., 2005).

With all the research and rapid proliferation of HF clinics, the most likely reason for success may be quite simple, communication. The improvement occurs whether the intervention improves patient-provider or provider-provider communication. HF clinics frequently include strategies that increase a patient's access to their health care providers. When a patient can contact a provider to communicate a change in health status, crisis is often averted (Whellan et al., 2005). Additionally, the creation of a HF clinic often involves discussions with multiple health care providers regarding their roles in the management of HF and related co-morbidities. Improved communication between health care providers reduces medication errors, conflicting plans of care, and inconsistent treatment goals (Hauptman et al., 2008).

Significance of Inquiry

Review of the research did not offer a panacea to improve HF outcomes. Additionally, veterans depart from the typical characteristics of most study samples, so an existing HF clinic cannot simply be replicated. While the current HF clinic was not deliberately planned,

intuitively, it seemed to have a positive impact on care of patients with HF. However, no evidence could be offered. This inquiry attempted to step back from the daily operation of the clinic and verify the value of the current program. In addition to documenting the typical measures of standards of care, communication was described by assessing the informal networks used by the clinic staff and by interviewing stakeholders regarding their perceptions of current care and perceived needs. Clarificative evaluation is not an end to the evaluation of a program, and this inquiry did not result in an answer to all the difficulties of managing veterans with HF. Instead, the researcher's goal was to evaluate the unique situation at this specific facility and to provide authentic recommendations for improvement. It was intended to be a first step of many in the cycle of evaluation.

Methods

This clarificative evaluation used a mixed method design. Clarificative evaluation concentrates on making the internal structure and function of a program clear. It is distinguished from program planning by the collection and analysis of data, preferably with the input of staff, to define the logic of an existing program (Owen, 2007). Quantitative data have not been effective in explaining the clinical constraints related to the treatment of HF (Oertle & Bal, 2010). Qualitative, stakeholder-centered, data were gathered to broaden the understanding of performance.

Question 1 through 3 were addressed under five aims using a descriptive, comparative design. Therefore, quantitative methods were employed. While numerical data were important to determine the strengths and weaknesses of a program, it did not tell the whole story. The opinions of the people who participated in the program, both as providers and patients, were

invaluable. Their judgments and experiences humanized the data and facilitated broader understanding. Question 4 was addressed descriptively using a semi-structured interview.

Question 1: Did the G.V. Sonny Montgomery VAMC NP HF Clinic's current population significantly differ from the general population, which may have an effect on the access and/or delivery of HF care?

Aim 1. Compare the current NP HF clinic population in terms of general characteristics and severity of disease to national data. The variables of interest and their operational definitions follow.

- Age in years according to birth date on electronic medical record registration form.
- Race according to electronic medical record. Race was self-selected by the veteran at time of registration for Veteran Affairs benefits.
- Classification of HF. HF is often classified as HF with reduced systolic function (< 40% ejection fraction on echocardiography or nuclear imaging results) versus HF with preserved systolic function (> 40% ejection fraction). Distinguishing the classification was important because few clinical trials have been completed on treatment of heart failure with preserved ejection fraction, and for the most part, these trials are inconclusive (Hunt et al, 2009).
- Severity of disease based on ejection fraction and New York Heart Association (NYHA) functional classification. Baseline ejection fraction was determined by echocardiography or nuclear imaging results. NYHA functional classification was also used to determine severity of illness because there can often be a discordance between ejection fraction and degree of functional impairment (Hunt et al, 2009). NYHA was determined by review of symptoms in progress notes.

- Co-morbidities to include hypertension, diabetes mellitus, dyslipidemia, tobacco use, coronary artery disease (CAD), valvular disease, and peripheral vascular disease. These co-morbidities are the leading causes of heart disease, and they contribute to or exacerbate the severity of symptoms (Hunt et al, 2009). The presence of co-morbidities was determined by review of the problem list and progress notes in the electronic medical record.

- Distance veterans travel for appointments in miles. Many subspecialists are now requiring patients live within a 50-mile radius in order to be eligible for disease management programs. Likewise, distance traveled can affect decisions related to frequency of appointments and aggressiveness of disease management. Distance traveled was calculated by entering home address of veteran, as recorded on electronic medical record registration form, and facility address into “Driving Directions” calculator on Google Map.

Aim 2. Determine how patients gain access to the NP HF clinic. The variables of interest and their operational definitions follow.

- Mode of referral to the NP HF clinic. Referral mode was determined based on note used to alert the NP staff (i.e. formal consultation, additional signer on progress note).

- Type of provider making referral. The number of patients cared for in the NP HF clinic is miniscule compared to the number of patients with HF managed by primary care providers at this facility. It was important to determine who made the request for services. Type of provider was determined from review of referral note in electronic medical record.

Question 2: Was the NP HF clinic adhering to standards of care?

Aim 3. Compare the adherence to pharmaceutical treatment goals for beta-blockers and angiotensin converting enzyme inhibitors in a sample of community-dwelling veterans managed

in the NP HF clinic to national data. The variables of interest and their operational definitions follow.

- Number of veterans enrolled in the NP HF clinic who were prescribed goal doses of angiotensin-converting enzyme inhibitors (ACEi). Goal dose was described as lisinopril 20 mg daily or enalapril 10 mg twice daily or fosinopril 80 mg daily or documented contraindication for not obtaining goal dose (Lindfield et al, 2010).
- Number of veterans enrolled in the NP HF clinic who were prescribed goal doses of beta-blockers. Goal dose was described as carvedilol 25 mg twice daily or metoprolol succinate 200 mg daily or documented contraindication for not obtaining goal dose (Lindfield et al, 2010).

Question 3: Did the NP HF clinic result in a change in the use of health care resources?

Aim 4. Compare the utilization of acute care resources for patients managed in the NP HF clinic to utilization six months prior to enrollment. The variables of interest and their operational definitions follow.

- Number of HF-related emergency department (ED) visits for veterans enrolled in NP HF clinic. ED visits were defined as occurring in the facility ED with documented 1010 note or as occurring in outside ED facility with records scanned into electronic medical record. Heart failure (ICD-9 code 428.x) must have been identified as one of the diagnoses and/or acknowledged as affecting the plan of care.
- Number of HF-related admissions for veterans enrolled in the NP HF clinic. Admission related to HF was defined as ICD-9 code of 428.x as one of the admission diagnoses and/or acknowledged as affecting the plan of care.

- Number of HF-related readmissions for veterans enrolled in the NP HF clinic. Re-admission related to HF was defined as ICD-9 code of 428.x as one of the diagnoses and/or acknowledged as affecting the plan of care. A re-admission was an admission that occurs within 30 days of discharge.

Aim 5. Compare the utilization of non-acute care resources for patients managed in the NP HF clinic to utilization six months prior to enrollment. The variables of interest and operational definitions follow.

- Number of interactions by phone with patients (or their designated caregiver) enrolled in the NP HF clinic.
- Frequency of outpatient visits for patients enrolled in the NP HF clinic.

Question 4: In what ways can stakeholder input be utilized to improve performance of the NP HF clinic?

The variables of interest follow.

- Stakeholder perceptions of the current NP HF clinic.
- Stakeholder input regarding an ideal NP HF clinic.

General categories of input for the above variables included access to HF services, provision of standard of care, transition from hospital to home upon discharge, and communication.

Population, Sample and Stakeholders

Population, in this inquiry, referred to the patient population starting in June 2011. The decision was made in view of the arrival of a new cardiologist and NP provider about that date.

These providers have committed to the inquiry and the improvement of the clinic for the foreseeable future. Therefore, the evaluator decided it would be most prudent to assess the clinic based on the data available from their tenure. Also, future recommendations need to be based on the current state of the clinic and to facilitate ideas for improvement for those who have to the power to do so. In order to appreciate as many points of view as feasible in the acute and chronic management of heart failure, stakeholders were selected from all points along the care continuum. Stakeholders included:

- Veterans currently enrolled in the NP HF clinic
- Nurse practitioners assigned to the primary care clinic
- Emergency department providers
- Physicians assigned to inpatient attending responsibilities
- Cardiology providers

Data Collection and Data Analysis for Aims 1 through 5

Using the clinic schedule lists, electronic medical records and NP telephone logbooks were reviewed by the evaluator. A data collection tool formatted on an Excel spreadsheet was created to facilitate the gathering of data. Each veteran was counted once regardless of the number of visits in the data collection time period. Patient identifiers were recorded in order to ensure that the same veteran was not counted multiple times on the tool. The list contained limited identifiable data (first initial of last name and last four of the social security number) and was kept separate from the data collection spreadsheet. This list will be destroyed in accordance with the requirements of the VAMC research department.

To verify the accuracy of the evaluator's collection of quantitative data, 10% of the data were reviewed by the other cardiology NP. The evaluator provided training regarding the data collection process prior to the start of chart review. Eight discrepancies were identified, which were discussed by the two reviewers to reach a consensus. Pearson's correlation coefficient was calculated to measure correlation among NP raters. To estimate intra-rater reliability of quantitative data, 10% of the data were reviewed a second time by the evaluator after a two-week break in data collection. Pearson's correlation coefficient was calculated to measure consistency.

All data were stored on a password-protected computer. Data were presented using descriptive statistics (frequencies, percentages, and measures of central tendency) facilitated by Statistical Package for the Social Sciences (SPSS) version 18. Comparisons were made to national averages when available or previous timeframe (as described above) to determine statistical significance using SPSS.

Data Collection and Data Analysis for Question 4

On a voluntary basis, a semi-structured interview (Appendix A) was conducted with the stakeholders using the following two questions:

- What is your perception of the current NP HF clinic in terms of access to HF services, provision of standard of care, transition from hospital to home upon discharge, and communication?
- What would a "great" NP HF clinic look like in terms of access to HF services, provision of standard of care, transition from hospital to home upon discharge, and communication?

Participation for all stakeholders was voluntary. For employee stakeholders, the evaluator made initial contact by an informational letter (Appendix B) sent by e-mail. The informational letter included dates/times for participation as well as the evaluator's contact information. A

focus group format for employee stakeholders was chosen to enhance brainstorming and theme generation. However, when an employee requested to participate in private, the evaluator made arrangements as necessary. All primary care providers requested a private meeting. Written consent for participation was waived. Consent to participate was implied by each stakeholder's appearance at the specified focus group meeting or request to participate privately. For veteran stakeholders, the evaluator or other trained Cardiology NP made initial contact in a face-to-face discussion during an already scheduled clinic visit to prevent additional travel. An informational letter/copy of consent (Appendix C) was given to each patient and accompanying family member, if present, describing the evaluation. If the veteran was willing to participate, an appointment was offered on a day when the veteran would already be at the facility to prevent any additional travel; however, all participants asked that the interview be conducted at the time of the initial discussion. Written consent was obtained to tape the interviews.

Recordings were used in the capturing of information accurately and the identification of recurrent themes. Clarification-seeking from participants during the interviews was used to enhance dependability and credibility. Interviews were transcribed to assist with data analysis as well as to ensure dependability of the data. Interview results were examined to elucidate recurrent themes in the dialogue. Data collection and analysis occurred simultaneously. Data collection continued until data saturation was reached or until all willing participants had been interviewed. Assistance with theme extraction was available from experts on the campus of the University of Mississippi Medical Center. Data were reviewed for major themes after each interview session. Interview data were stored in a Word document. Participants were identified by pseudonyms only. Transcripts were destroyed once themes were identified.

Human Research Protection

This inquiry was submitted to the Institutional Review Board (IRB) of the University of Mississippi Medical Center (UMMC) and the G.V. Sonny Montgomery VAMC simultaneously. This project met the criteria for expedited review according to the Code of Federal Regulations of 45 CFR (U.S. Department of Health and Human Services, 1983). Both UMMC IRB and the G.V. Sonny Montgomery VAMC IRB (Appendix D) deemed this project not human subject research/not requiring IRB approval in January 2012.

Findings

A total of 51 unique patients were seen in the NP-led HF clinic between June 2011 and November 2011. One patient was excluded because he resides in the nursing home due to lack of autonomy and flexibility with HF management. This veteran was unable to contact HF NP providers independently or self-titrate medications for change in symptoms and/or weight. An attempt was made to engage the nursing home staff in his HF care, but their medical policy required all changes and communication to go through an off-site medical director. Missing quantitative data were rare. However, five patients enrolled at the VAMC for services within two weeks of being evaluated in the NP HF clinic; therefore, there was no information for the 6 months prior to the initial visit in the NP HF clinic regarding health care resource utilization. For these patients, prior admissions, prior emergency department visits, prior outpatient appointments, and prior telephone advice calls were inputted to the median.

A total of 100 items (14% of total data) was reviewed by the other cardiology NP to verify accuracy. The Pearson's correlation coefficient was 0.99 ($p < 0.01$). All discrepancies between the two reviewers were discussed and consensus was reached without the need for a

third party reviewer. A total of 100 items were also reviewed to determine intra-rater reliability. This was high with a Pearson's correlation coefficient of 0.99 ($p < 0.01$).

For the collection of qualitative data, interview participants included three physicians assigned to inpatient attending responsibilities, three primary care providers, two emergency department providers, seven cardiology providers, and five veterans enrolled in the NP HF clinic. Due to scheduling and suspected self-segregation, the inpatient attending, cardiology, and emergency department providers had separate focus group meetings. All of the primary care providers were interviewed independently.

Aim 1: Veteran Characteristics

Of the final sample, 98% (49) were male and 2% (1) were female. Nationally, HF occurs equally in men and women; however, the majority of veterans enrolled at the facility are men. The age range was between 37 to 88 years with a mean of 64.3. Sixty percent (30) of patients were under the age of 65 years. Twenty-two percent (11) of patients were between the ages of 65 and 74 years, and 18% (9) of patients were 75 years or older. Using a one-sample t-test, no significant difference ($p = 0.63$) in age between this sample and the national standard of 65 years existed. Fifty-two percent (26) of patients in the sample described themselves as Caucasian, and 48% (24) of patients described themselves as African-American. Using a one-sample t-test, a significant difference ($p < 0.01$) in race between this sample and the national average was found. African Americans are 1.5 times more likely than Caucasians to have heart failure.

Eighty-four percent (42) of patients had HF with reduced systolic function, or systolic HF, and 16% (8) of patients had HF with preserved systolic function, or diastolic HF. Nationally, one-third of all patients with HF have diastolic dysfunction. This sample had a statistically

significant ($p < 0.01$) lower rate of diastolic HF than the national average. The mean left ventricular ejection fraction (LVEF) for the entire sample was 26.26%. The mean LVEF for the members of the sample with systolic HF was 21.02%. Using a one-sample t-test, a statistically significant difference ($p < 0.01$) was found in LVEF when compared to the national average LVEF of 35% for both groups. NYHA classification of functional status showed 10% (5) of patients as Class I, 30% (15) of patients as Class II, and 60% (30) of patients as Class III. No patients were described as Class IV even though one is currently on the transplant list, which generally requires Class IV symptoms.

Mean LVEF for Caucasian veterans with systolic HF was 24.70% while the mean LVEF for Black veterans was 17.68% in this sample. A significant difference between mean LVEF and race existed ($p = 0.02$; Levene's test $p = 0.76$; $F = 0.09$). Veterans with systolic HF with a NYHA classification of III or IV (moderate to severe functional impairment) had a mean LVEF of 17.27%. Veterans with NYHA Classification of I or II (mild to moderate functional impairment) had a mean LVEF of 27.13. A significant difference between mean LVEF and NYHA Classification was found ($p < 0.01$; Levene's test $p = 0.05$; $F = 4.29$).

The mean number of co-morbidities was 3.98 with a median of 4.0. Ten percent (5) of patients had 2 co-morbidities, and 20% (10) of patients had 3 co-morbidities. Thirty-eight percent (19) of patients had 4 co-morbidities, and 26% (13) of patients had 5 co-morbidities. Six percent (3) of patients had all 6 co-morbidities. In this sample, the most common co-morbidity was hypertension occurring in 98% (49) of patients. Eighty-two percent (41) of patients had a diagnosis of dyslipidemia. Seventy-six percent (38) of patients had a history of tobacco use. Seventy-four percent (37) of patients had coronary artery disease. Fifty percent (25) of patients

were diagnosed with diabetes mellitus. The least common co-morbidities were peripheral vascular disease and valve disease with 12% (6) of patients and 6% (3) respectively.

Nationally, two-thirds of patients with HF have hypertension, which is significantly lower than this sample ($p < 0.01$). Likewise, two-thirds of patients with HF nationally have underlying coronary artery disease. A statistically significant ($p < 0.01$) difference existed between the national average and this sample in regards to CAD. One third of patients with heart failure have diabetes mellitus nationally. A statistically significant ($p < 0.01$) difference existed between the national average and this sample in terms of diabetes mellitus (33% versus 50% respectively). The mean LVEF for veterans with 4-6 co-morbidities was 27.97%, and the mean LVEF for veterans with 1-3 co-morbidities was 22.27%. No significant difference between LVEF and number (3 or less versus 4 or more) of co-morbidities ($p = 0.23$; Levene's test $p = 0.15$; $F = 2.19$) existed.

The mean distance travelled to attend NP HF clinic appointments was 66.54 miles with a range of 5 to 150 miles. Using a one-sample t-test, a significant difference ($p < 0.01$) in distance traveled between this sample and the standard subspecialist mandate of living within a 50-mile radius of the clinic existed. Mean LVEF for veterans with systolic HF who traveled more than 50 miles to the medical facility was 21.44% while mean LVEF for veterans who travel less than 50 miles was 20.27%. No significant difference between LVEF and distanced traveled was found ($p = 0.71$; Levene's test $p = 0.66$; $F = 0.20$) in this sample.

See Appendix E for complete table of descriptive statistics for demographic data.

Aim 2: Access to Clinic

Eighty-two percent (41) of patients accessed the NP HF clinic by adding the NP providers as an additional signer to an electronic progress note requesting assistance with management of and/or follow-up for HF. Eighteen percent (9) of patients accessed the NP HF clinic by a formal electronic cardiology consultation. Seventy-two percent (36) of the requests were from cardiology providers. Twenty-eight percent (14) of the requests were from primary care providers.

Aim 3: Standards of Care

Of the 42 patients with HF with reduced systolic function, 93% (39) were on goal doses of appropriate beta-blocker unless contraindication for not reaching goal doses was present. There was no significant ($p < 0.01$) difference in this sample and the national VHA average of 94%. However, only 33% (14) of the 42 patients were able to reach true target doses of beta-blockers. There was no significant ($p < 0.01$) difference between this sample and the national VHA average of 25% in terms of patients unable to reach target doses of beta-blockers due to contraindications. Sixty-one percent (17) were not able to reach goal due to symptomatic hypotension. Twenty-nine percent (8) of the patients did not reach goal due to symptomatic bradycardia or atrioventricular heart block. Seven percent (2) patients were using other medications to reduce heart rate for atrial fibrillation (Multaq or Cardizem) and were not able to tolerate an additional agent. One veteran (3%) was not started on a beta-blocker because of recent cocaine use.

Ninety-five percent (40) of patients with HF with reduced systolic function were at goal doses of angiotensin-converting enzyme inhibitors (ACEi) unless contraindication for not reaching goal doses was present. There was no significant ($p < 0.01$) difference between this sample and the national VHA average of 91%. Only 38% (16) of the 42 systolic HF patients

were able to reach true target doses of appropriate angiotensin-converting enzyme inhibitors. Thirty-eight percent (10) of patients were not able to tolerate true goal doses due to symptomatic hypotension. Thirty-five percent (9) of patients were not able to tolerate the medication due to history of elevated creatinine and/or potassium with use. Twenty-seven percent (7) of patients were not able to use ACEi due to documented allergies. All suffered from cough.

Aim 4: Use of Acute Care Resources

The average number of HF related ED visits prior to enrollment in the NP HF clinic was 1.35 per patient. This decreased to an average of 0.80 ED visits per patient after management in the NP HF clinic. Using a paired t-test, a significant difference in amount of ED visits was found ($p = 0.01$, correlation = 0.51, Mean = 0.55, $t = 2.85$). The average number of HF related admissions was 0.78 prior to enrollment in the NP HF clinic and 0.80 after enrollment. There was not a significant difference in the number of admissions ($p = 0.91$, correlation = 0.33, Mean = -0.02, $t = -0.12$). Three HF related re-admissions occurred for patients enrolled in the NP HF clinic. There was a significant ($p < 0.01$) difference between this sample's readmission rate and the national average Medicare re-admission rate of 24%. There was also a significant ($p < 0.01$) difference between this sample and the national VHA mandate of a re-admission rate of less than 20%. The mean LVEF of the veterans requiring readmission was 15%. The average distance traveled for the veterans requiring admission was 66 miles, which was the same as the sample mean.

There was no significant ($p = 0.13$) difference in the number of admissions after management in the NP HF clinic and the severity of heart failure (LVEF greater than 35% versus LVEF less than or equal to 35%). Likewise, there was no significant ($p = 0.63$) difference in the

number of admissions after management in the NP HF clinic and the severity of functional impairment (NYHA Class I & II versus NYHA Class III & IV). In terms of medication, there was no significant ($p = 0.44$ and $p = 0.54$) difference in the number of admissions after management in the NP HF clinic and the use of appropriate beta-blockers and ACE inhibitors respectively.

Aim 5: Use of Non-Acute Care Resources

The average number of interactions by telephone with patients or their designated caregiver was 2.16 per patient prior to enrollment in the NP HF clinic. Telephone interactions increased to an average of 2.26 per patient after enrollment in the NP HF clinic, which was not statistically different ($p = 0.83$). The average number of outpatient visits was 5.70 per patient. Outpatient visits decreased to 4.98 per patient after enrollment in the NP HF clinic, which did not reach statistical significance ($p = 0.16$).

Question 4: Stakeholder Input

Based on review of stakeholder input during semi-structured interviews, the major themes were communication, collaboration, and basic mechanics of the clinic. All employee stakeholders lacked a degree of awareness regarding the existence of the NP HF clinic. None of the primary care providers knew the clinic existed or how to refer a patient. The majority of the inpatient attending and cardiology providers knew peripherally that the clinic existed, but they were not sure if the clinic was “officially up and running”. Likewise, they verbalized uncertainty regarding who to refer and how to refer. One internist commented, “I knew that it was in the works, but I figured someone would have told me it was officially open.”

Employee stakeholders who had used the clinic praised the ability to contact the NP when one of their HF patients was having problems. They appreciated a “life-line” for questions or to

ensure follow-up. They applauded the availability of clinic spots and/or timely phone calls so that patients did not have to go to the ED. “It seemed like my patients in the HF clinic had a safety net because I could communicate with the [cardiology] NP providers” was a typical comment. Veteran stakeholders commented that they felt like the NP worked with their primary care providers to make sure “nothing fell through the cracks”. All of the Veteran stakeholders appreciated the ability to contact their HF provider directly. “So many of my concerns don’t require a trip to the clinic or to the ED, but I get nervous and want some reassurance. I don’t want to spend my time in the ED, but that is where the telephone advice nurse tells me to go.”

All the patients noted that they did not know how they were referred to the clinic. They voiced concern that that the service would disappear or that they would be discharged from the clinic. Similarly, providers questioned how certain patients were enrolled in the NP HF clinic and what patients would benefit from the services in the future. None of the providers were sure what diagnostic evaluation was included nor did they know if/when their patients would be discharged from the NP HF clinic.

In terms of an “ideal” HF clinic, all employee stakeholders had difficulty imagining what that would look like because of their reluctance to “dream”. Many cited limitations of the facility resources and leadership as making such an endeavor not worthy of their effort. One provider commented, “I don’t know why you are interested in the ideal. It isn’t going to happen. Look at this place. [long pause] I think I have become too jaded. I can’t even picture an ideal anymore. When did that happen?”

Most employee stakeholders wanted a formalized method to refer their patients to the NP HF clinic. Primary care providers requested that all HF patients be seen in the NP HF clinic

upon diagnosis for determination of etiology, titration of medications, and completion of education prior to discharge back to primary care. At the same time, employee stakeholders verbalized a desire to have more open lines of informal communication for questions. Many providers commented that they wanted a relationship with cardiology providers so that minor questions did not require a formalized consult. One provider commented, “Why can’t I just pick up the phone and ask a question on an established HF patient instead of sending additional consults, delaying care to get an answer, and frustrating everyone involved. It is not just cardiology...it is this way with all the services.”

At the same time, the cardiology staff commented that once a patient is seen in the NP HF clinic, primary care providers inappropriately relinquish all responsibility for care related to the heart. One cardiologist commented, “Even if you haven’t seen a patient in a year, the primary care provider will insist that we refill heart failure medications –really, just simply hypertensive medications. This needs to be a team effort.” Some providers requested the NP have more of a role as a resource person. For primary care providers, this was described as the NP being available for phone calls or separate electronic consultation. The creation of facility specific HF algorithms was also mentioned. For attending physicians, the emphasis was on collaborating with NP prior to discharge to reduce the frequency of re-admissions. For example, they mentioned an alert to the NP in order to, establish a HF action plan, schedule close outpatient follow up and receive contact information for questions in the interim.

In terms of mechanics of the NP HF clinic, expansion of the NP HF clinic was discussed, but the employee stakeholders forewarned of difficulty maintaining the level of access and personalized care with increased enrollment. Instead, most focused on the need to formalize the NP HF clinic as a dedicated clinic as a means to solidify its importance and to garner formal

support from potential collaborating services such as social work, nutrition, and physical medicine and rehabilitation. They also encouraged thinking about formalizing relationships with tertiary treatment facilities in the metro area for the possibility of referrals for left ventricular assisted devices (LVAD) and transplantation. On the other end of the spectrum, both employee and Veteran stakeholders voiced a need for palliative care options.

Discussion of Findings

Nationally, HF occurs equally among men and women. While the Veterans Health Administration (VHA) has seen a steady increase in women veterans receiving care at its facilities, the population continues to be predominantly male. The findings in this evaluation are similar to other HF studies completed at medical facilities within the VHA. For example, Weisenberg et al (1996), Nguyen, Schnittger, & Heidenrieck (2011), and Marcum et al (2012) utilized samples with 99%, 95%, and 90% of the sample population being male respectively.

This sample did not differ in terms of age from the national average even though veterans are more likely to have risk factors related to lifestyle, such as smoking, excessive alcohol use, and exposure to toxic chemicals (Dao, 2009) that increase the likelihood of younger age of onset of HF. One possible explanation is that this evaluation documented age at time of visit to the NP HF clinic as opposed to age of onset.

Unlike the national population where HF is one and one-half times more likely in minorities, this sample had an essentially equal number of Caucasian and African American veterans enrolled in the NP HF clinic. One explanation for this difference is that while African Americans make up to 40% of the population for the State of Mississippi, only 11% of Mississippi veterans are African American (Office of Actuary, 2007). However, minority

veterans are more likely to qualify for services based on low income or unemployment (National Center for Veterans Analysis and Statistics, 2010).

Research with pharmacological treatment of HF tends to focus on HF with reduced systolic function, or systolic HF, because this type of HF has the most robust guidelines. Unfortunately, many HF studies involving disease management do not discern the category of HF in the samples. One possible explanation for the lower rate of diastolic heart failure in the NP clinic sample as compared to national data is gender. Diastolic HF is more common among women (Guterierrez & Blanchard, 2004), and this sample only had one female participant. Another explanation is that systolic HF is easier to recognize because it is defined by LVEF while diastolic HF does not have well defined diagnostic criteria, can be attributed to many other conditions, and often is a diagnosis by exception (Gutierrez & Blanchard, 2004). Given the ambiguity of the syndrome, some primary care providers may be less confident in requesting the consultation of a cardiologist from the HF clinic for probable diastolic HF.

While the leading causes of HF used to be hypertension and valvular heart disease, it is now CAD (Lindenfield et al., 2010). As a result of the increased survival rate of myocardial infarction (MI), CAD is believed to be the underlying cause of two-thirds of patients with HF with reduced LVEF. The presence of CAD also contributes to the long-term progression of HF (Hunt et al, 2009). The sample had a higher rate of underlying CAD. In this sample, hypertension continues to be the most common co-morbidity at almost 100% of the sample. No research could be found to explain this phenomenon, however, it may be indirectly related to lifestyle choices such as smoking and delay in seeking health care. The good news is that these two co-morbidities have the most potential for modification (Baker & Romani, 2011). Interestingly, patients with 4-6 co-morbidities had an average LVEF higher than those with 1-3

co-morbidities. While this difference is not statistically significant, it leads one to wonder whether there is some difference in the aggressiveness that HF is diagnosed and/or treated in patients with multiple risk factors. Likewise, one may need to consider the importance of treating each co-morbidity aggressively regardless of total number.

The classification of functional status was subjective; however, statistically, NYHA Functional Classification seemed appropriate based on associated LVEF. There may be a reluctance to classify patients as Class IV considering none of the sample was in this category. However, one of the patients has been evaluated for heart transplantation, which requires Class IV symptoms.

There is no research to support the exclusion of patients that live greater than 50 miles from a health care facility from enrollment. This sample supports the idea that arbitrary distance qualifications may not be the best way to decide which patients are enrolled or which patients are most likely to benefit.

The patients enrolled in the NP HF clinic are most likely to be internally referred. One must question whether the population-at-large has adequate knowledge of how to access the clinic and whether the providers outside of the cardiology department feel comfortable making referrals. Likewise, the NP providers might question whether the limited numbers of patients enrolled in the clinic are the patients with the most to gain from a disease management clinic.

The patients receiving care in the NP HF clinic are receiving the appropriate beta-blocker and ACE inhibitors although the statistics caution the focus on medication as the panacea for reduced hospital admissions. While the number of HF patients titrated to goal tolerable doses is high, the number who actually reach goal doses is quite small (93% versus 33% for beta

blockers; 95% versus 38% for ACE inhibitors). Although the goal is to titrate medications to doses proven in clinical trials, recently published data suggest that even low dose ACE inhibitors and beta-blockers improve outcomes in patients who cannot tolerate higher doses (Baker & Ramani, 2011).

The use of ED resources decreased after enrollment in the NP HF clinic. No improvement was found in terms of admissions. One possible explanation is the short time frame used to collect these data. In this evaluation, documentation of resource utilization started on the day the patient was first evaluated in the NP clinic. Anecdotally, some of these initial visits resulted in admission for stabilization, which might have resulted in a spike in the initial data. Many studies do not assess for change in resource utilization until a patient has been enrolled for at least 6 months or use at least a 12-month collection time frame to allow adequate time for stabilization of symptoms (Whellan et al., 2005).

The bulk of the disease management interventions are aimed to maximize non-acute health care resources to prevent the use of acute, and more costly, resources. At the same time, one must find balance so that outpatient resources do not become overburdened. This evaluation showed that the decrease in acute resources did not result in an increase in non-acute services.

In terms of stakeholder input, it is not surprising that most stakeholders did not know about or how to access the NP HF clinic considering it was created without planning or official designation. As Whellan et al (2005) surmised in their meta-analysis, the most likely reason for success, or failure, of any HF program is communication. While communication was praised by those currently engaged in the HF clinic, it was a major issue for those on the periphery.

Overall, employee stakeholders were complimentary of each other's efforts to provide high quality care to Veterans with HF. Likewise, Veteran stakeholders voiced an appreciation for

the dedication of their providers. However, all stakeholders perceived a need for improved teamwork among providers. While literature is readily available regarding the importance of teamwork in terms of satisfaction, safety, and quality of care, there is no literature specific to this facility. However, historical factors may be useful. For example, after the facility director's retirement in January 2010, the center was managed by acting service chiefs or interim directors. Without a unifying leader, perhaps various services became more entrenched in following formalized service agreements. Additionally, one must consider the formal nature of the system where budgets and workloads tend to focus on a particular department or service as opposed to a service line.

Most of the suggestions in terms of the mechanics of the clinic are quite easily remedied without any additional cost such as a formalized announcement regarding the clinic, the addition of a formal electronic HF consult, and collaboration with ancillary services. The most important decision may be the determination of criteria for patient admission to and discharge from the NP HF clinic in order to maximize benefits to veterans while assuring the best use of limited resources for the facility.

Limitations of the Inquiry

This inquiry does have limitations to consider. First, this evaluation captured a very small percentage of the total HF population at this facility. Likewise, the time frame was limited to June 2011 to November 2011. The bulk of the new patients were enrolled during the summer months, which is not the traditional peak time for HF exacerbations. Whether this affected the characteristics of the population is unknown.

Statistical analysis should be reviewed cautiously since the sample size in this evaluation is small, especially when compared to national data sets. However, the purpose of this evaluation was to create change in this specific facility, and the results were not intended to be generalized beyond this facility.

Another methodological factor to consider is the sampling of the stakeholders. Since the interviewing process was completely voluntary, the stakeholder sample may have varied from the stakeholder population-at-large. Likewise, the evaluator was a colleague of or a health care provider for the stakeholders. This factor may have led to some degree of trying to please the evaluator, which could skew the results. A possible limitation is the relatively large number of cardiology providers that participated when compared to the small number of primary care providers. However, all of the cardiology staff in the sample have previously worked in primary care, and their comments reflected an appreciation for the overwhelming nature of the primary care as opposed to denigrating these providers. Lastly, the employee stakeholders ultimately segregated themselves for the focus groups, which negated brain-storming across departments.

Conclusion

Several conclusions can be made from this evaluation. The current group of patients enrolled in the NP HF clinic differs significantly from the general population. Specifically, they are more likely male, equally Caucasian and Black, have lower LVEF, have higher rates of co-morbidities, and travel a greater distance to clinic visit. The patients are being treated according to pharmacological standards of care. In terms of utilization of health care resources, the NP HF clinic significantly decreased HF-related ED visits without increasing burden on non-acute

resources. Based on stakeholder input, communication and collaboration are most significant for current and future success.

Implications for Practice/Recommendations

While the NP HF clinic was created without any formalized training or planning, the quantitative data show that the clinic is meeting established standards of care and reducing the use of other health care resources. Based on stakeholder comments, it is appreciated by both employees and Veterans. The evaluation confirms the value of the NP HF clinic.

Secondly, this evaluation establishes a needed database. While it is only a snapshot in time, it can serve as a baseline to track seasonal, provider, or other trends. Likewise, it is a starting point for the addition/deletion of variables used to determine quality of care.

More specific recommendations are:

- Establishment of criteria for admission to and discharge from the NP HF clinic.
- Facility-wide announcement regarding the existence of a NP HF clinic.
- Creation of an electronic consultation for HF patients. Due to the limited slots available, the focus may need to be narrow initially. For example, creation of a consult for inpatients with HF exacerbation at risk for readmission. This may include a mechanism for the NP to meet with the Veteran while inpatient to establish communication.
- Establish individualized HF action plan that is shared by cardiology NP with the Veteran and the primary care providers. Once HF regime has been maximized, a formal action plan could be given to the Veteran and primary care provider as a way to solidify an understanding regarding maintenance medications, symptoms that warrant prompt follow up, and contact information to increase collaboration and communication.

- Establish relationships with ancillary departments such as dietetics, social work, physical medicine and rehabilitation, palliative care, and transplant centers to facilitate collaboration.

Lastly, opportunities to promote team building need to be created. Informal meetings that include members of multiple departments may be a starting point for future collaboration.

Leadership should seek opportunities to identify systems that create siloing of departments and to promote programs that create seamless movement of information between departments. More than any other recommendation, team building has the potential to benefit Veterans and providers beyond the confines of HF.

As discussed above, one of the goals of this evaluation was to act as an exemplar by using a form of evaluation, which is new to this facility. While the effect of this evaluation can never be fully known, the stakeholders' comments highlighted a desire to see a change. The comments also underscored the sense of anticipation among employees to see what, if any, changes will result from the evaluation. For this reason, the evaluator would emphasize the importance of following through with the recommendations to show others that change is possible.

Future study

During this evaluation, two topics repeatedly arose that might be considered in further evaluation of the NP HF clinic. Arrhythmias, both as a risk factor for and as a secondary problem of HF, are receiving increasing importance in the study of HF. Specific to disease management, arrhythmias are a significant indicator of the increased use of resources (Baker & Romoni, 2011). This can be appreciated at this facility in the use of costly implantable devices as well as the multiple appointments needed for the management of medications of

anticoagulation (i.e. warfarin). Evaluators might consider taking a closer look at how arrhythmias impact use of health care resources.

Renal insufficiency is a growing concern. Renal insufficiency can negatively impact the prognosis in patients with both systolic and diastolic HF (McAlister, Ekekowitz, Tonelli, & Armstrong, 2004; Baker & Romoni, 2011). Anecdotally, persons with borderline renal function require more frequent follow up and cannot be treated as aggressively with oral diuretics for acute exacerbations. Data collection on this risk factor may prove telling as the NP HF clinic progresses. It also might prove useful in the consideration of ultrafiltration as a treatment option within the facility. Secondly, these data may indicate a need for increased collaboration between the NP and nephrology providers.

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Appendix A

Semi-Structured Interview Script for Employees and Veterans

- What are your perceptions of the current nurse practitioner-led heart failure clinic in terms of access to heart failure services? In terms of provision of standard of care? In terms of transition from hospital to home upon discharge? In terms of communication?
- What input do you have regarding an ideal nurse practitioner-led heart failure clinic in terms of access to heart failure services? In terms of provision of standard of care? In terms of transition from hospital to home upon discharge? In terms of communication?

Appendix B

Informational Letter to Employees

Dear G.V. Sonny Montgomery VAMC Colleague,

I am one of the nurse practitioners in cardiology. I am also a student in the doctor of nursing practice program within the School of Nursing at the University of Mississippi Medical Center, Jackson, Mississippi. I am conducting an evaluation of the nurse practitioner-led heart failure clinic as part of the degree requirement and in hopes of improving the care of heart failure at our facility. I would like to learn about the ways you perceive the current care and ideas you have for improvement.

You are being invited to participate in a focus group because you are a primary care nurse practitioner, emergency department provider, hospital attending, or cardiology provider. If you choose to participate, you will come to a meeting to give me your ideas. Each meeting will last about one hour and will be recorded on audiotape to prevent the loss of information. Your participation in this study is voluntary. Taking part in this meeting is your choice. You may choose not to take part or to leave the meeting at any time. The results of the study may be published and the ideas from the meeting may be used to plan ways to improve nurse practitioner heart failure clinic at this facility. Your name will not be used, and your identity will not be revealed.

The University of Mississippi Medical Center and G.V. Sonny Montgomery VAMC Institutional Review Board have reviewed this evaluation inquiry. No risks or direct benefits are known for this study.

If you have any questions concerning the evaluation, please call me at extension 6147 or e-mail me at Jennifer.mccaffery@va.gov or Dr. Spencer at extension 1251.

The focus group will meet on _____ (time) at _____ (place). Coming to the meeting will be your agreement to participate and to be audiotaped.

Sincerely,

Jennifer McCaffery, FNP

Appendix C

Consent Form for Veteran Participation in Interview

Disclosure of Potential Conflict of Interest

I am one of the nurse practitioners in cardiology at the G.V. Montgomery VA Medical Center. I am also a student in the doctor of nursing practice program within the University of Mississippi Medical Center School of Nursing, Jackson, Mississippi. I am conducting an evaluation of the nurse practitioner-led heart failure clinic as part of my degree requirement and in order to improve the care provided to veterans with heart failure. As a healthcare provider, I am interested in your well-being. I do not receive any salary or financial support for conducting this evaluation. You are under no obligation to participate in any study offered to you.

Research Statements

You are being asked to take part in an evaluation project under the direction of Jennifer McCaffery, Principal Investigator. The evaluation is entitled “A Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic”. The purpose of this study is to evaluate the current care provided by the nurse practitioner-led heart failure clinic and to determine ways to improve upon the care to benefit both veterans and their health care providers.

Your participation in this study will require one visit, which will be scheduled on a day that you are already at the facility. You will not be asked to make a separate visit to participate. You will be asked to meet with the evaluator for approximately 15 minutes.

Procedures

If you agree to participate in this evaluation, you will be asked to participate in an interview with the evaluator. The interview will include two general, open ended questions about the care of heart failure. You were asked to be a participant since you are already enrolled in the nurse practitioner-led heart failure clinic.

Foreseeable Risks or Discomforts

There are no physical risks related to this evaluation. An interviewee may feel emotions when thinking about or answering questions related to the disease or its treatment.

Reasonable Expected Benefits to Subjects or Others

There are no direct benefits to participation; however, the knowledge learned from this evaluation may benefit you or others in the future.

Appropriate Alternatives

The alternative is not to participate in this evaluation without risk to your on-going care.

Extent of Confidentiality/"Who Will See My Data?"

Only the principal investigator will have possession of the data such as the audiotapes and transcripts. They will be secured in a password protected computer file. No names will be recorded on the transcripts. Pseudonyms will be used. The audiotapes will be destroyed once transcription is completed. The transcripts will be destroyed once data analysis is completed.

Compensation

You will not receive any payment for your participation. You will not receive travel pay for your participation; however, the interview will be scheduled on a day when you are already at the facility for an already scheduled appointment. If you are otherwise eligible, you can receive travel pay for the already scheduled appointment.

Contact Information

Questions about the validity of the evaluation itself can be answered by the Research Compliance Officer or the Administrative Officer for Research at 601-364-1315.

The principal investigator is Jennifer McCaffery and can be reached at 601-362-4471 extension 6147.

Questions regarding Patients' Rights, complaints, questions, concerns or comments can be directed to the Research Compliance Officer at 601-364-1315 or Patient Advocate at 601-362-4471. For research related complaints, questions, concerns, or to make comments related to your participation in the research, please contact Patient Advocate at 601-362-4471.

Voluntary Participation Statement

Taking part in this evaluation is completely voluntary. You may choose to participate or not. If you decide not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled. If you choose to participate but later change your mind, you may withdraw from the study at any time. By doing so, you will not lose any benefits to which you are entitled.

Signatures:

I have read and understand the information stated above and I sign this consent form willingly. I have received a copy of this consent form.

Signature of Person Obtaining Consent/Date

Signature of Participant/Date

Signature of Legal Guardian/Date
(If Applicable)

Signature of Witness/Date

Signature of Principal Investigator

Date

I am unable to read, but this consent form has been read and explained to me by _____.
(Name of Reader)

I understand the information stated above and I willingly sign this consent form.

Signature of Person Obtaining Consent/Date

Signature of Participant/Date

Signature of Legal Guardian/Date
(If Applicable)

Signature of Witness/Date

Signature of Principal Investigator

Date

Appendix D

**Institutional Review Board
G.V. (Sonny) Montgomery VAMC (586)**

1500 East Woodrow Wilson Drive • Jackson, MS 39216-5199 • 601-364-1315 • Fax: 601-364-1390

IRB ACKNOWLEDGMENT - Initial Review

Date: January 11, 2012
From: Angela Jones, RPh, Chair
Investigator: Jennifer McCaffery, FNP-BC
Protocol: Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic
ID: 00451 Prom#: N/A Protocol#: N/A

The following items were acknowledged at the 01/05/2012 meeting:

- Abstract (12/15/2011)
- Conflict of Interest Statement - McCaffery (12/15/2011)
- Informed Consent Document (12/15/2011)
- Key Personnel Form - McCaffery (12/15/2011)
- Project found to be not research. (12/30/2011)

After reviewing the protocol ("Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic") and Request to Review, I do not believe this is a research project. PI's project is a combination of – After reviewing the protocol ("Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic") and Request to Review, I do not believe this is a research project. PI's project is a combination of Program Evaluation and Performance Improvement – all her aims focus on examining her clinic and evaluating how well it is working. She has no hypotheses, is not seeking generalizable knowledge, and has no plans to publish her work.

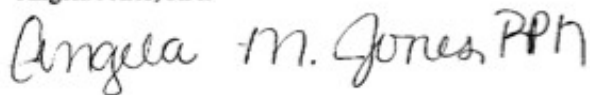
PI's methods are very comprehensive, but are otherwise typical of the kind of approaches used to evaluate the functioning and effectiveness of a clinical program. Risk to all who might volunteer is minimal, and she describes adequate protections for her volunteers. There is a possibility that both Veteran participants and Employee participants may personally benefit from the information obtained by PI because her aims focus on improving the functioning of the clinic they are either treated in or work in.

- Checklist for Reviewing Privacy, Confidentiality and Information Security in Research (12/15/2011)
- Informational Letter to Employees to Participate (12/15/2011)
- Institutional Resource Requirements (12/15/2011)
- Request for Waiver or Alteration of HIPAA Requirements (12/15/2011)
- Research Clinical Service Impact Statement (12/15/2011)
- Semi-Structured Interview Questions for Employees and Veterans (12/15/2011)
- Training- McCaffery (12/15/2011)
- Request to Review Research Proposal (12/15/2011)
- Scope of Practice - McCaffery (12/15/2011)
- Protocol (12/15/2011)

After reviewing the protocol ("Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic") and Request to Review, I do not believe this is a research project. PI's project is a combination of – After reviewing the protocol ("Clarificative Evaluation of a Nurse Practitioner-Led Heart Failure Clinic") and Request to Review, I do not believe this is a research project. PI's project is a combination of Program Evaluation and Performance Improvement – all her aims focus on examining her clinic and evaluating how well it is working. She has no hypotheses, is not seeking generalizable knowledge, and has no plans to publish her work.

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Angela Jones, RPh

A handwritten signature in black ink that reads "Angela M. Jones RPh". The signature is written in a cursive style with a large initial 'A' and 'J'.

Appendix E**Descriptive Statistics for Demographic Variables (n=50)**

	Frequency	Percentage
Age		
37	1	2.0
45	1	2.0
49	1	2.0
50	1	2.0
53	1	2.0
54	2	4.0
55	1	2.0
56	1	2.0
58	1	2.0
59	3	6.0
60	5	10.0
61	2	4.0
62	6	12.0
63	3	6.0
64	1	2.0
65	3	6.0
68	2	4.0
69	2	4.0
70	1	2.0
73	1	2.0
74	2	4.0
75	1	2.0

76	2	2.0
77	2	4.0
80	1	2.0
84	1	2.0
87	1	2.0
88	1	2.0

Race

Caucasian	24	48.0
African American	26	52.0

Gender

Male	49	98.0
Female	1	2.0

Classification of HF

Systolic	42	84.0
Diastolic	8	16.0

New York Heart Association (NYHA) Functional Classification

Class I	5	10.0
Class II	15	30.0
Class III	30	60.0

Number of Co-Morbidities

1	0	0.0
2	5	10.0
3	10	20.0
4	19	38.0
5	13	26.0
6	3	6.0

Distance Traveled

0-15 miles	9	18.0
16-30 miles	5	10.0
31-45 miles	2	4.0
46-60 miles	7	14.0
61-75 miles	6	12.0
76-90 miles	4	8.0
91-105 miles	8	16.0
106-120 miles	3	6.0
121-135 miles	5	10.0
136-150 miles	1	2.0

